European Health Data Space regulation

What does it mean for accessing data?

Agenda

1. Introduction
2. EHDS for secondary use of data

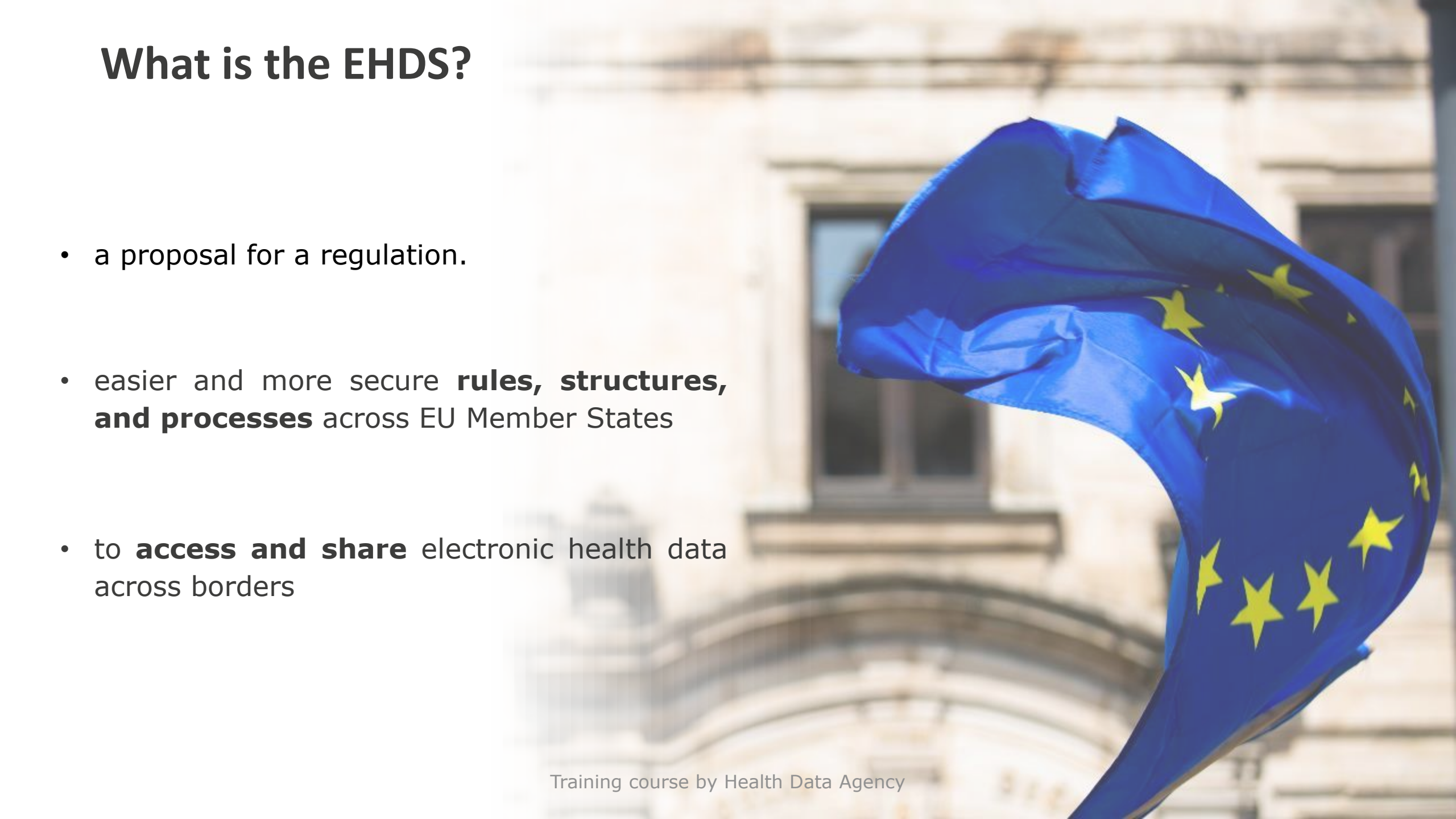
Before we begin…

- This session is merely meant to inform you on the current proposal of the EHDS regulation
- The HDA did not draft the EHDS regulation
- The implementing acts still need to follow and the regulation is still to be signed officially
- There is a difference between the theory and putting it in practice
  - The HDA is participating in several working groups at EU-level where ongoing developments, examples form other member states and implementing acts are being discussed
- Feel free to raise concerns, ideas & questions during or after this session but note that we are focussing on requesting data during this session.
  - Thus, keep concerns, ideas & questions relevant to the purpose of our working group
  - It is not the purpose to solve and discuss all concerns during this session
  - Please raise your hand in case of any questions or paste them in the chat

Introduction

What is the EHDS?

- a proposal for a regulation.
- easier and more secure **rules, structures, and processes** across EU Member States
- to **access and share** electronic health data across borders



What is the EHDS?

*"…ensure that **natural persons** in the EU have **increased control** in practise **over their electronic health data.** It also aims to ensure a legal framework consisting of trusted EU and Member State **governance mechanisms and a secure processing environment**. This would allow researchers, innovators, policymakers and regulators at EU and Member State level to **access relevant electronic health data to promote better diagnosis**, treatment and well-being of natural persons, and **lead to better and well-informed policies**. It also aims to contribute to a genuine single market for digital health products and services, by harmonising rules, and so boost healthcare system efficiencies."*

Source: Proposal for a Regulation of the European Parliament and of the Council on the EHDS

What is the EHDS?

Pillars of the EHDS

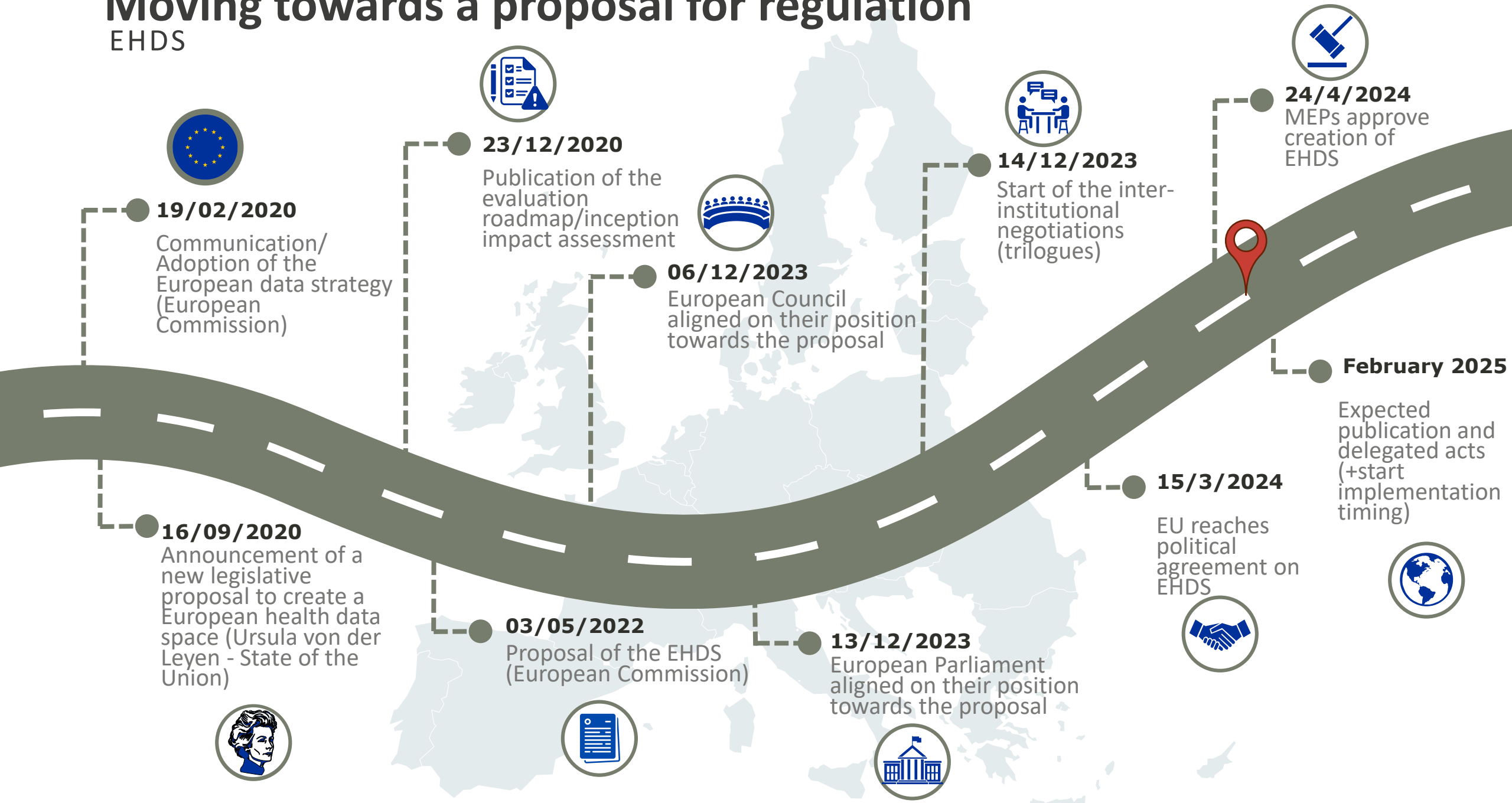
Establishing a legal framework for data access and exchange

Ensuring (health) data quality and interoperability.

Creating a strong infrastructure

Moving towards a proposal for regulation

EHDS



19/02/2020

Communication/ Adoption of the European data strategy (European Commission)

16/09/2020

Announcement of a new legislative proposal to create a European health data space (Ursula von der Leyen - State of the Union)

23/12/2020

Publication of the evaluation roadmap/inception impact assessment

03/05/2022

Proposal of the EHDS (European Commission)

06/12/2023

European Council aligned on their position towards the proposal

13/12/2023

European Parliament aligned on their position towards the proposal

14/12/2023

Start of the inter-institutional negotiations (trilogues)

15/3/2024

EU reaches political agreement on EHDS

24/4/2024

MEPs approve creation of EHDS

February 2025

Expected publication and delegated acts (+start implementation timing)

BENEFICIARIES AND IMPACTED BY THE EHDS

Individuals

Healthcare providers

Researchers

Healthcare professionals

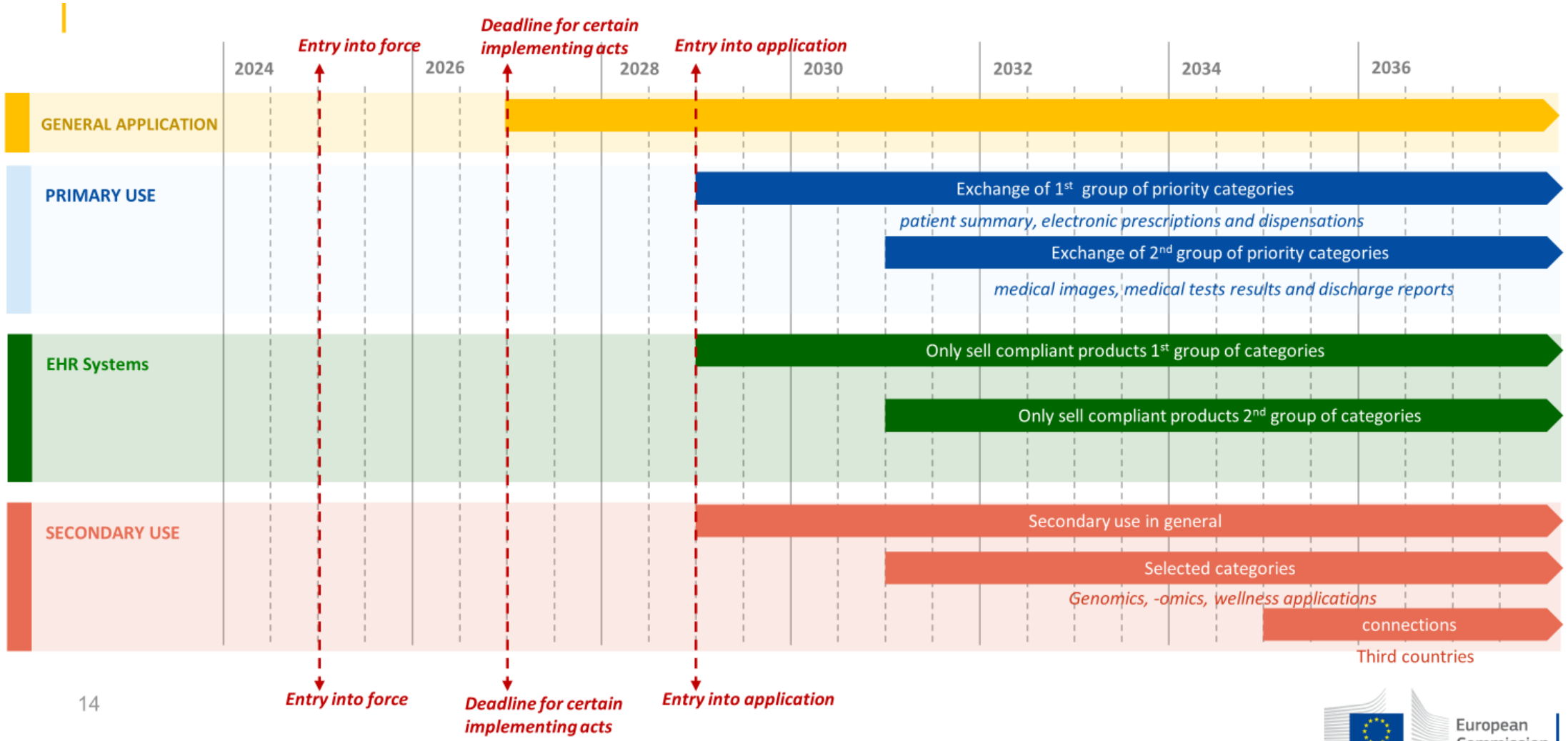
Regulators

Industry

Why have an EHDS?

- From primary to secondary use of data
- Complement and further specify existing legislation
- Create new and decentralized EU infrastructure
- Connect Health Data Access Bodies from Member States
- Establish European Health Data Space Board to facilitate cooperation and exchange

Timeline for implementation



European Commission

HDA

EHDS for secondary use of data

Primary and Secondary Use

EHDS
an Ecosystem of…

Rules

Standards

Infrastructure

Governance

Primary Use

Empower individuals through digital access to and control over their data

Support free movement and genuine single market for electronic data systems

Secondary Use

Provide consistent, trustworthy and efficient set-up of activities:

- Use for research and innovation
- Policy-making
- Regulation

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What data is covered?

Data related to **clinical and health records**

- Data from EHRs (Electronic Health Records)
- Population-based registries
- Medical and mortality registries
- Data from clinical trials, studies, and investigations
- Health data from medical devices

Data related to **(scientific) research**

- Pathogen data
- Human genetic, epigenomic, and genomic data
- Human molecular data (proteomic, transcriptomic, metabolomic, lipidomic, and other omics data)
- Data from research cohorts, questionnaires, & surveys (after publication of first results)
- Data from biobanks & databases

Data related to **healthcare system & administrative** data

- Data on healthcare needs, resources, provision, and access to healthcare
- Administrative data (incl. dispension, claims, and reimbursements)
- Health professional status, specialization, and institution data
- Medicinal products & medical devices registries

Data related to **health determinants**

- Data on factors impacting health (socioeconomic, environmental, behavioral data)

Data related to **personal health and lifestyle**

- Automatically generated personal electronic health data (through medical devices)
- Data from wellness applications

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For what secondary use purpose can it be used?

Improving delivery of care, treatment optimization and providing healthcare

Public interest in the area of public and occupational health*

Scientific research including:

- Development and innovation activities for products or services
- Training, testing and evaluating of algorithms, including in medical devices, in-vitro diagnostic medical devices, AI systems and digital health applications;

Policy making and regulatory activities*

Education or teaching activities

Statistics*

** Reserved for public sector bodies and Union institutions, bodies, offices and agencies exercising their tasks conferred to them by Union or national law, including where processing of data for carrying out these tasks is done by a third party on behalf of that public sector body or of Union institutions, agencies and bodies.*

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For what purpose can it not be used?

Advertising or marketing activities

Activities in conflict with ethical provisions pursuant to national law

Taking decisions in relation to a natural person or groups of natural persons in relation to job offers or offering less favourable terms in the provision of goods or services, including to exclude them from the benefit of an insurance or credit contract or to modify their contributions and insurance premiums or conditions of loans, or taking any other decisions in relation to a natural person or groups of natural persons having the effect of discriminating on the basis of the health data obtained;

Developing products or services that may harm individuals, public health or societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco and nicotine products, weaponry or products or services which are designed or modified in such a way that they create addiction or that they contravene public order or cause a risk for human health

Taking decisions detrimental to a natural person or a group of natural persons based on their electronic health data;

HDA

Any clarifications needed?

Any reflections or questions?

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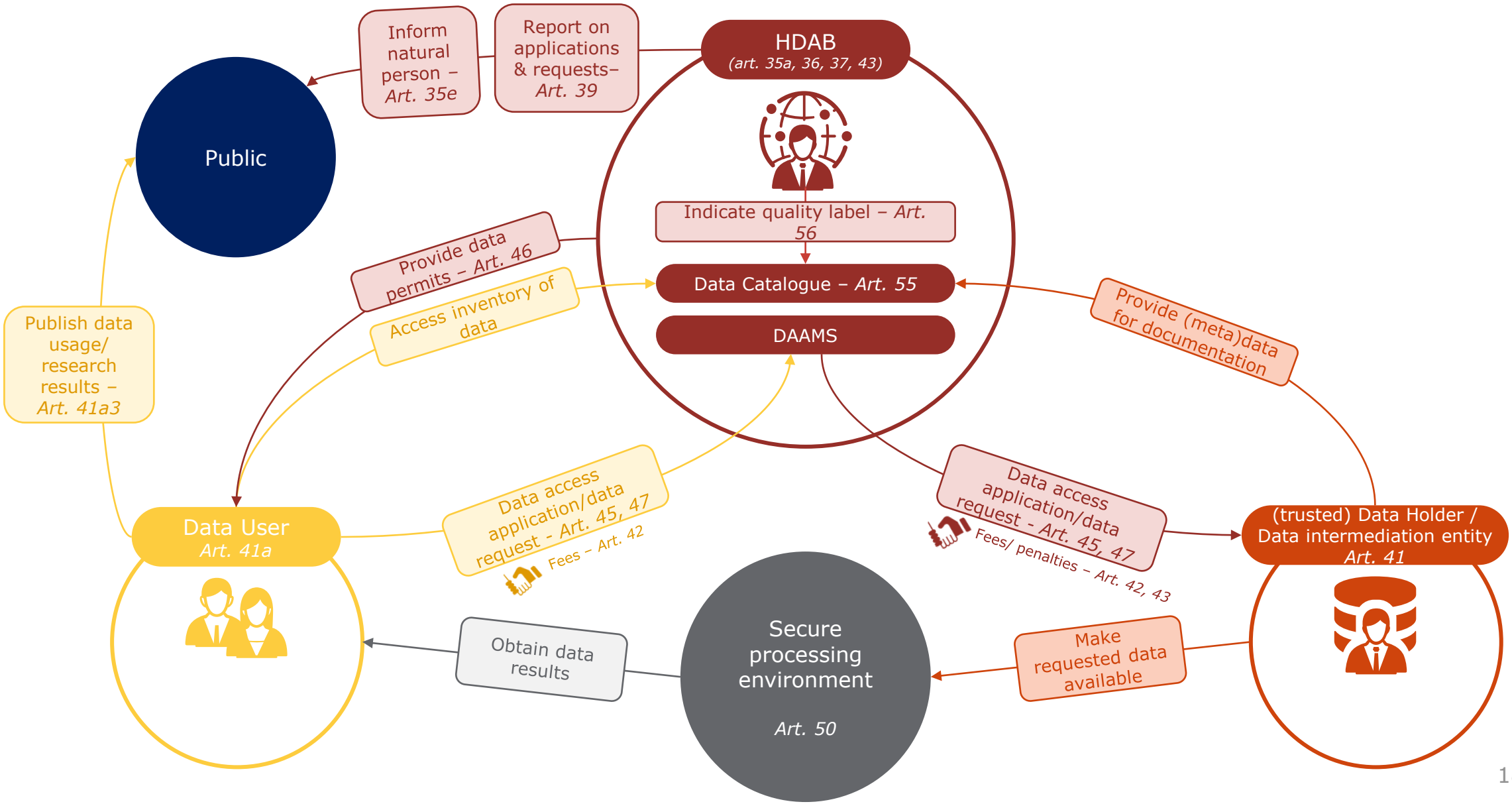
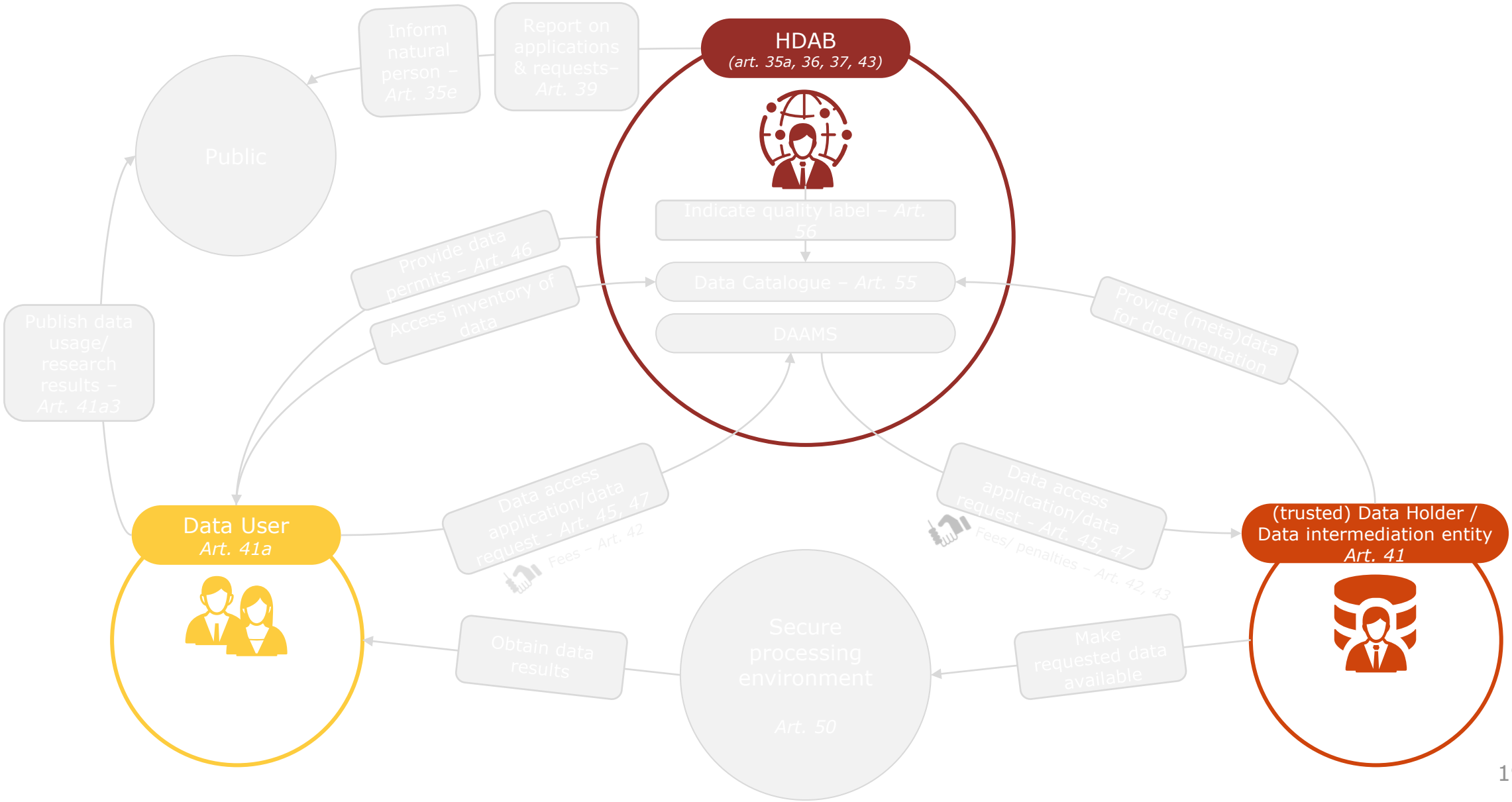
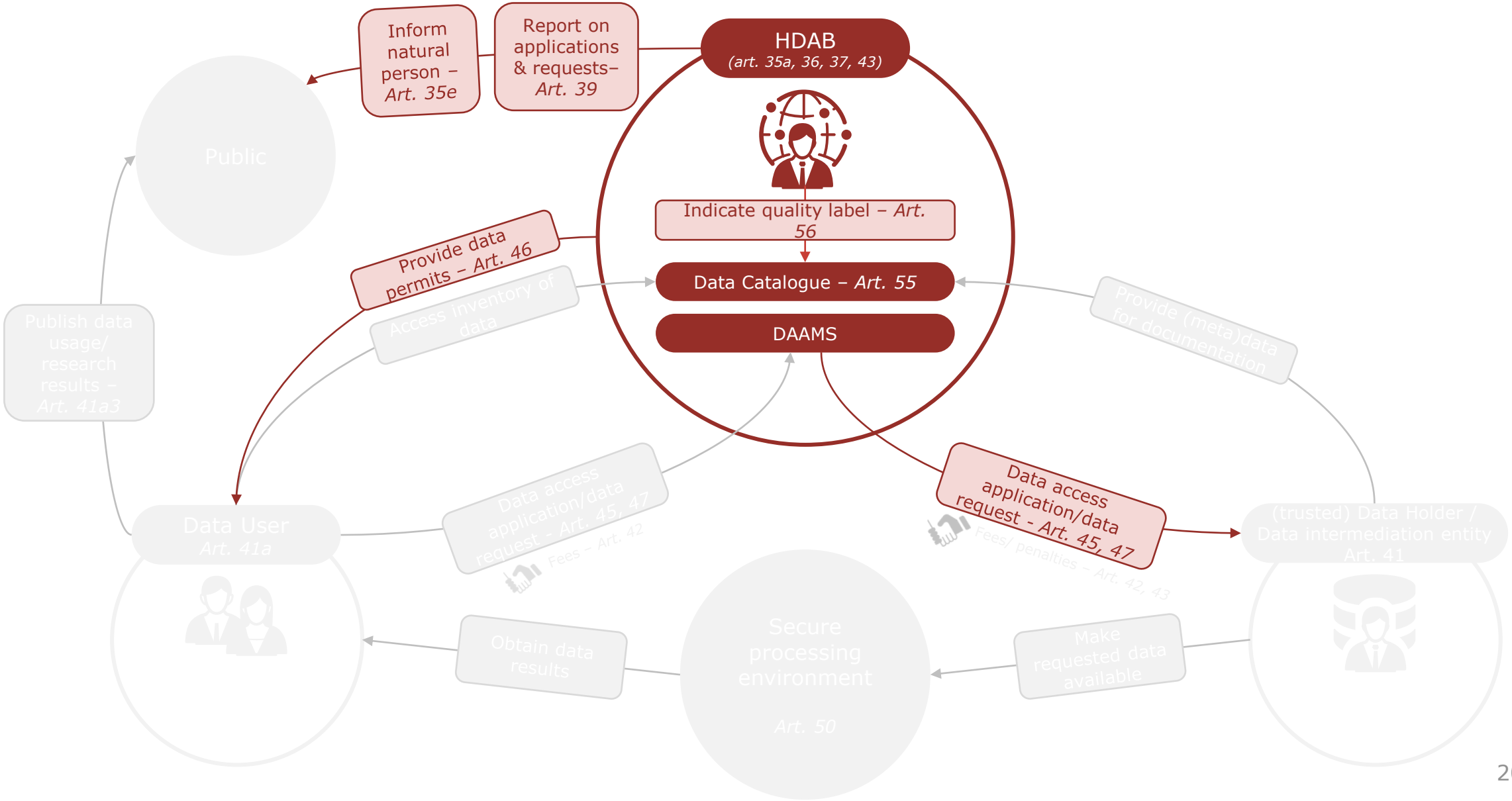
Secondary use within EHDS made visual



Zoom-in in roles



HDAB


Inform natural person – Art. 35e
Report on applications & requests– Art. 39
HDAB
(art. 35a, 36, 37, 43)
Public
Indicate quality label – Art. 56
Provide data permits – Art. 46
Data Catalogue – Art. 55
Access inventory of data
DAAMS
Provide (meta)data for documentation
Publish data usage/ research results – Art. 41a3
Data access application/data request - Art. 45, 47
Fees – Art. 42
Data access application/data request - Art. 45, 47
Fees/ penalties – Art. 42, 43
Data User
Art. 41a
(trusted) Data Holder / Data intermediation entity
Art. 41
Obtain data results
Secure processing environment
Art. 50
Make requested data available

HDAB

A **HDAB**, or **Health Data Access Body**, is an organization or entity designated to facilitate secure, ethical, and efficient access to health data.*

What are the tasks of an HDAB?

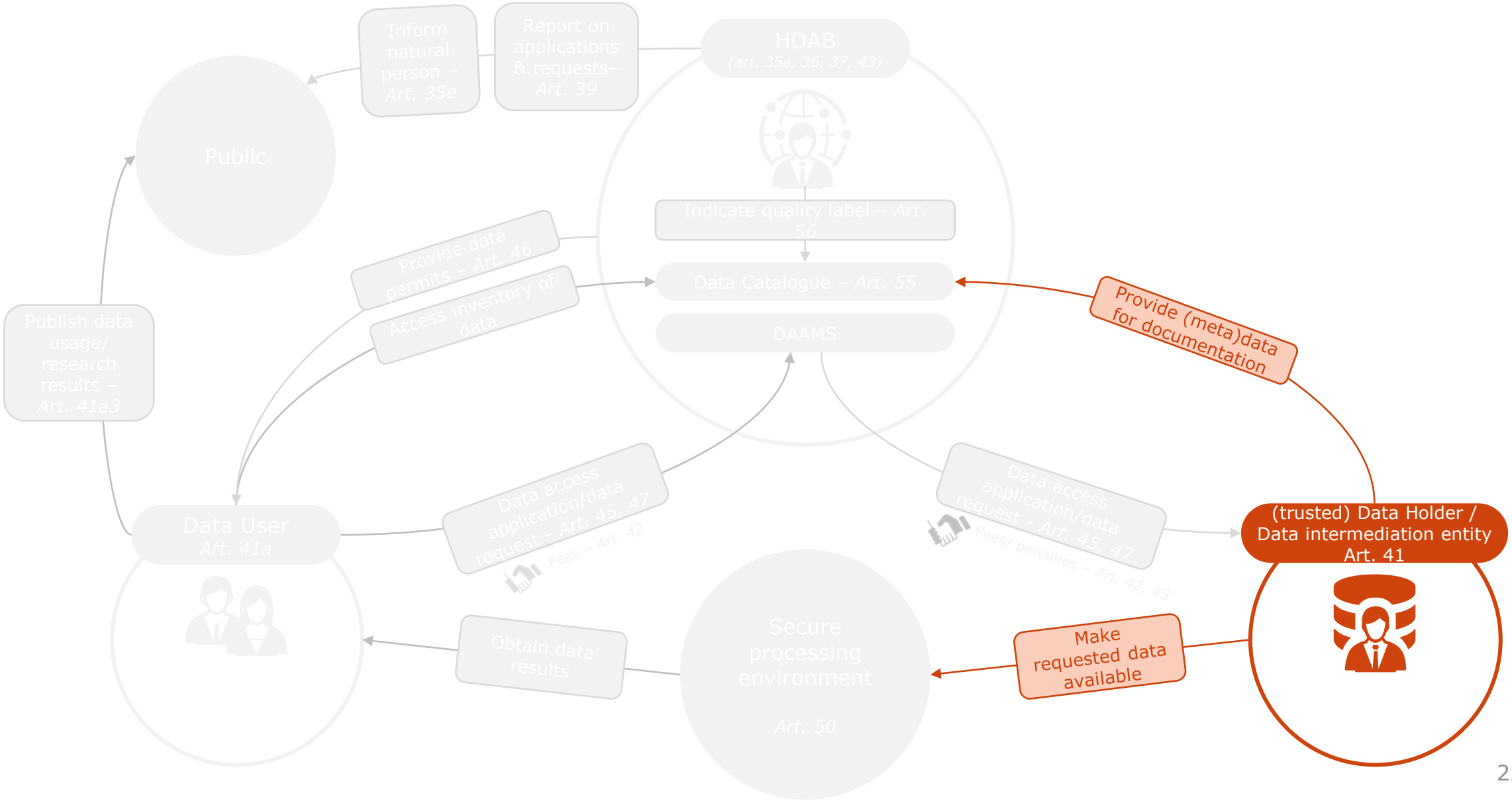
- Decide on data access applications & data requests, authorise and issue data permits
- Process electronic health data
- Preserve the confidentiality of IP rights
- Cooperate with and supervise data holders to ensure the implementation of the data quality and utility label …
- Maintain a management system to record and process data access applications & data requests
- Cooperate at Union and national level to lay down common standards, technical requirements and appropriate measures for accessing electronic health data in a secure processing environment;
- Cooperate at Union and national level and provide advice to the Commission on techniques and best practices for the secondary use and management of electronic health data;
- Facilitate cross-border access to electronic health data for secondary use
- publish detailed information about the conditions for the use of electronic health data. (slide 41)

There can be more than one HDAB per member state. In that case, one HDAB takes on the role of coordinating HDAB.

*unofficial definition

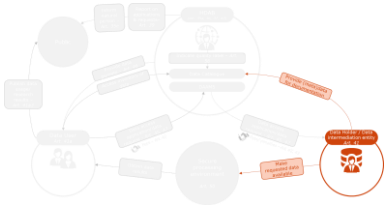
Reference: Article 35a, 36, 37, 43

(Trusted) Data Holder & Intermediation Entity



Data Holder

A **Data Holder** is defined as an organization, institution, or entity that collects, stores, and manages health-related data, making it available for primary or secondary use under the EHDS framework.*



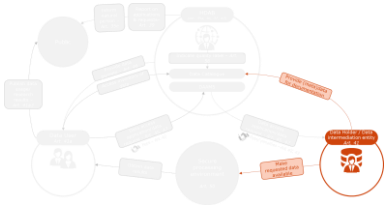
What are the duties of a Data Holder?

- Make relevant electronic health data available
- Communicate to the health data access body a description of the dataset it holds & at least annually check that its dataset description in the national datasets catalogue is accurate and up to date.
- Provide sufficient documentation to the health data access body to confirm the accuracy of the data quality label (if any) applied to his data.
- Ensure access to data through trusted open databases to ensure unrestricted access for all users and data storage and preservation.

*unofficial definition

Reference: Article 41

Intermediation entity



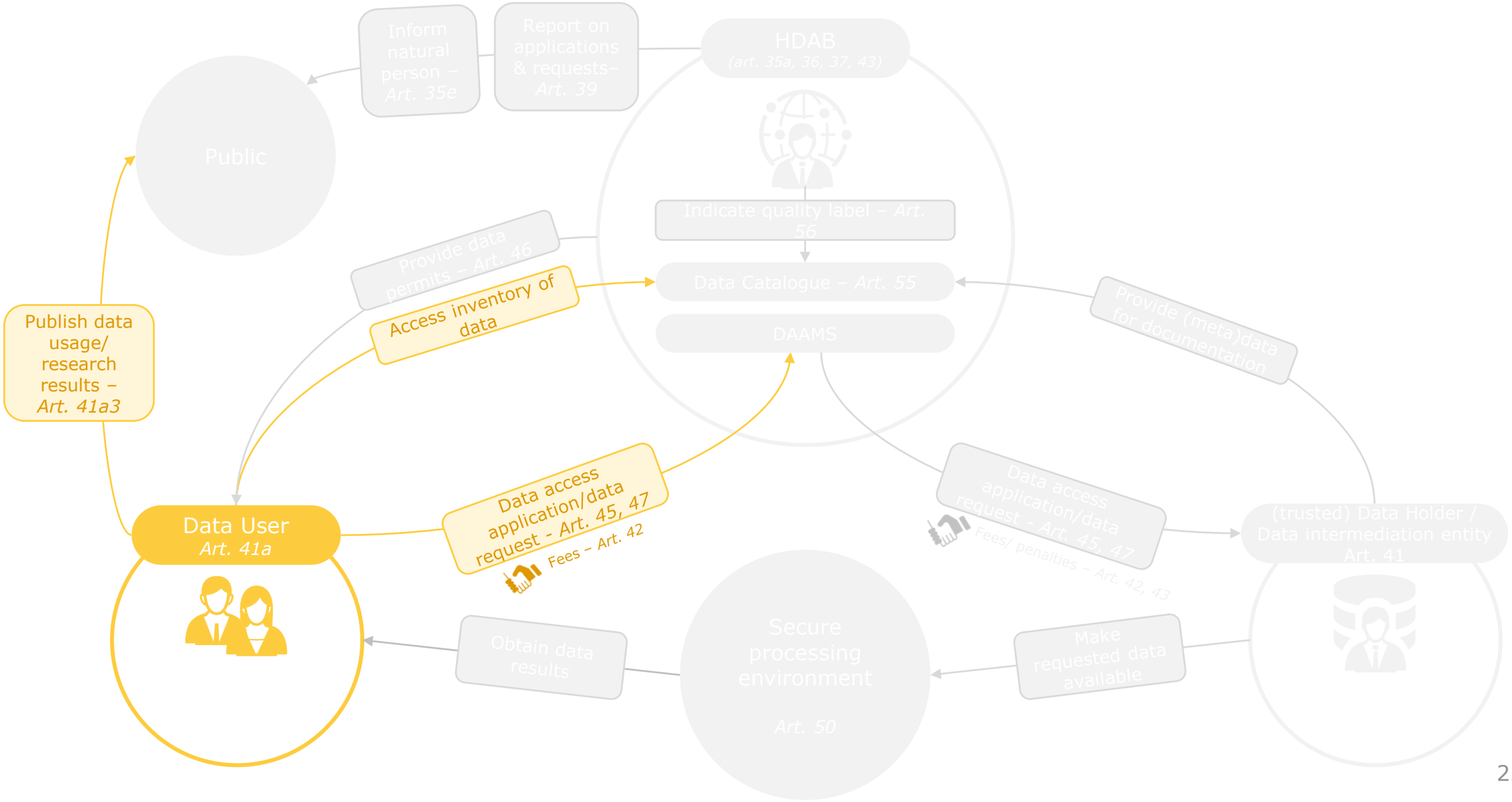
An Intermediation Entity acts as trusted intermediaries, ensuring that data access and sharing align with EHDS regulations, particularly regarding data privacy, security, and ethical use.*

*unofficial definition

What is an intermediation entity and why do they exist?

- Member States may, by virtue of national legislation, provide that the duties of certain categories of data holders shall be fulfilled by health data intermediation entities. In that case, the data shall still be considered as being made available from several data holders.
- Intermediation Entities could relieve the administrative burden of small enterprises (e.g. doctors)

Data user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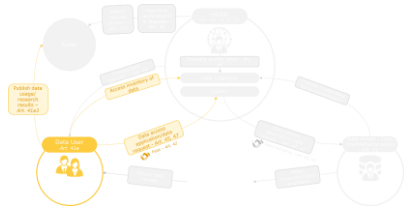
Data User

A **Data User** is an individual or organization authorized to access and use health data for specific purposes within the EHDS framework. *



What are the duties of a Data User?

- Access & process electronic health data for secondary use in accordance with
  - A data permit
  - A data request
  - An approval of a relevant authorized participant
- Prohibited to provide access to or make electronic health data available to third parties
- Prohibited to re-identify or seek to re-identify the natural persons to which the electronic health data which they obtained
- Make public the results or output of the secondary use of electronic health data within 18 months after the completion of the electronic health data processing
- Cooperate with the health data access body

*unofficial definition

Reference: Article 41a

Any clarifications needed?

Any reflections or questions?

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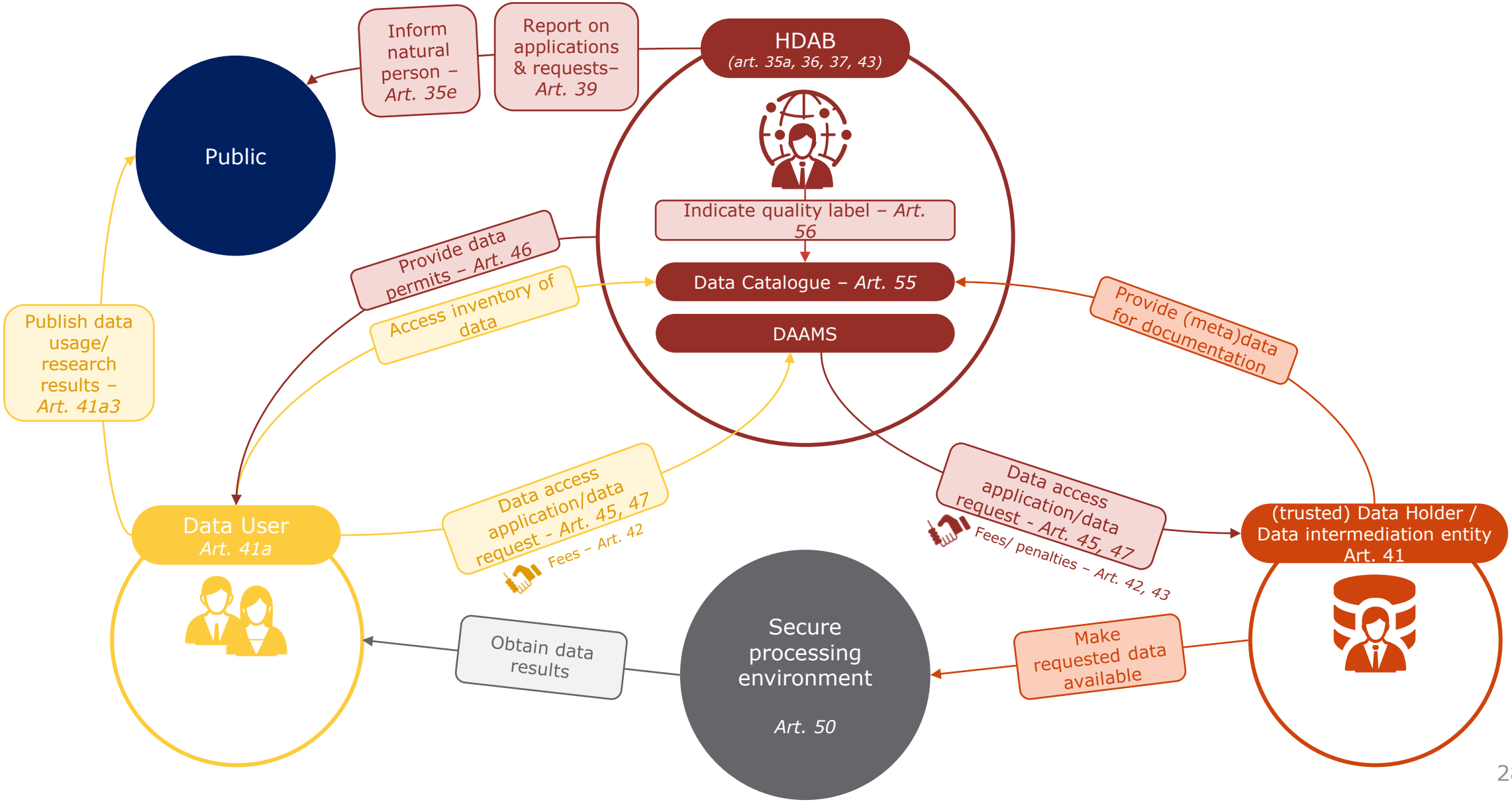
Zoom-in on data findability



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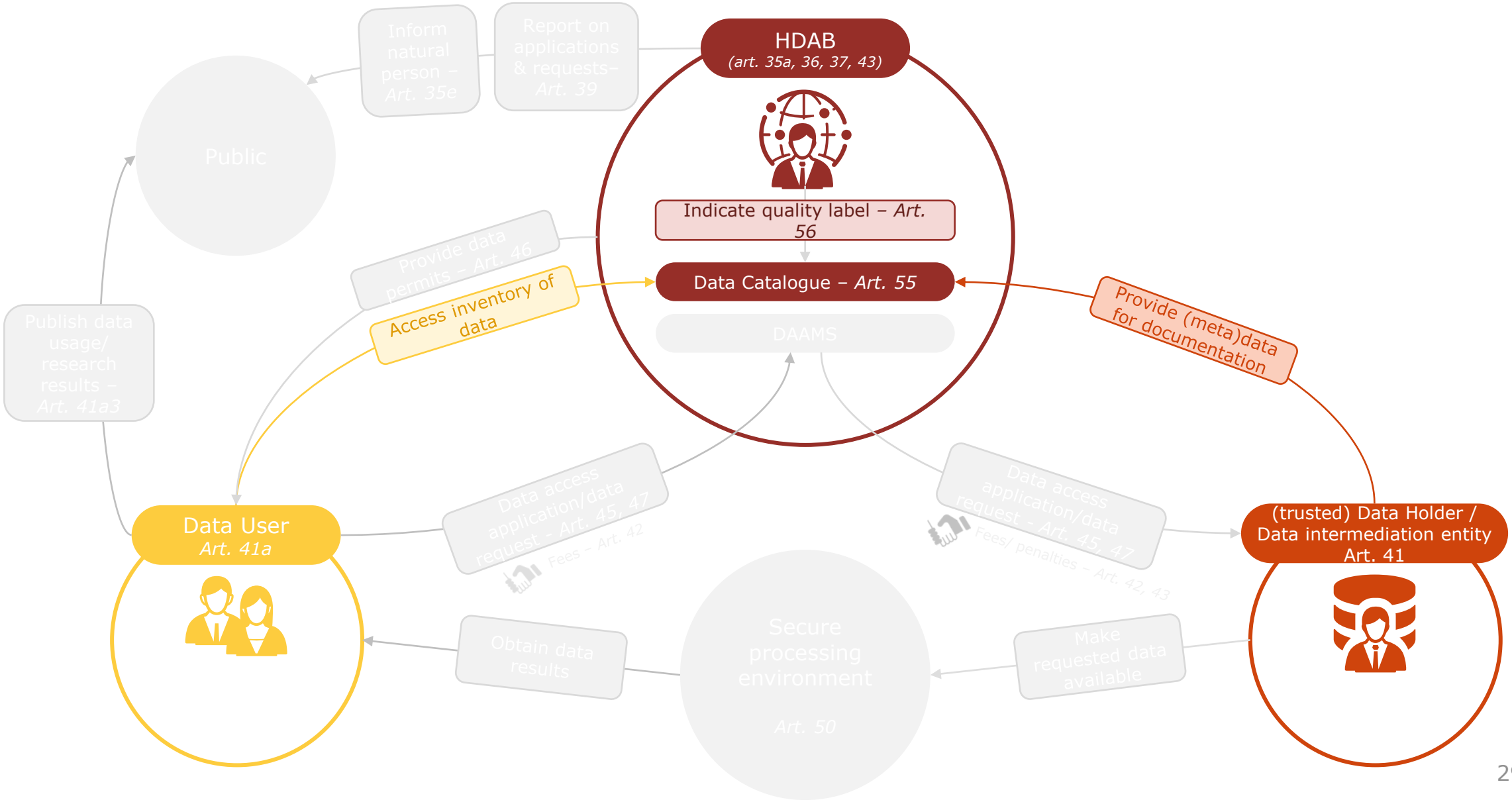


Data findability

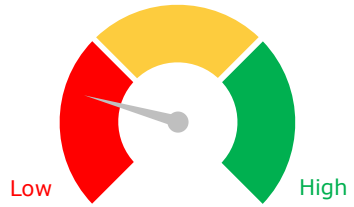
Data Catalogue

The HDAB will offer a **publicly accessible**, **machine-readable metadata catalogue** about health datasets. It will be **accessible at single information points** as specified by EU regulation.

Reference: Article 55

Data quality label

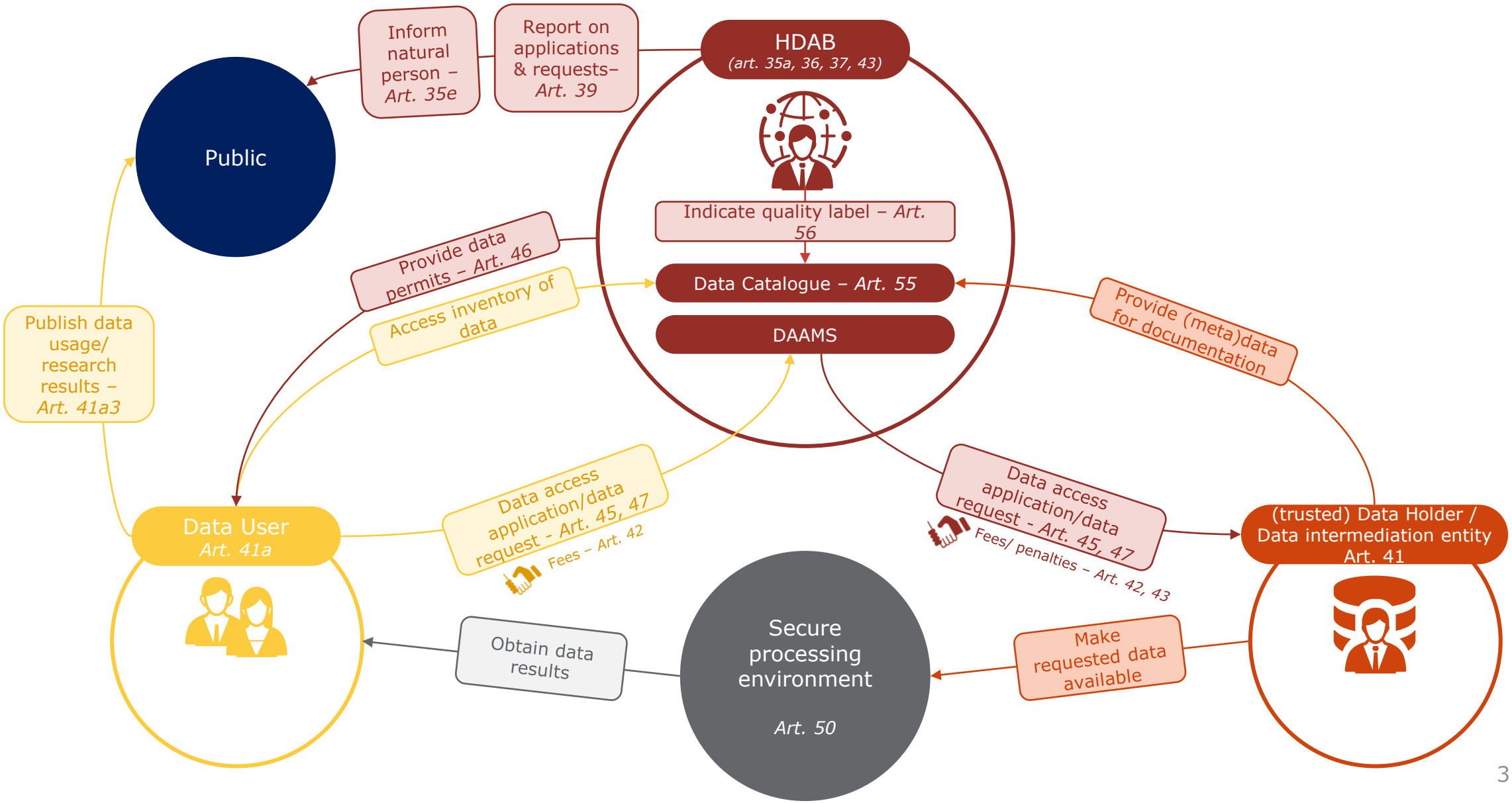
Datasets obtained via HDAB's can be labeled with a "**Union data quality and utility label**" by the **data holders**. This label is **mandatory for datasets funded by the Union or national public funds**, aligning with specific criteria.



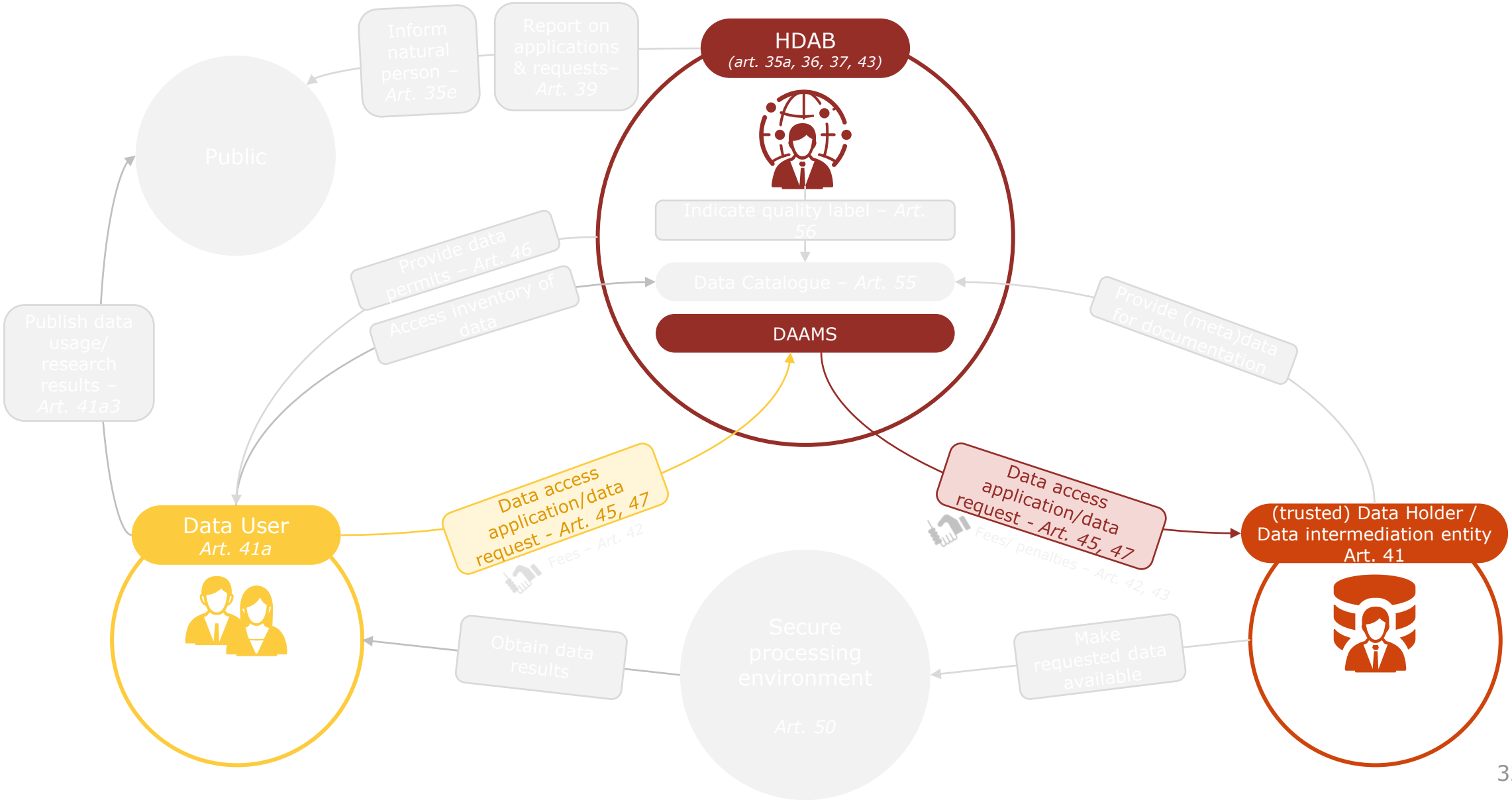
QUANTUM
THE HEALTH DATA QUALITY LABEL

Reference: Article 56

Zoom-in on requests



Zoom-in on requests



Data requests & applications

Two types of access requests can be submitted depending on the type of data requested

Requested data in SPE

Data access application

What is a data access application? Applicants can apply to a HDAB to obtain electronic health data, outlining datasets needed, safeguards, expected duration, ethical aspects and legal exceptions.

- Single application even when data is sought from multiple EU member states
- For pseudonymized personal data, compliance with EU and national data protection laws must be detailed
- Public sector bodies and EU institutions must provide similar information as applicants

Reference: Article 45

Requested data in Statistical format

Health data request

What is a health data request? Applicants may request health data with the intention of receiving a response in anonymized statistical format.

- The HDAB is restricted to providing answers exclusively in statistical format.
- The HDAB will review the completeness of the request, evaluate associated risks, and deliver the anonymized statistical results within 3 months if possible.

Reference: Article 46

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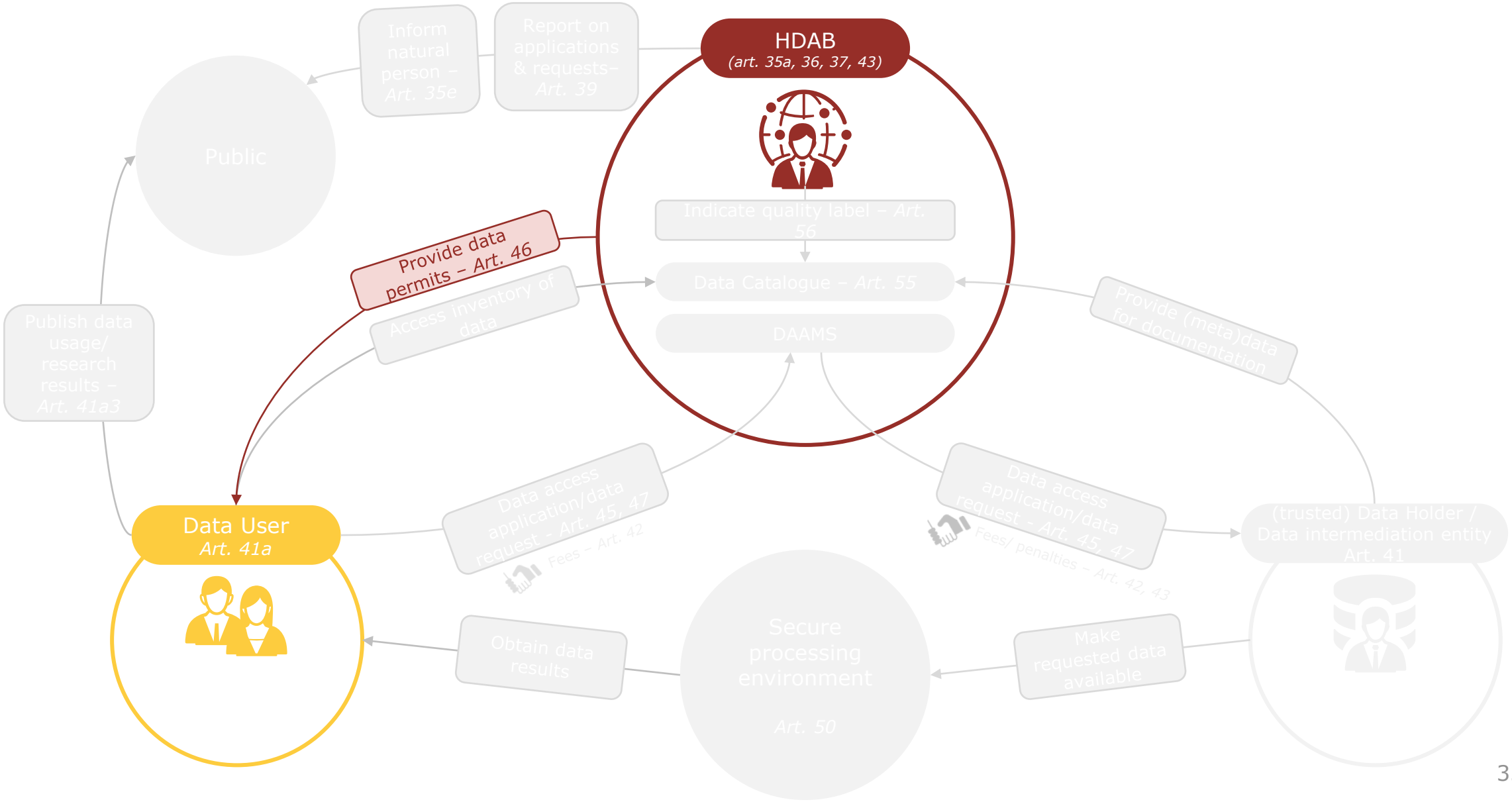
Data permits



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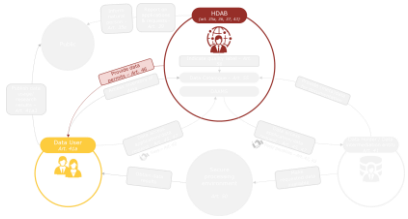


HDAB's will **grant access to electronic health data** if the applicant **fulfils certain criteria** and **issue a data permit**

Rejections are communicated with **justifications**

(statistical format answers may be provided if suitable)

Cross-border data access involves coordination among HDAB's

(incl. mutual recognition of permits)

Once a data permit is granted, the **HDAB requests data from the data holder** and provides it to the data user

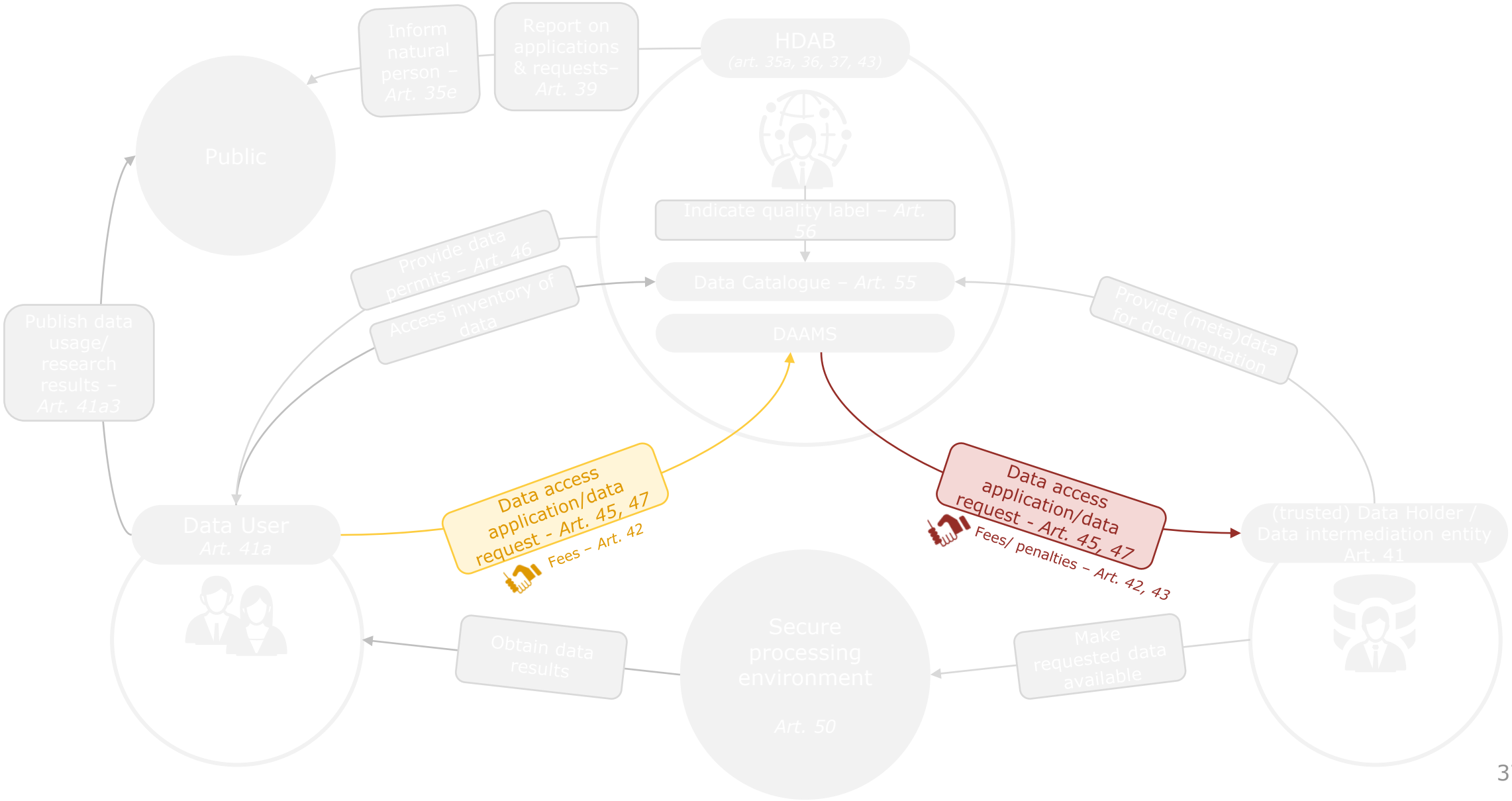
Data permits are **valid up to 10 years**

(Permits can be extended one time)

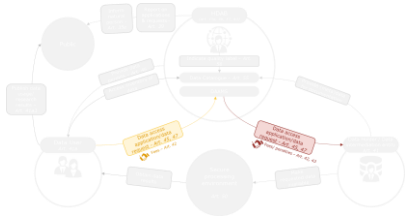
Permit updates are possible through amendment requests

Reference: Article 47

Fees & Penalties



Fees & Penalties



HDAB's have implemented **fees and penalties** to ensure compliance, cover operational costs, and promote responsible use of health data

Fees

- HDAB's may **charge fees** (reflecting costs involved) **for providing electronic health data**. Reduced fees might apply to specific groups
- **Additional fees** may be **charged by data holders for their expenses** in preparing data
- **Applicants** will be **informed of expected fees in advance**
- The EU Commission is responsible for establishing principles for fee policies and structures

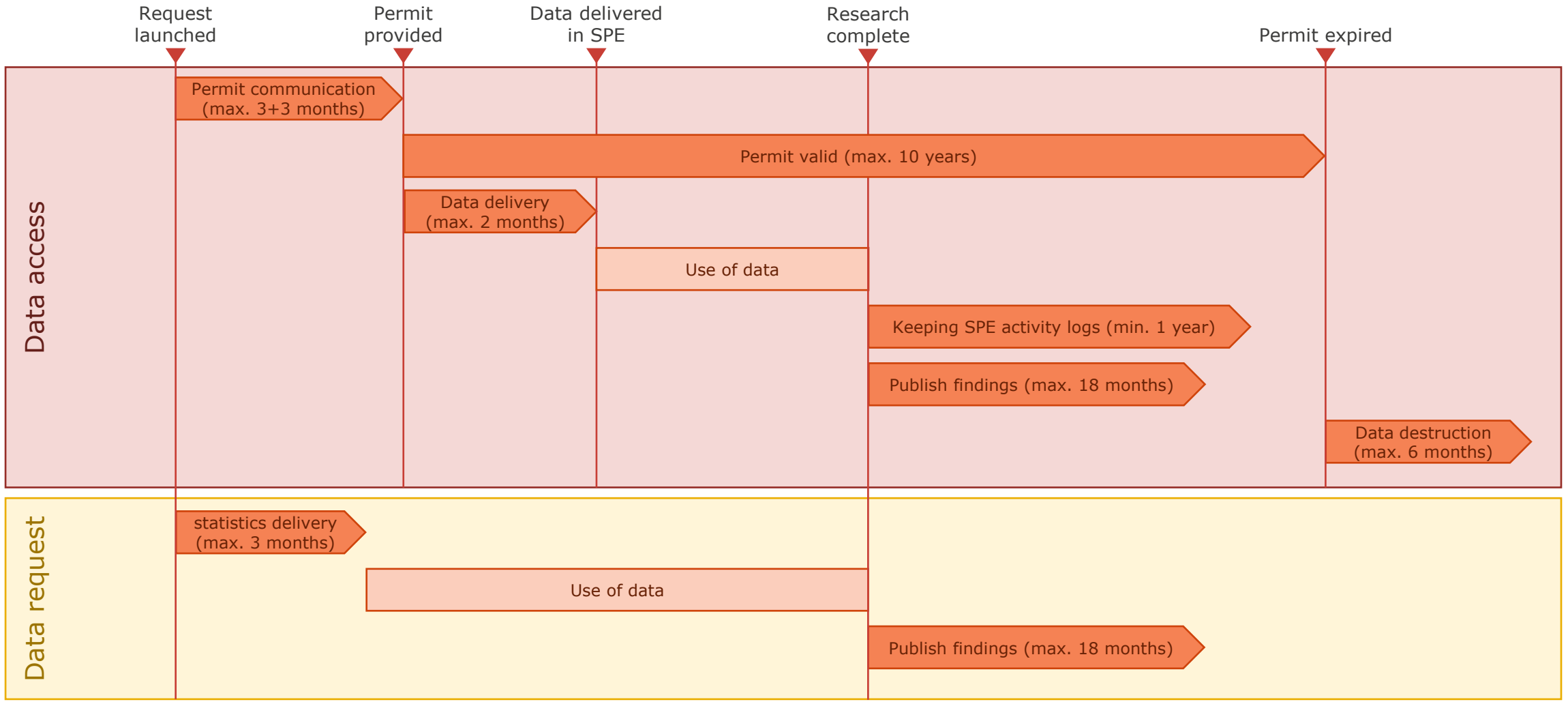
Reference: Article 42

Penalties

- **HDAB's supervise compliance with regulations** and can revoke data permits, halt data processing, or exclude non-compliant parties from accessing electronic health data for up to five years
- In cases where **health data holders obstruct data access** or fail to meet deadlines, the **HDAB can impose fines**.
- **Non-compliance information is shared between HDAB's** and may be published online.
- The **HDAB's must ensure that administrative fines are effective**, proportionate, and dissuasive.

Reference: Article 43(a)

Timing of request



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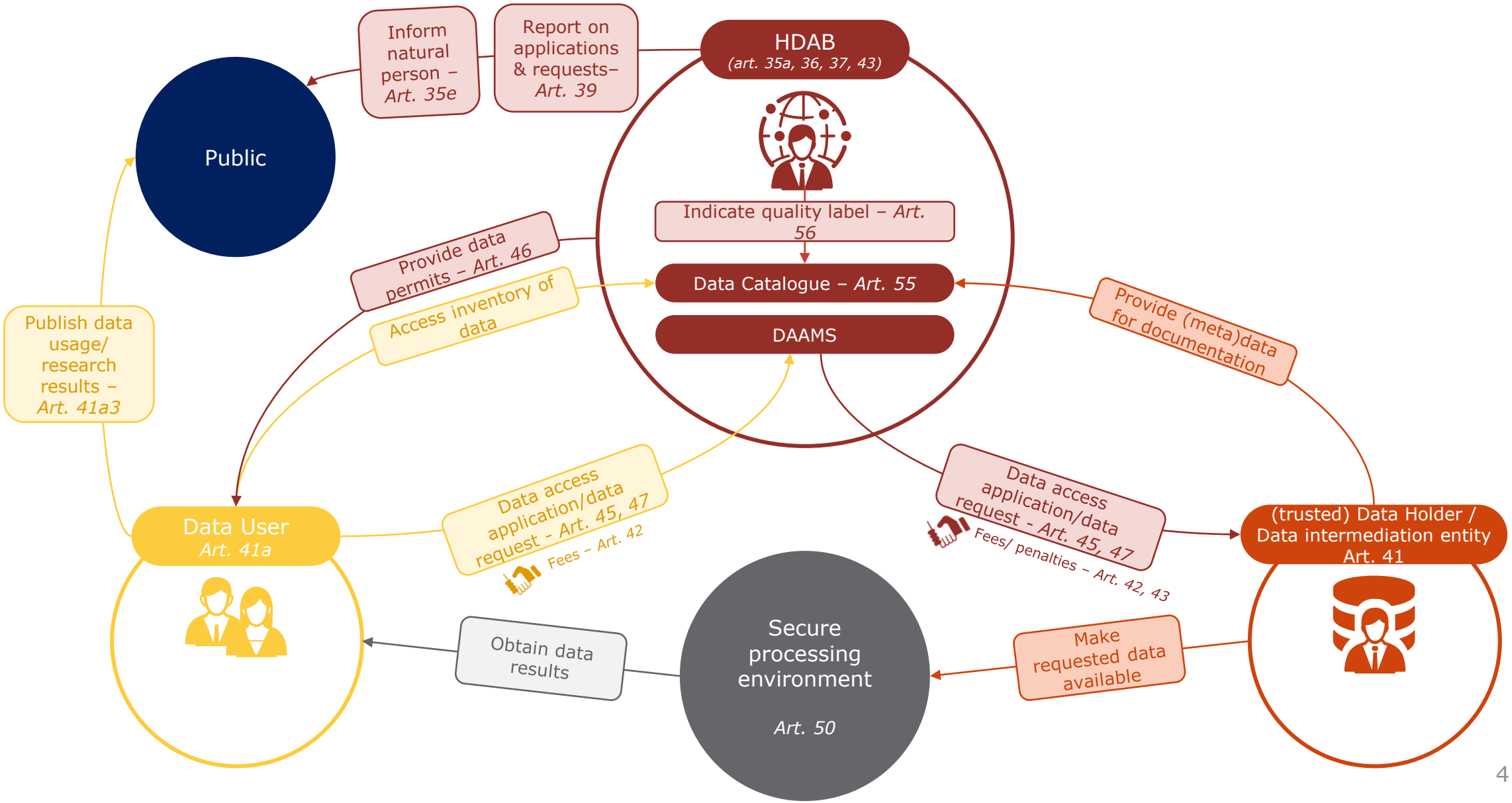
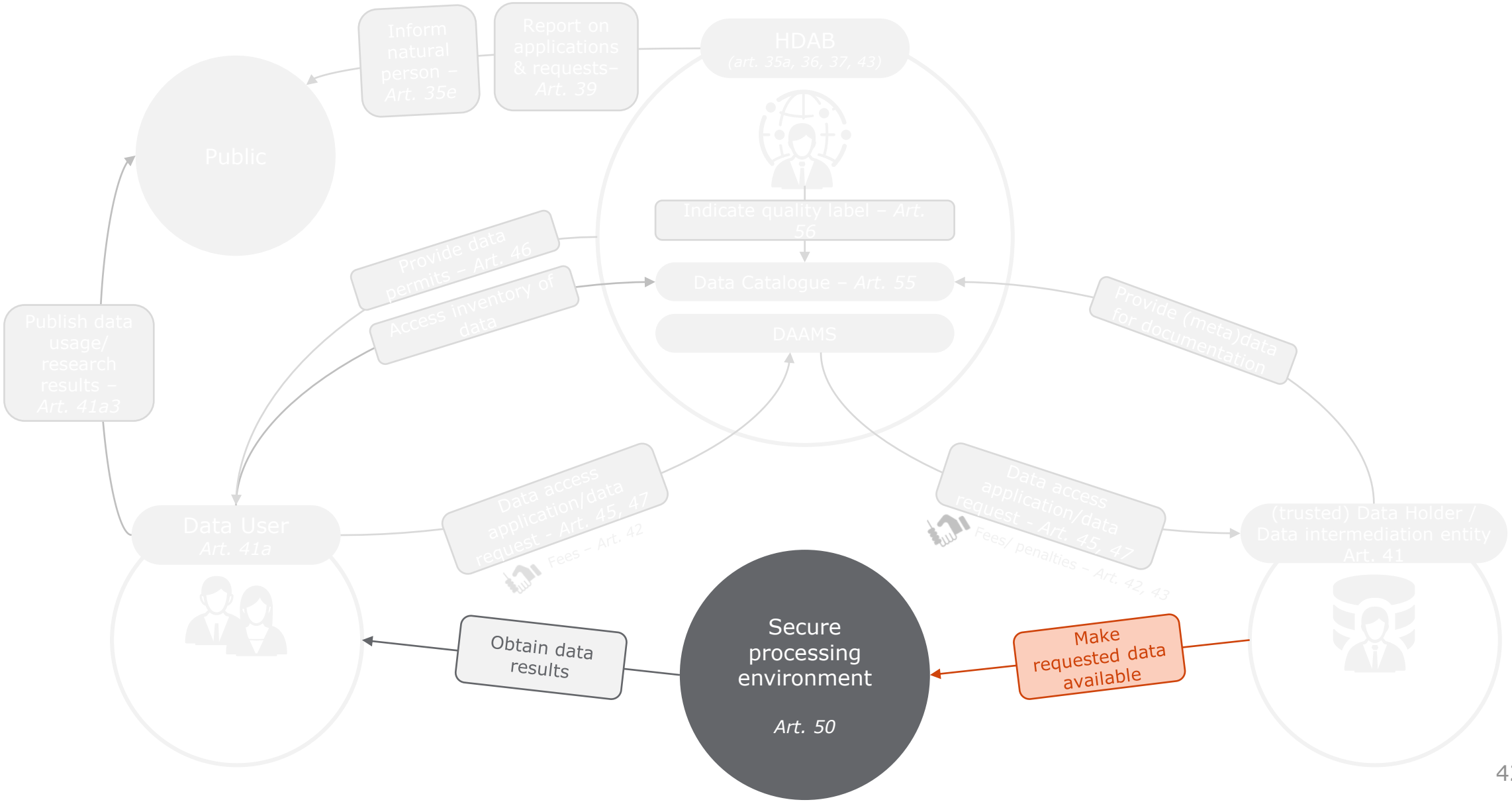
Zoom-in in data processing



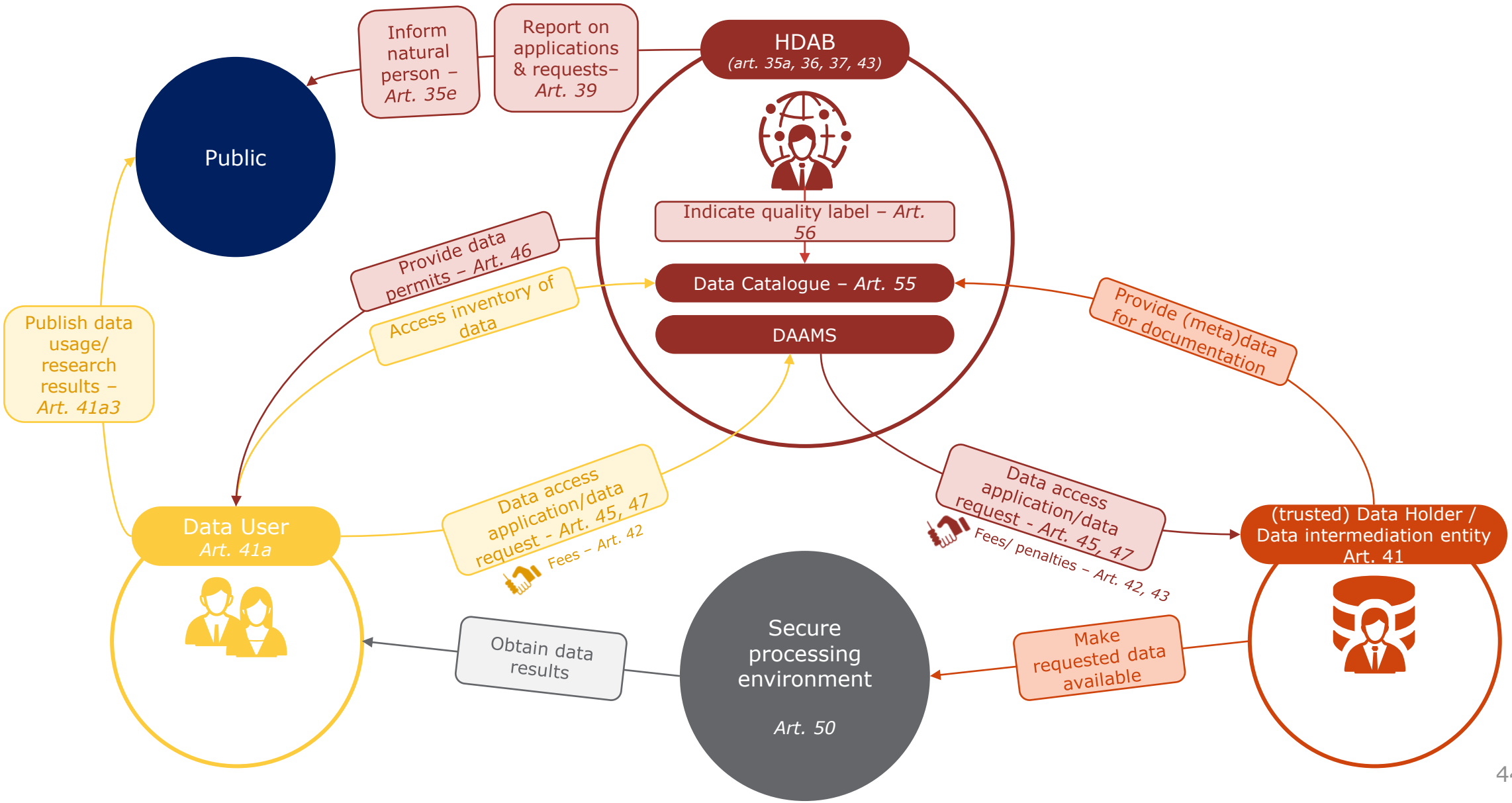
Data processing



Secure processing environment

HDAB's are required to provide **access to pseudonymized electronic health data** exclusively through a **secure processing environment**.

Zoom-in in obligations towards the public



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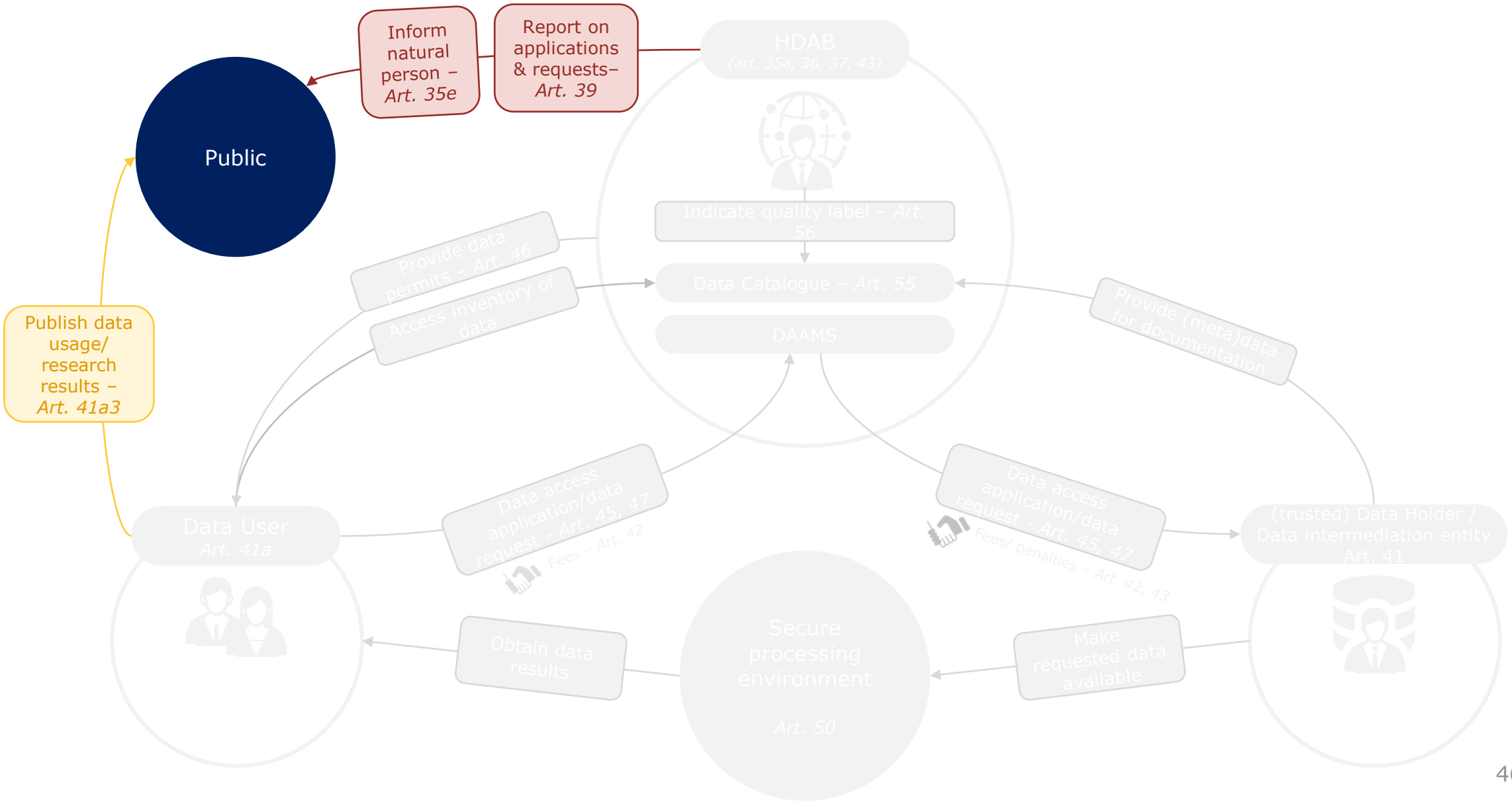
Obligation towards the public



Obligation towards the public – Information obligation

HDAB's are mandated to **publish detailed information** about the conditions for the **use** of electronic health data.

1. Legal basis for granting user access to health data.
2. Measures to protect individuals' rights.
3. Rights of individuals regarding the secondary use of their health data.
4. How individuals can exercise their rights under EU data protection regulations.
5. Contact details of the HDAB.
6. Records of granted access to data sets, including permitted processing purposes.
7. Results or outcomes from projects that used the health data.

Reference: Article 35e

Obligation towards the public – Reporting obligation

Each HDAB is required to publish a **biennial report** on its website. In cases where a Member State has multiple HDAB's, a coordinating HDAB organizes this report.

1. Types and numbers of data access applications and requests, types of applicants, data permits issued and refused, purposes of access, types of health data accessed, and a summary of data usage results.
2. Data related to regulatory and contractual obligations, fines imposed, and audits to ensure compliance within the secure processing environments.
3. Information on requests from individuals to exercise their data protection rights.
4. A description of stakeholder engagement and consultation activities.
5. Financial details including revenue from permits and requests.
6. Practical details such as the average time taken to grant access to data.
7. The number of data quality labels assigned by data holders, categorized by quality.
8. The number of research publications, policy documents, regulatory procedures, and digital health products/services, including AI applications, developed using data from the EHDS.

Reference: Article 39

Any clarifications needed?

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Thank you

For your attention and participation!

Further questions? Please contact us!


HDA

Appendix

Request journey