

# Made in and for Europe: Data Spaces, Gaia-X and the European Health Data Space (EHDS) Regulation Proposal

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## **Agenda:**

### **1. Motivation**

### **2. Demystifying Data Spaces**

### **3. Brief Gaia-X Introduction**

### **4. The European Health Data Space (EHDS)**

### **5. Health-X dataLOFT**

# 1. Motivation

## Status Quo in the Age of Platforms and their One-Dimensional View on Business Models

Google

amazon



facebook

Microsoft

- The most **successful economic business models** are almost exclusively **data-based platforms** (Fehrer et al., 2018; Gawer, 2022) and have generated numerous innovations, including in the **healthcare sector** (Gleiss et al., 2021), BUT they:
  - Are mostly designed to **maximize profits** (Eisenmann et al., 2006)
  - Promote „**winner-takes-all**“ mechanisms (Parker & van Alstyne, 2018)
  - Lock-in valuable data (Lis & Otto, 2020); leading to practices referred to as **data colonization** (Couldry & Mejias, 2019; Ozalp et al., 2022)
- Necessity to **re-examine value creation** of **platform-based business models**
- Problem: Data is worth protecting (privacy as informational self-determination) vs. access and use of it brings enormous potential for society
- Solution: Data spaces need to focus on **achieving societal goals** from the very beginning
  - By **integrating** these **overriding norms and values** into companies' day-to-day activities through the development of business models oriented towards the **common good** and **public values**
  - Data spaces need to adhere to specific **participatory governance mechanisms**

Couldry, N., & Mejias, U. A. (2019). Data colonialism: Rethinking big data's relation to the contemporary subject. *Television & New Media*, 20(4), pp. 336–349.

Eisenmann, T., Parker, G., & Van Alstyne, M. W. (2006). Strategies for two-sided markets. *Harvard Business Review*, 84(10), pp. 1-11

Fehrer, J. A., Woratschek, H., & Brodie, R. J. (2018). A systemic logic for platform business models. *Journal of Service Management*, 29(4), pp. 546-568.

Gawer, A. (2022). Digital platforms and ecosystems: remarks on the dominant organizational forms of the digital age. *Innovation: Organization and Management*, 24(1), pp. 110–124.

Gleiss, A., Kohlhagen, M., & Pousttchi, K. (2021). An apple a day – how the platform economy impacts value creation in the healthcare market. *Electronic Markets*, 31(4), pp. 849–876.

Lis, D., & Otto, B. (2020). Data governance in data ecosystems – Insights from organizations. *AMCIS 2020 Proceedings*, 12, pp. 1-10.

Ozalp, H., Ozcan, P., Dinckol, D., Zachariadis, M., & Gawer, A. (2022). “Digital Colonization” of Highly Regulated Industries: An Analysis of Big Tech Platforms’ Entry into Health Care and Education. *California Management Review*, 64(4), pp. 78-107.

Parker, G., & Van Alstyne, M. (2010). Innovation, openness & platform control. In *Proceedings of the 11th ACM conference on Electronic commerce*, pp. 95-96.

# 1. Motivation

## The European Answer

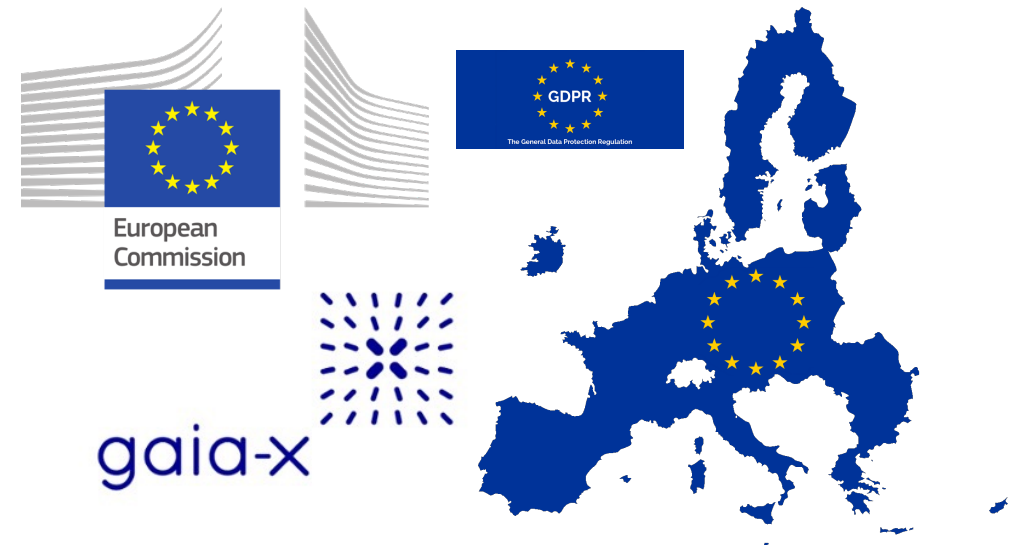


### European Counter Proposal

As a **counter model**, the European Commission introduced a regulatory proposal for the first sector-specific **data space** aiming to... (European Commission, 2022)

- Establish **health data exchange**
- Give citizens free and **electronic data access**
- Improve **reusability** of data for secondary use
- Enable data flows **across national borders**

### European Health Data Space (EHDS)



Starting only as attempts for regulation, the EU started to actively construct developments that adhere to European values such as citizen centricity, sovereignty, and transparency.



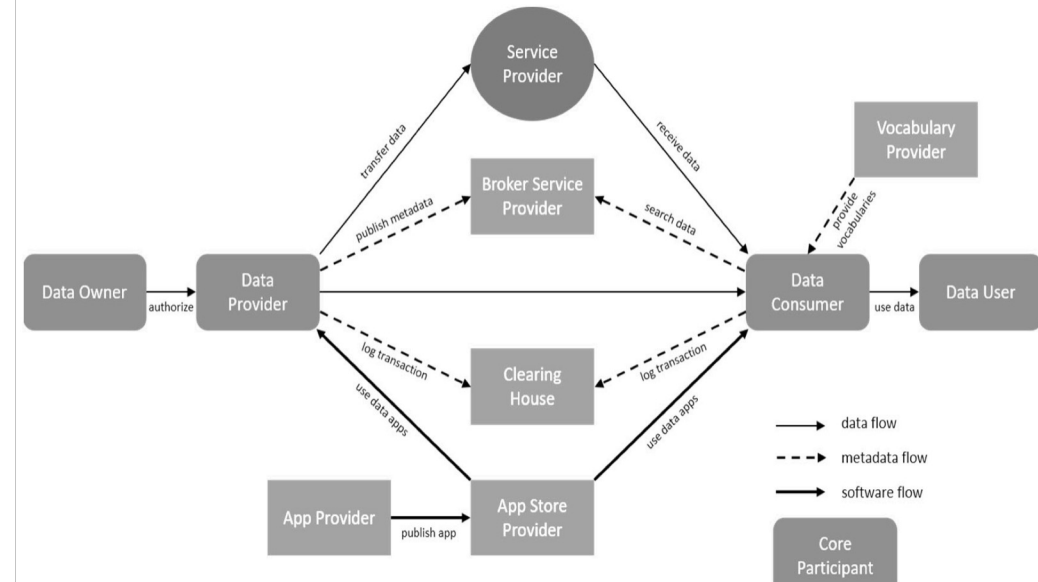
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## 2. Demystifying Data Spaces

How do we define and characterize (participatory) data spaces?

- Data spaces are forms of **multi-sided platforms** with **participatory governance** that **distribute decision rights** among stakeholders (Beverungen et al., 2022; Cuno et al., 2019; Otto & Jarke, 2019)
- They facilitate open yet **secure, non-discriminatory data-sharing ecosystems** that enable the reuse of data and collaborative innovations following **jointly agreed standards, rules, and policies** (Janev et al., 2022; Otto & Jarke, 2019)
- Data spaces are based on commonly specified **federated data infrastructures** that afford distributed data management (Curry et al., 2019) and **sovereignty** in compliance with regulatory frameworks, which create **trust** by **strengthening data privacy and security** (Ferretti, 2022; Genovese et al., 2022)



Otto, B., Rubina, A., Eitel, A., Teuscher, A., Schleimer, A. M., Lange, C., Stingl, D., Loukipoudis, E., Brost, G., Pettenpohl, H., Langkau, J., Gelhaar, J., Mitani, K., Hupperz, M., Huber, M., Jahnke, N., Brandstädter, R., Wessel, S., Bader, S. (2021): GAIA-X and IDS. International Data Spaces.



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# 3. Brief Gaia-X Introduction

An introduction to the goals of Gaia-X

## Data-driven business models

Enabling self-determined and data-driven business models.

## Federated Infrastructure

Facilitate access to a trustworthy, next-generation federated IT infrastructure that boots productivity.

## Fairness and transparency

Promote fair and transparent business models by establishing rules for such collaborative approaches, including legally compliant data use.

## Adding value to data

Support innovative, cross-industry collaborations to aggregate data and increase its value.

## Interoperability

Enabling cross-industry collaboration to create federated, interoperable services at the infrastructure level.

gaia-x

## Commercialization of data

Provide shared data monetization systems, sharing models, and appropriate enforcement rules. This makes data commercialization less complex and more cost-effective.

## Privacy

Support detection of and compliance with data protection classes and confidentiality rules, even for "mixed" data mappings. This prevents the loss of value of corporate data.

## Gaia-X Memberships and Hubs:

- Representative alliance of organizations in Europe
  - 350 companies and organizations
  - 3 out of 4 organizations are private companies, about half of which are SMEs
  - Organizations from different industries, such as Mobility, Energy, Manufacturing, Finance, etc.

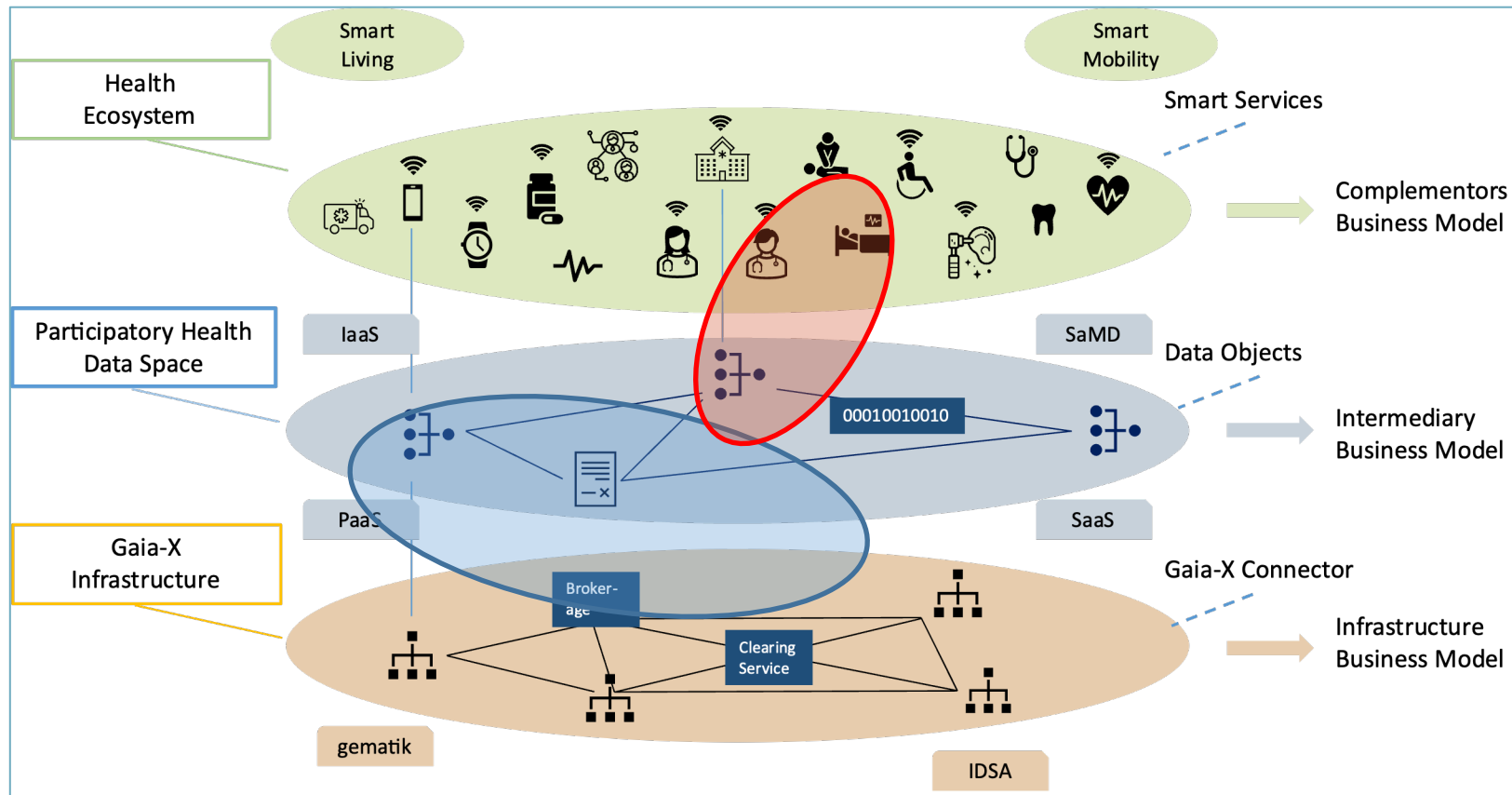


Bonfiglio, F. (2022). Gaia-X – Zoom-in the Big Picture of European Digital Ecosystems Future. Available at: [https://gaia-x.eu/wp-content/uploads/2022/07/Gaia-X-standard-Presentation\\_06072022.pdf](https://gaia-x.eu/wp-content/uploads/2022/07/Gaia-X-standard-Presentation_06072022.pdf).



# 3. Brief Gaia-X Introduction

Business model options at the level of infrastructure, data space services and use cases



**G2P/ B2C/P** , e.g.,: „secure processing environment (SPE) incl. EHR-connection“, e.g., for health insurance apps , Digital Therapeutics, DiGA/ DiPA, Health-Apps, FitBit,...

**G2B/B2B**, e.g.,: infrastructure/white label solutions for SPE according to EHDS, Apple Toolkit, IONOS Cloud, Siemens TDHP, gematik (TI 4.0, TIM & KIM) ...

Gersch & Danelski (2022). Integrationsarchitektur zu Dateninfrastrukturen, Datenräumen und Datenökosystemen aspired by Otto & Burmann (2021): Europäische Dateninfrastrukturen - Ansätze und Werkzeuge zur Nutzung von Daten zum Wohl von Individuum und Gemeinschaft. Informatik Spektrum 44(4), 283–291.



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# 4. The European Health Data Space (EHDS)

Why to the need the EHDS Proposal?

## Primary Health Market:

- Heavily regulated by a wide variety of laws
- Inadequate use of data and initial electronic format
- Patients have no access to data and cannot understand who is accessing data and for what purpose
- Insufficient data flow between institutions (e.g., second opinion)

## Secondary Health Market:

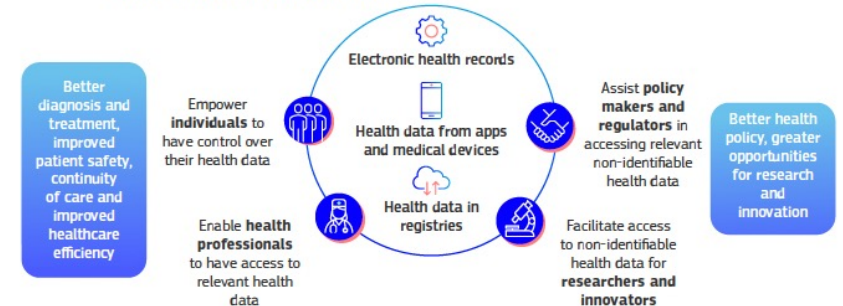
- Fitness data is locked in at large U.S. corporations
- No use in primary care, although it could provide valuable insights
- Significant barriers to preventive and data-driven healthcare
- Minimal research options

Requires European Health Data Space based on data sovereignty and citizen-centeredness, which would significantly improve primary and secondary data use



## OBJECTIVES

- ✓ Empower individuals through better digital access to their personal health data; support free movement by ensuring that health data follow people;
- ✓ Unleash the data economy by fostering a genuine single market for digital health services and products;
- ✓ Set up strict rules for the use of individual's non-identifiable health data for research, innovation, policy-making and regulatory activities.



European Commission, (2022), Factsheet – European Health Data Space #EUDigitalHealth, [https://ec.europa.eu/commission/presscorner/detail/en/f\\_22\\_2713](https://ec.europa.eu/commission/presscorner/detail/en/f_22_2713), last accessed on 23.11.2022

# 4. The European Health Data Space (EHDS)

A first overview, subdivision into primary and secondary data use

- First sector-specific data space of the European data strategy
- EHDS in line with other relevant European legislation (GDPR, Digital Services Act and Digital Markets Act).
- Overarching goal: Single European market for digital health services and products (establishing harmonization and interoperability in the way health is delivered).

## Primary data use:

- Provide citizens with immediate, free, and electronic access to health data.
- Access to and exchange of digital health data also across borders

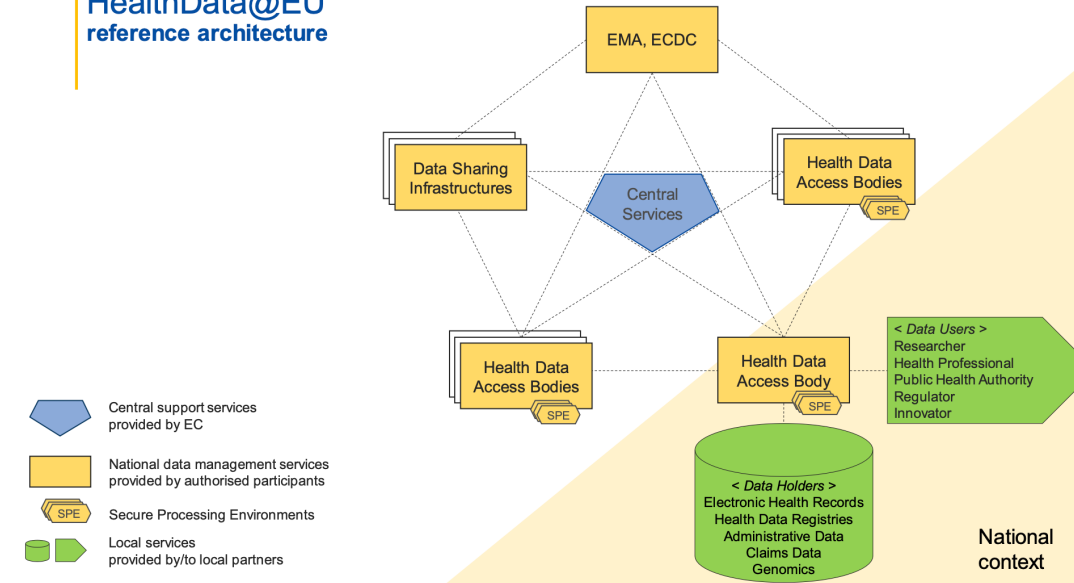
## Secondary data use:

- Improvement of research & development in Europe
- Better and personalized healthcare
- Processing of data without consent if data is pseudonymized or anonymized, and research serves the public interest



Kari et al. (2023)

HealthData@EU  
reference architecture



The 22nd Meeting of the eHealth Network (2022), “5 Update on EHDS”, retrieved from: [https://health.ec.europa.eu/events/22nd-meeting-ehealth-network-2022-11-07\\_en](https://health.ec.europa.eu/events/22nd-meeting-ehealth-network-2022-11-07_en), last accessed: 24<sup>th</sup> March, 2023.

2022	2023	2024	2025	2026	2027+
EHDS negotiations		?	EHDS in force	?	EHDS in application
		PS, eP/eD transitional period		?	
		Lab, images, discharge reports transitional period			2028?
		Joint Action EHDS1 (EU4H WP2022)			
		Capacity building, 1 <sup>st</sup> phase (EU4H WP2021)		?	Capacity building, 2 <sup>nd</sup> phase TBC (EU4H WP2021)

The 22nd Meeting of the eHealth Network (2022), “5 Update on EHDS”, retrieved from: [https://health.ec.europa.eu/events/22nd-meeting-ehealth-network-2022-11-07\\_en](https://health.ec.europa.eu/events/22nd-meeting-ehealth-network-2022-11-07_en), last accessed: 24<sup>th</sup> March, 2023.

# 4. The European Health Data Space (EHDS)

## Current structure of the proposed legislation

The scope of the law comprises 110 pages, today we will limit ourselves to a few essential aspects:

- Chapter 1: General (subject matter, scope, definitions, and relation to other EU instruments) (Art. 1 - 2).
- Chapter 2: Primary use of electronic health records (rights of individuals, obligations of health professionals, access to and transfer of personal electronic health records for primary use, types of electronic health records and their priority, interoperability of health records and national digital health authorities, MyHealth@EU) (Art. 3 - 13).
- Chapter 3: Regulation of EHR systems and wellness apps (obligations for EHR operators and related economic entities, self-certifications, conformity, and market surveillance authorities of/for EHR systems and other interoperability provisions, EU database for certified EHR system and wellness apps) (Art. 14 - 32)
- **Chapter 4: Secondary use of electronic health data** (general **conditions** for **secondary use** of electronic health data, description of **data types** and **uses**, data authorization, **governance** and **mechanisms for secondary use of electronic health data**, benefits and costs of health data for secondary use, cross-border access for secondary use, **national access point for health data availability from data holder to data user**, data set descriptions and quality requirements, and implementation of data altruism) (Arts. 33 - 58)
- Chapter 5: Supporting capacity development by member states (exchange of information on digital public services, funding, and rules for data transfers to third countries of non-personal data) (Art. 59 - 63)
- Chapter 6: European governance and coordination through EHDS Board (composition of the committee and its functioning) (Art. 64 - 66).
- Chapter 7: Delegation and committee (an expert group with various tasks; advice and assistance in the preparation of delegated legal measures) (Art. 67 - 68)
- Chapter 8: Other (rules on cooperation, sanctions & final provisions) (Art. 69 - 70)

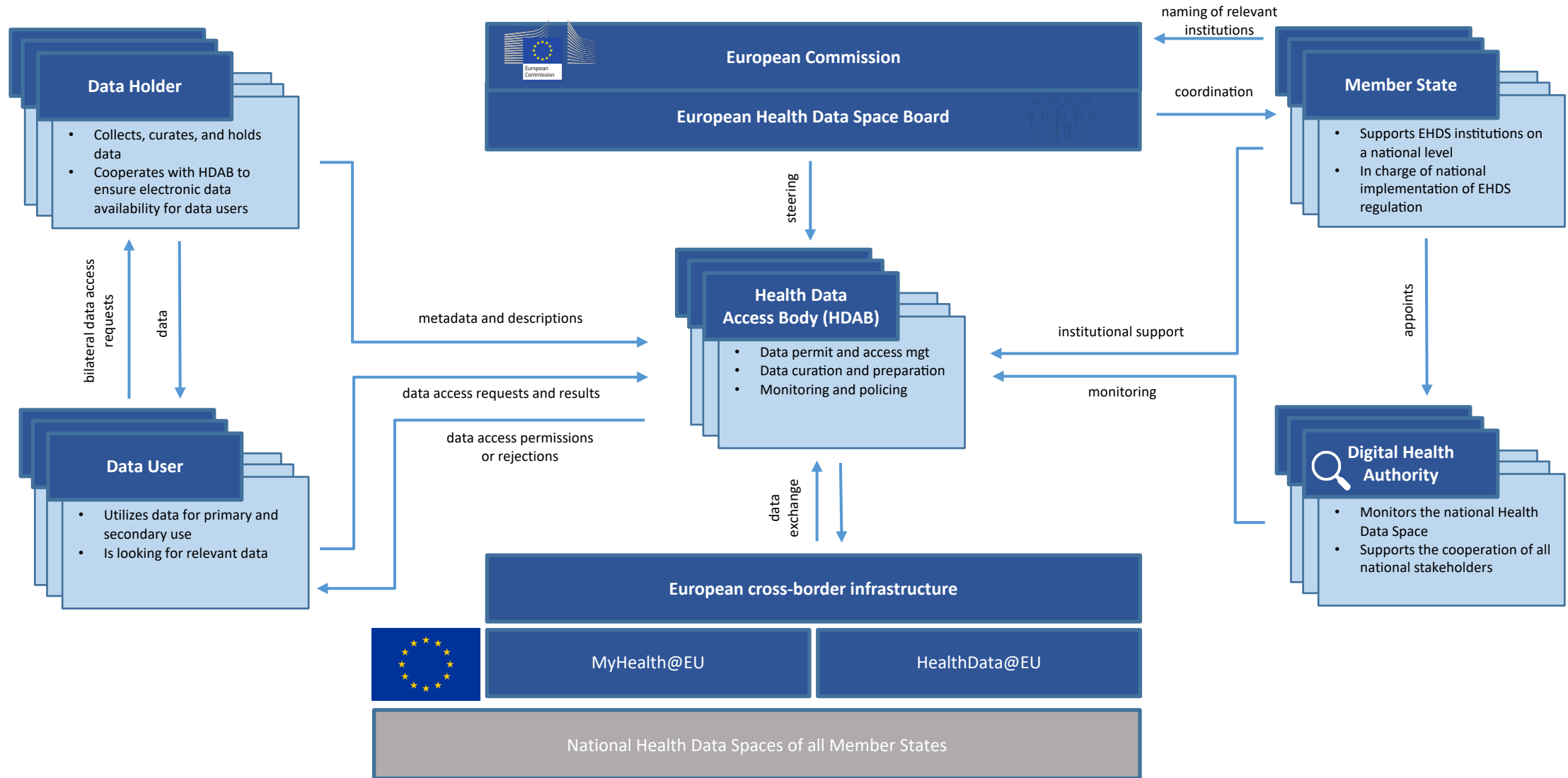
# 4. European Health Data Space (EHDS)

## WP6 & Innovation Hub: Summary of key roles, functions as well as institutional anchors

Role	Institutional anchoring	Primary functions
Supranational Regulator	European Commission	<ul style="list-style-type: none"> <li>Regulatory framework for the EHDS</li> <li>Facilitate the cross-border data exchanges</li> <li>Support member states in developing security standards and frameworks</li> </ul>
Supranational Orchestrator	European Health Data Space Board (Representatives of HDAB and Authorities)	<ul style="list-style-type: none"> <li>Support member states in coordinating practices between national Digital Health Authorities</li> <li>Link primary and secondary use of electronic health data</li> </ul>
National Orchestrator	Member States	<ul style="list-style-type: none"> <li>Appointment and establishment of a national HDAB and Digital Health Authority</li> <li>Establish data access services at local, regional, and national levels</li> <li>Ensure national EHDS compliance</li> </ul>
National Supervisory Body	Digital Health Authority (appointed by the member states, can consist of several institutions)	<ul style="list-style-type: none"> <li>Monitoring of compliance with the rights of individuals with regard to their personal data</li> <li>Ensure the adoption of relevant local, regional, or national rules and mechanisms</li> <li>Monitoring the data space and avoiding compromising conflicts of interest</li> <li>Receiving and handling complaints</li> <li>(Annual) report on activities in the data space.</li> </ul>
Operator of the national data space	<b>Health Data Access Body (HDAB)</b> (appointed by member states; must be a public institution)	<ul style="list-style-type: none"> <li>Issuing <b>data permits</b>, preparing, combining, and making data available for secondary use (Data Permit Management: reviewing, approving, and denying requests for data access)</li> <li>Granting data access in a <b>secure processing environment (SPE)</b></li> <li>Data Access Management: provision of publicly accessible and discoverable health data; establishment of Data Access Services; processing as well as pseudonymization and anonymization of data; ensuring data set quality and labeling (metadata catalog), as well as fee and charge regulation.</li> <li>Monitoring and policing, as well as the possibility of re-contacting (patient or physician) in the case of relevant findings</li> <li>Transparency of applications, granted authorizations (incl. purpose of use), and findings of data use</li> </ul>
Data Holder	Public, private, non-profit institutions and individual researchers	<ul style="list-style-type: none"> <li>Providing health data</li> <li>Description of own health data</li> <li>Data holders may also submit data requests (any natural person is eligible to apply)</li> </ul>
Data User	Public, private, and non-profit institutions and associations, as well as individual scientists	<ul style="list-style-type: none"> <li>Description of the projects for which data is necessary</li> <li>Submission of applications for the use of data according to the minimum principle</li> <li>Use of health data to optimize services, science, or policy making</li> </ul>

# 4. European Health Data Space (EHDS)

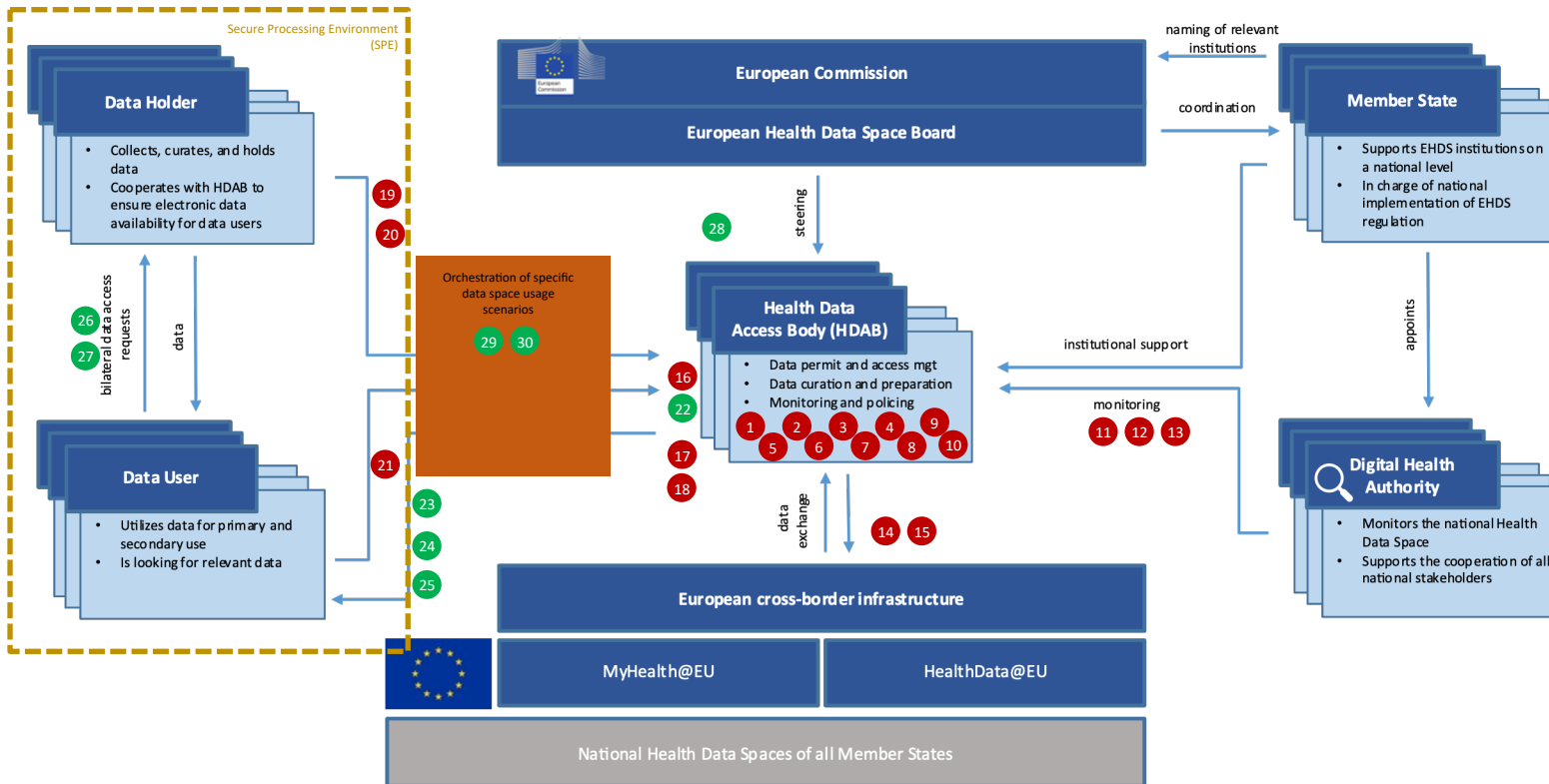
## Results: Specified Roles in the EHDS



# 4. European Health Data Space (EHDS)

## Mapping of roles and functions

### Functions within the EHDS:



- |  |  |
|--|--|
| <ul style="list-style-type: none"> <li>1 Provision of publicly accessible health data</li> <li>2 Data access services at national, regional and local level</li> <li>3 Data permit management services (including approval, issuance, revocation)</li> <li>4 Aggregation (e.g., collecting, combining, processing) of health data for secondary use</li> <li>5 Pseudonymization, anonymization, randomization and generalization</li> <li>6 Operation of a metadata catalog and discovery services</li> <li>7 Classification of the data quality of data sets</li> <li>8 Emergency access</li> <li>9 Preparation of an annual activity report</li> <li>10 Publication of the data permits</li> <li>11 Monitoring services</li> <li>12 Implementation of defined penalties (up to exclusion)</li> <li>13 Control of the public interest orientation of data exchange</li> <li>14 Interoperability with HealthData@EU and MyHealthData@EU</li> <li>15 Interoperability of the national metadata catalog</li> <li>16 Control of compliance with rules by data user and data holder</li> <li>17 Provision of information on the secondary use of data</li> </ul> | <ul style="list-style-type: none"> <li>18 Provision of information on research projects and results</li> <li>19 Consent management applications (e.g., data wallet app)</li> <li>20 <b>Technical onboarding (including identity management) of data holders</b></li> <li>21 Technical infrastructure for n:m data exchange</li> <li>22 Information security and contact with affected stakeholders</li> <li>23 Assisting data users in selecting appropriate data sets</li> <li>24 Assist in the development and delivery of healthcare services.</li> <li>25 Conceptual and organizational onboarding of data users</li> <li>26 <b>Community building and stakeholder management</b></li> <li>27 <b>Establishment and operation of participatory governance function</b></li> <li>28 Promoting the development of common (interoperability) standards</li> <li>29 <b>Coordination and support of specific usage scenarios for concrete data users</b></li> <li>30 <b>Creation of technical and organizational interoperability with the superordinate data space</b></li> </ul> |
|--|--|

### Legend:

● Development and operation of technical architecture and related services

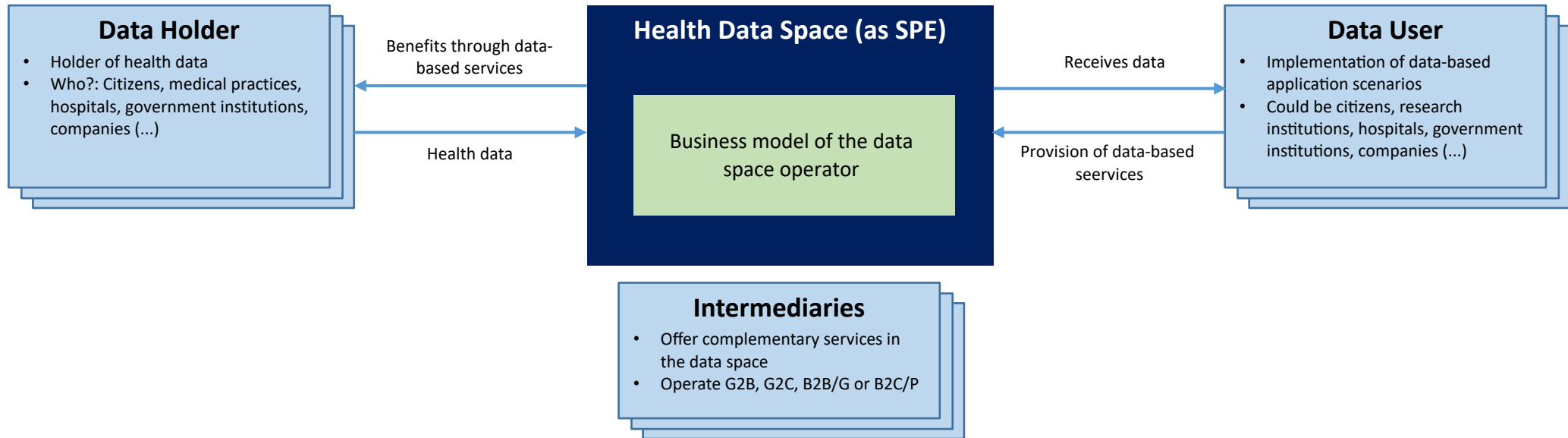
● Organizational- and conceptual management functions

**Bold** Additions that are not mentioned in the EHDS, but will likely arise within its ecosystem



# 4. The European Health Data Space (EHDS)

A possible mapping of emerging business model innovations



Relationship	Government to Business (G2B) /Customer (G2C)	Business to Business (B2B) /Governance (B2G)	Business to Patient (B2P) /Customer (B2C)
New Roles (examples of new business models)	Health Data Access Body	Data space orchestrators (technical-organizational)	DataWallet
	(Health) Data Institute	Data aggregators/algorithm trainers	Data Trustee
	Digital Identity Provider	B2B-/B2G Data Trustees	Digital Disease Manager (dDM)
	Digital Agency	Orchestrators (research/supply scenarios)	Comparative portals
	...	Federated Services/White Labels/Certification ...	Explainer / Representative/ Communities ...



## 4. The European Health Data Space (EHDS)

### Open Questions of the current version of the draft

- The timeline of the EHDS seems to be ambitious – does it requires an update on the implementation schedule?
- Alignment with the GDPR in some areas of the proposal seems to be too unspecific yet
- Technical specification leaves much room for interpretation – central vs. decentral infrastructure approach?
- How can harmonization in application between member states be assured and fragmentation avoided?
- Possibility to insert data (e.g., private wellness data) into EHR systems?
- Many issues still arise regarding secondary use of health data within EHDS proposal:
  - Possibility of (i) objection, (ii) Opt-In, or (iii) Opt-Out approach?
  - Scope of mentioned data categories for secondary use of the data is yet somehow arbitrary
  - Fees and economic sustainability of the infrastructure for secondary use of data (how can a “fair price” be determined)?
  - To what extent can/should the data release by the HDAB be (partially) automated?



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5. **Health-X dataLOFT**

# 5. Health-X dataLOFT

## Building a Legitimate, Open, FederaTed European Health Data Space

### Status Quo:

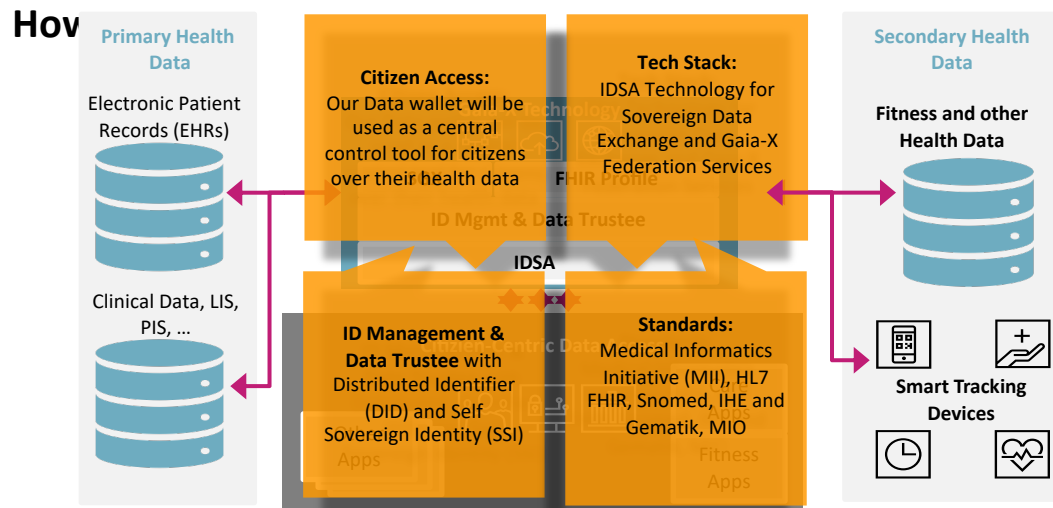
- Primary use of healthcare data is strongly regulated
  - Secondary use of healthcare data is dominated by GAFAM
  - European healthcare data is fragmented, largely inaccessible and stored in data silos
  - Centralized data collection contradicts European values and our European regulatory framework
- => Need for a (European) Health Data Space

### Our Vision and Mission:

- Through our Health-X dataWallet, we aim to provide **voluntary, consent-based**, legally compliant & **patient/citizen-centric** access to health data
- **Decentral** and **federated** approach to increase **trust** and **security**
- Utilization of primary and secondary health data for **improved data-driven care** and **prevention**

### Our Approach:

- Fine-granular access control: **Who** can access my health data **when** for which **purpose**?
- **EHDS** conform data exchange ecosystem enabling research and platform-based smart services
- **Interoperability** to existing **standards**, integrating existing **infrastructure**, and **cooperating** with other **initiatives and stakeholders**
- **Four Use Cases:** (1) Autonomous Everyday Health, (2) Clinical Accompaniment, (3) Personalized Health Services, and (4) Secondary Use of Data
- Four Innovation Price Winners: eCovery, NichtraucherHelden, Thryve, Zeeds



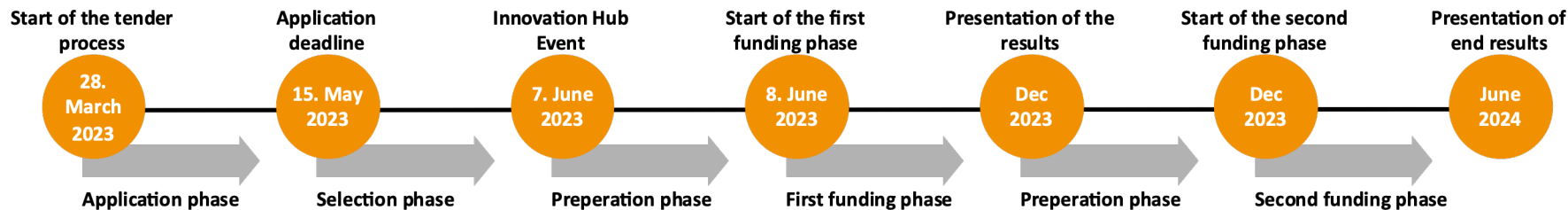
# 5. Health-X dataLOFT

Call for participation: The 2<sup>nd</sup> round of the Health-X Innovation Price Competition just opened

- Award of two Health-X prizes, each with up to **75,000 €**
  - Innovation Price (HxIP: **focus on startups & researchers**)
  - Fellowship Price (HxFP: **focus on established companies**)
- Benefits for participants:
  - **Financial support** for the development of digital health innovation in the health data space of the future.
  - **Expertise & mentoring by developers** of the data space and **use of the Health-X Tech Stack** (access to technologies, information, documentation, and consortium partners)
  - First Mover Advantage in **integrating your solution into a federated data space** - "Get ready for EHDS!"



Who?	<ul style="list-style-type: none"> <li>• Researchers, Start-Ups, Incumbents and Innovators</li> </ul>
What?	<ul style="list-style-type: none"> <li>• Developing digital Health Innovations in form of initial proof of concepts or MVPs for a participatory data space (e.g., EDHS).</li> </ul>
Why?	<ul style="list-style-type: none"> <li>• Financial support up to 75.000 EUR</li> <li>• Using the tech stack, expertise of a lighthouse project, as well as receiving mentoring</li> </ul>
How?	<ul style="list-style-type: none"> <li>• Application for participation through submitting a concept</li> </ul>
When?	<ul style="list-style-type: none"> <li>• Submission of proposal until Mid May 2023</li> <li>• Selection in June 2023</li> <li>• Start working already in June 2023</li> </ul>
Details	<ul style="list-style-type: none"> <li>• More information at: <a href="http://www.health-x.org/innovationsforen">www.health-x.org/innovationsforen</a></li> </ul>

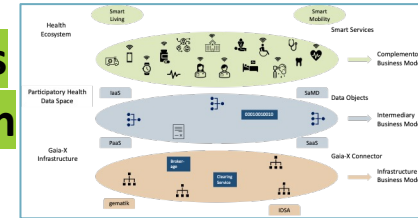


# Summary of the presentation

How do Data Spaces, Gaia-X, the EHDS and Health-X relate to each other?

## Data spaces...

- are new forms of **multi-sided platforms** which adhere to **participatory governance mechanisms** so that they become **inclusive** to all interested (sizes of) organizations and **increase competition**
- can but does not have to build upon Gaia-X infrastructure



## Gaia-X...

- is a technical and sector-independent **data infrastructure initiative** funded by the Commission
- builds a **common standard** for an **open, transparent** and **secure** digital ecosystem that enables **reliable data exchange** and supports **data and cloud sovereignty**



## The EHDS...

- is a **regulatory** and **technology agnostic** proposal to establish European health data spaces
- empowers patients to take **control** over their data and support **secondary use** of health data



## Health-X...

- is a research project funded by the German Federal Ministry of Economy and Climate Affairs
- is a potential **technical reference architecture** for the German implementation of the EHDS



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Thanks for listening!

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**Any open questions? Let's discuss!**