TMF – Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V.

EHDS – Be prepared for public consultations in TEHDAS2:

Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies

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Dr. Ana Mužinić, Bundesinstitut für Arzneimittel und Medizinprodukte BfArM

September 25th, 2025 | 8 a.m. to 9 a.m.

online workshop series | September 15th to October 1st, 2025

Download guidelines for public consultations:
https://tehdas.eu/public-consultations/

Disclaimer Recording of the online workshop

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Agenda

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   - 3.3 Purpose of the document
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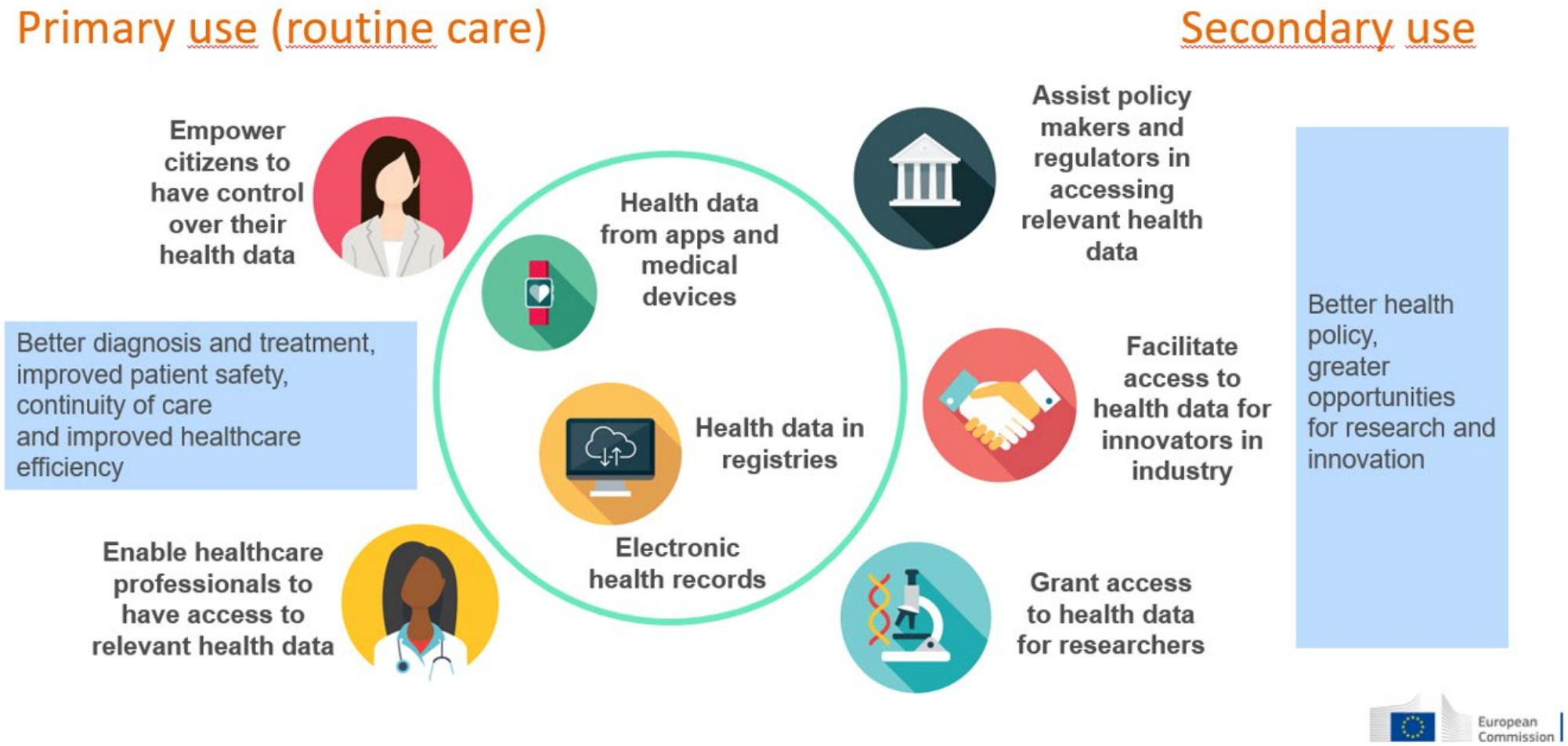
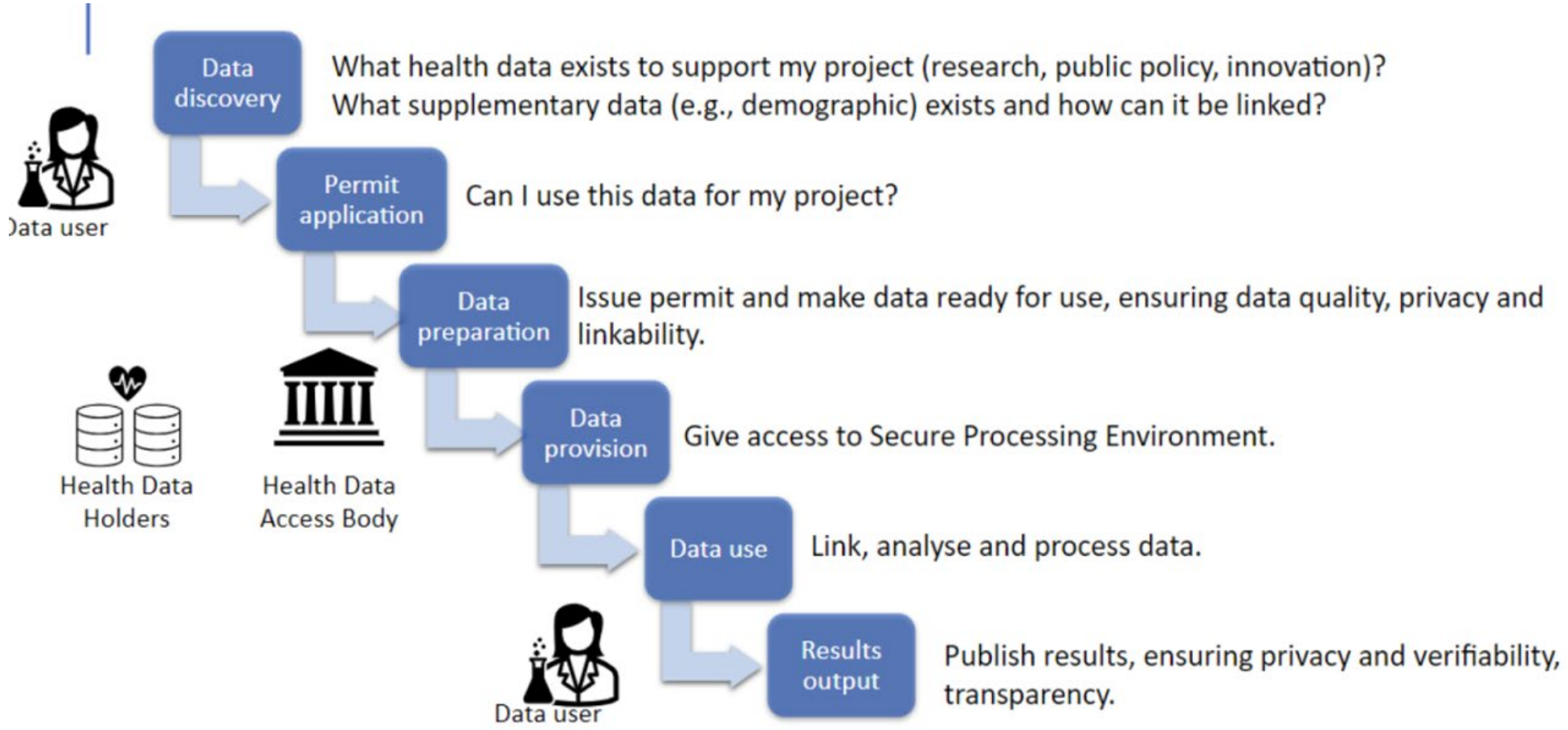
1. EHDS and TEHDAS2 in a nutshell

European Health Data Space (EHDS) – AIMS FROM User perspectives



1. EHDS and TEHDAS2 in a nutshell

EHDS2: Secondary Use of Electronic Health Data



EHDS – Stand der Gesetzgebung

- Das Europäische Parlament hat am 24. April 2024 die legislativen Grundlagen zur Schaffung eines **Europäischen Gesundheitsdatenraums (EHDS)** gelegt.
- Sprachjuristische Endfassung, vom ER am 21.01.2025 verabschiedet.
- Die EHDS-Verordnung wurde am 5. März 2025 im Amtsblatt der EU veröffentlicht **und trat 20 Tage später, am 25. März 2025, in Kraft.**
- Die Vorschriften der EHDS-Verordnung werden schrittweise angewendet: teilweise nach zwei Jahren, teilweise nach vier, sechs oder zehn Jahren nach Inkrafttreten. Direkt rechtswirksam in allen EU-Mitgliedstaaten, so auch in Deutschland.
- **MyHealth@EU** (**EHDS I**) regelt **elektronische grenzüberschreitende Gesundheitsdienste** in der EU (und die hierfür notwendigen Voraussetzungen).
- Im Rahmen von **HealthData@EU** (**EHDS II**) soll das Potenzial der **(Sekundär-)Nutzung von vorhandenen Gesundheitsdaten für Forschung und Innovation** in anonymisierter oder pseudonymisierter Form im öffentlichen Interesse erschlossen werden.
- ➔ Detailierung durch **Durchsetzungsrechtsakte** (*Implementing Acts*) bis 26. März 2027

Document 32025R0327

Verordnung (EU) 2025/327 des Europäischen Parlaments und des Rates vom 11. Februar 2025 über den europäischen Gesundheitsdatenraum sowie zur Änderung der Richtlinie 2011/24/EU und der Verordnung (EU) 2024/2847 (Text von Bedeutung für den EWR)

PE/76/2024/REV/1

ABl. L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj (BG, ES, CS, DA, DE, ET, EL, EN, FR, GA, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV)

In force

ELI: http://data.europa.eu/eli/reg/2025/327/oj

Amtsblatt
der Europäischen Union

DE
Reihe L

2025/327

5.3.2025

VERORDNUNG (EU) 2025/327 DES EUROPÄISCHEN PARLAMENTS UND DES RATES

vom 11. Februar 2025

über den europäischen Gesundheitsdatenraum sowie zur Änderung der Richtlinie 2011/24/EU und der Verordnung (EU) 2024/2847

(Text von Bedeutung für den EWR)

DAS EUROPÄISCHE PARLAMENT UND DER RAT DER EUROPÄISCHEN UNION —

gestützt auf den Vertrag über die Arbeitsweise der Europäischen Union, insbesondere auf die Artikel 16 und 114,

auf Vorschlag der Europäischen Kommission,

nach Zuleitung des Entwurfs des Gesetzgebungsakts an die nationalen Parlamente,

nach Stellungnahme des Europäischen Wirtschafts- und Sozialausschusses [1],

nach Stellungnahme des Ausschusses der Regionen [2],

gemäß dem ordentlichen Gesetzgebungsverfahren [3],

in Erwägung nachstehender Gründe:

(1) Ziel dieser Verordnung ist es, den europäischen Gesundheitsdatenraum (European Health Data Space, im Folgenden „EHDS") einzurichten, um den Zugang natürlicher Personen zu ihren personenbezogenen elektronischen Gesundheitsdaten und ihre Kontrolle über diese Daten im Zusammenhang mit der Gesundheitsversorgung zu verbessern und andere Zwecke, die mit der Verwendung elektronischer Gesundheitsdaten im Gesundheitswesen und im Pflegesektor verbunden sind und der Gesellschaft zugutekämen, wie etwa Forschung, Innovation, Politikgestaltung, Vorbereitung und Reaktion auf Gesundheitsbedrohungen, auch zur Prävention und Bewältigung künftiger Pandemien, Patientensicherheit, personalisierte Medizin, amtliche Statistik oder Regulierungstätigkeiten, besser zu erreichen. Darüber hinaus ist es Ziel dieser Verordnung, das Funktionieren des Binnenmarkts zu verbessern, indem im Einklang mit den Werten der Union ein einheitlicher Rechtsrahmen und technischer Rahmen insbesondere für die Entwicklung, Vermarktung und Verwendung von Systemen für elektronische Gesundheits-aufzeichnungen (electronic health records, EHR) (im Folgenden „EHR-Systeme") festgelegt wird. Der EHDS wird ein

(2) Die COVID-19-Pandemie hat deutlich gemacht, dass ein zeitnaher Zugang zu hochwertigen elektronischen [illegible] möglicherweise zu einer wirksameren Bewältigung künftiger Pandemien, geringeren Kosten und einer besseren [illegible] System für das klinische Patientenmanagement im Eilverfahren an, um es den Mitgliedstaaten zu ermöglichen, elektronische Gesundheitsdaten von COVID-19-Patienten auszutauschen, die während des Höhepunkts dieser Pandemie den Gesundheitsdienstleister wechselten oder sich von einem Mitgliedstaat in einen anderen begaben. Diese Anpassung war jedoch nur eine Notfalllösung, die verdeutlichte, dass ein struktureller und kohärenter Ansatz auf Ebene der Mitgliedstaaten und der Union erforderlich ist, um die Verfügbarkeit elektronischer Gesundheitsdaten für die Gesundheitsversorgung zu verbessern und den Zugang zu elektronischen Gesundheitsdaten zu erleichtern und so wirksame politische Maßnahmen zu steuern und zu hohen Standards für die menschliche Gesundheit beizutragen.

(3) Durch die COVID-19-Krise wurde die Arbeit des Netzwerks für elektronische Gesundheitsdienste (e-Health-Netzwerk), eines freiwilligen Netzwerks von für digitale Gesundheit zuständigen Stellen, zur tragenden Säule für die Entwicklung mobiler Kontaktnachverfolgungs- und Kontaktwarn-Apps für mobile Geräte und der technischen

[1] ABl. C 486 vom 21.12.2022, S. 123.
[2] ABl. C 157 vom 3.5.2023, S. 64.
[3] Standpunkt des Europäischen Parlaments vom 24. April 2024 (noch nicht im Amtsblatt veröffentlicht) und Beschluss des Rates vom 21. Januar 2025.
[4] Durchführungsbeschluss (EU) 2019/1269 der Kommission vom 26. Juli 2019 zur Änderung des Durchführungsbeschlusses 2014/287/EU der Kommission zur Festlegung von Kriterien für die Einrichtung europäischer Referenznetzwerke, für die Evaluierung dieser Netzwerke und ihrer Mitglieder und zur Erleichterung des Austauschs von Informationen und Fachwissen in Bezug auf die Einrichtung und Evaluierung solcher Netzwerke (ABl. L 200 vom 29.7.2019, S. 35).

Official Journal
of the European Union

EN
L series

2025/327

5.3.2025

REGULATION (EU) 2025/327 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 February 2025

on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 16 and 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

Having regard to the opinion of the Committee of the Regions [2],

Acting in accordance with the ordinary legislative procedure [3],

Whereas:

(1) The aim of this Regulation is to establish the European Health Data Space (EHDS) in order to improve natural persons' access to and control over their personal electronic health data in the context of healthcare, as well as to better achieve other purposes involving the use of electronic health data in the healthcare and care sectors that would benefit society, such as research, innovation, policymaking, health threats preparedness and response, preventing and addressing future pandemics, patient safety, personalised medicine, official statistics or regulatory activities. In addition, this Regulation's goal is to improve the functioning of the internal market by laying down a uniform legal and technical framework in particular for the development, marketing and use of electronic [illegible] of such electronic health data. Such timely access could potentially contribute, through efficient public health surveillance and monitoring, to more effective management of future pandemics, to a reduction of costs and to improving the response to health threats, and ultimately could help to save more lives. In 2020, the Commission urgently adapted its Clinical Patient Management System, established by Commission Implementing Decision (EU) 2019/1269 [4], to allow Member States to share electronic health data of COVID-19 patients moving between healthcare providers and Member States during the peak of that pandemic. However, that adaptation was only an emergency solution, showing the need for a structural and consistent approach at Member State and Union level, both in order to improve the availability of electronic health data for healthcare and to facilitate access to electronic health data in order to steer effective policy responses and contribute to high standards of human health.

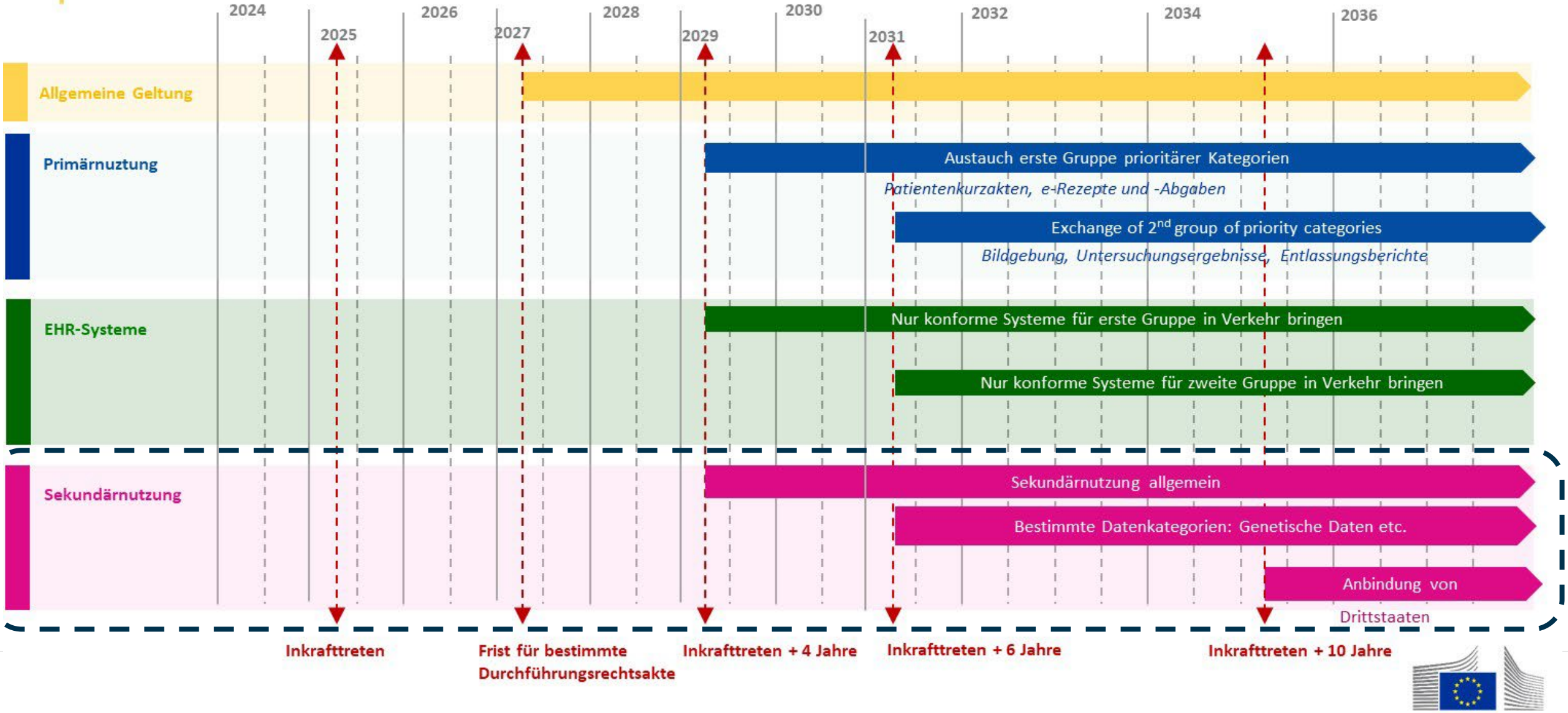
(3) The COVID-19 crisis strongly cemented the work of the eHealth Network, a voluntary network of authorities responsible for digital health, as the main pillar for the development of contact-tracing and contact-warning

[1] OJ C 486, 21.12.2022, p. 123.
[2] OJ C 157, 3.5.2023, p. 64.
[3] Position of the European Parliament of 24 April 2024 (not yet published in the Official Journal) and decision of the Council of 21 January 2025.
[4] Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks (OJ L 200, 29.7.2019, p. 35).

Finale Fassung (05.03.2025 veröffentlicht) – deutsch / englisch:
https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=OJ:L_202500327&qid=1741704307107
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202500327&qid=1741704307107

https://health.ec.europa.eu/document/download/4dd47ec2-71dd-49fc-b036-ad7c14f6ed68_en?filename=ehealth_ehds_qa_en.pdf

EHDS – Inkrafttreten und Geltung



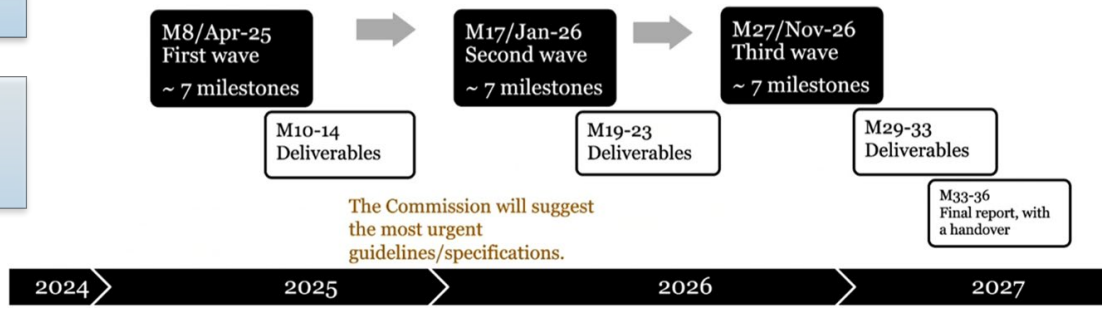
1. TEHDAS2 in a nutshell

TEHDAS2 in a nutshell

1. A joint action with clear scope, timeline and budget
2. Structured in independent work packages but common working methods
3. Aims for harmonised implementation of EHDS – secondary use of health data
4. Produces tangible results in the form of guidelines and technical specifications
5. High emphasis also on external communication and interlinks with other projects

für Deutschland: **BMG, BfArM, gematik, TMF**

- TEHDAS2 bereitet die Durchsetzungsrechtsakte der EU zum EHDS II durch **Guidelines** vor.
- (Für EHDS I entsprechend: xt-EHR)
- in 3 „Wellen“ (1. bereits erfolgt)
- Die Guidelines werden vor Verabschiedung und Annahme durch die EU öffentlich zur Kommentierung gestellt. Beginn: 30. Sept. 2025 (2 Monate)



2. TEHDAS2 Guidelines

Upcoming public consultations

https://tehdas.eu/

SEP-OCT 2025
TOPIC: Processes to manage permits or data pseudonymisation

Documents scheduled for public consultation(Click to view)

1. Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance regulated to the EHDS regulation

2. Draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data

3. Draft guideline for data holders on making personal and non-personal electronic health data available for reuse

4. Draft guideline for Health Data Access Bodies on the procedures and formats for data access

5. Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies

6. Draft technical specification for Health Data Access Bodies on data minimisation and de-identification

7. Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure

8. Draft technical specification for Health Data Access Bodies on the implementation of secure processing environments

9. Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data

10. Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data

MAY-JUN 2026
TOPIC: Collaboration with third countries, data enrichment and informing citizens

Documents scheduled for public consultation(Click to view)

1. Draft guideline for Health Data Access Bodies on collaboration with other parties

2. Draft guideline for Health Data Access Bodies on international and third country access and transfer of electronic health data

3. Draft guideline for Health Data Access Bodies on enrichment of health datasets

4. Draft guideline for Health Data Access Bodies on linkage of health datasets

5. Draft guideline for Health Data Access Bodies on informing natural persons about the use of health data – "Citizen Information Point"

6. Draft guideline for data users on handling research outcomes

2. TEHDAS2 Participate in the public consultations

TEHDAS2 develops guidelines and technical specifications to enable seamless secondary use of electronic health data across Europe under the European Health Data Space (EHDS).

→ The next wave of public consultations will be in **Sept-Oct 2025**

2. TEHDAS2 Documents for public consultation on September 30th, 2025

2nd Wave: Processes to manage permits or data pseudonymisation | SEP-OKT 2025

MS/D	Description
4.1	Draft guideline for Health Data Access Bodies on **fees and penalties for non-compliance** related to the EHDS regulation
5.2	Draft guideline for Health Data Access Bodies on **minimum categories and limitations on the reuse of health data**
6.1	Draft guideline for data holders on **making personal and non-personal electronic health data available for reuse**
6.3	Draft guideline for Health Data Access Bodies on the **procedures and formats for data access**
6.4	Data Access **Application Management System (DAAMS)** – Draft technical specification for health data access bodies
7.2	Guideline for Health Data Access Bodies on **data minimisation, pseudonymisation, anonymisation and synthetic data**
7.3	Draft technical specification for Health Data Access Bodies on the **implementation of the common IT infrastructure**
7.4	Draft technical specification for Health Data Access Bodies on the **implementation of secure processing environments**
8.1	Draft guideline for Health Data Access Bodies on **implementing opt-out** from the secondary use of health data
8.1	Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a **significant finding** from the secondary use of health data

2. TEHDAS2 Online-Workshop-Serie 15.09.-01.10.2025

Date	Workshop
Sep 15th, 2025	5.2 Draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data, *Dr. Anna Niemeyer (TMF e. V., Germany)*
Sep 16th, 2025	8.1.1: Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data, *Irene Schlünder (TMF e. V., Germany)*
Sep 17th, 2025	7.2: Draft guideline for Health Data Access Bodies on data minimisation, pseudonymisation, anonymisation and synthetic data, *Pia Brinkmann (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)*
Sep 18th, 2025	6.1: Draft guideline for data holders on making personal and non-personal electronic health data available for reuse, *Dr. Marije van Melle (Nictiz, Netherlands)*
Sep 24th, 2025	6.3: Draft guideline for Health Data Access Bodies on the procedures and formats for data access, *Rosa Juuti (Findata, Finland)*
Sep 25th, 2025	6.4: Draft Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies, *Dr. Ana Mužinić (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)*
Sep 26th, 2025	7.3: Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure, *Amélie Schäfer (Health Data Hub, France)*
Sep 29th, 2025	7.4: Draft technical specification for Health Data Access Bodies on the implementation of secure processing environments, *Heikki Lehväslaih (CSC - IT Center for Science, Finland)*
Sep 30th, 2025	8.1.2: Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data, *Dr. Gergely Mikesy (Semmelweis University Health Services Management Training Centre, Hungary)*
Oct 1st, 2025	4.1: Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation, *Pia Brinkmann (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)*

Mehr Information & Anmeldung: https://www.tmf-ev.de/news/ehds-oeffentliche-konsultationen-starten-im-herbst

3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

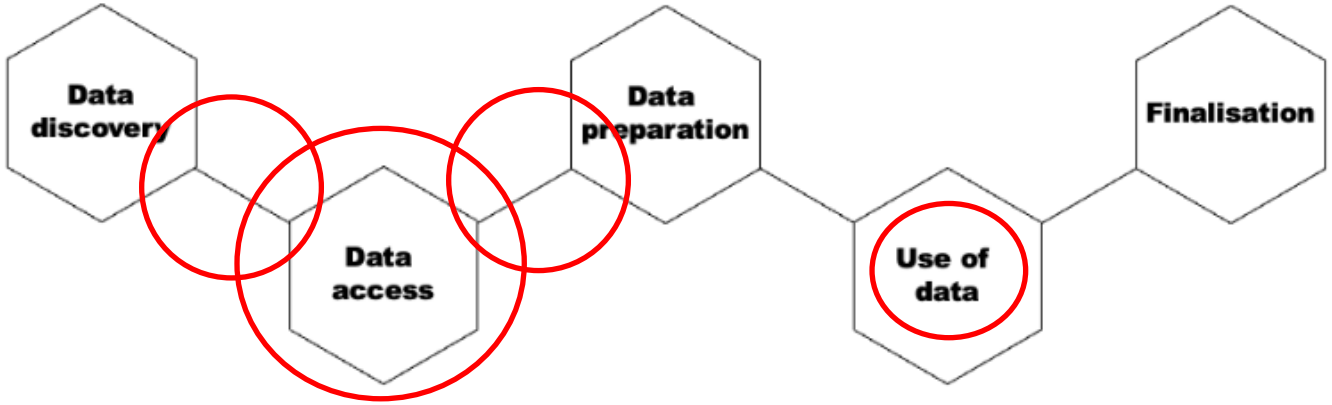
3.1 Legal background

- **Health Data Access Body (HDAB)**
  - Member state-designated authority that facilitates the secondary use of electronic health data.
  - Article 55 (1):
    - ‘Member States shall designate one or more health data access bodies responsible for carrying out the tasks and obligations set out in Articles 57, 58 and 59.’
    - ‘Where a Member State designates several health data access bodies, it shall designate **one health data access body to act as coordinator**’
- **National Contact Point (NCP)**
  - Article 75 (1)
    ‚Each Member State shall designate **one national contact point for secondary use**. That national contact point for secondary use shall be an organisational and technical gateway, enabling and responsible for the making available of electronic health data for secondary use in a cross-border context. The national contact point for secondary use may be the coordinator health data access body pursuant to Article 55.‘
- The term **'Data Access Application Management System’ (DAAMS)**
  - Not mentioned explicitly in the EHDS-Regulation
  - However, Article 57(1) defines the tasks of health data access bodies, including
    - e) maintaining a **management system** to record and process health data access applications, health data requests, decisions on those applications and requests and the data permits issued and health data requests handled, providing at least information on the name of the health data applicant, the purpose of access, the date of issuance, the duration of the data permit and a description of the health data access application or the health data request;
      i) **facilitating cross-border access** to electronic health data for secondary use hosted in other Member States through HealthData@EU referred to in Article 75 and cooperating closely with each other and with the Commission;

3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.2 Definition of DAAMS (6.4)

‚The Data Access Application Management System (DAAMS) is a **national platform** designed to enable secure and compliant **access to electronic health data for secondary usage across the European Union**, in alignment with the European Health Data Space (EHDS) regulation. Its primary role is to support the handling of both health data access applications and health data requests for secondary uses purposes, such as research, innovation, policymaking and other purposes listed in *Art. 53 EHDS*.
DAAMS is **operated by** Health Data Access Bodies (**HDABs**) **at national level**. It manages the **full application lifecycle and interacts with both national applicants and the cross-border EHDS infrastructure (via the National Contact Point).** ’



EHDS User journey, D6.2 – Guideline for data users on good application and access practice

3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.3 Purpose of the document

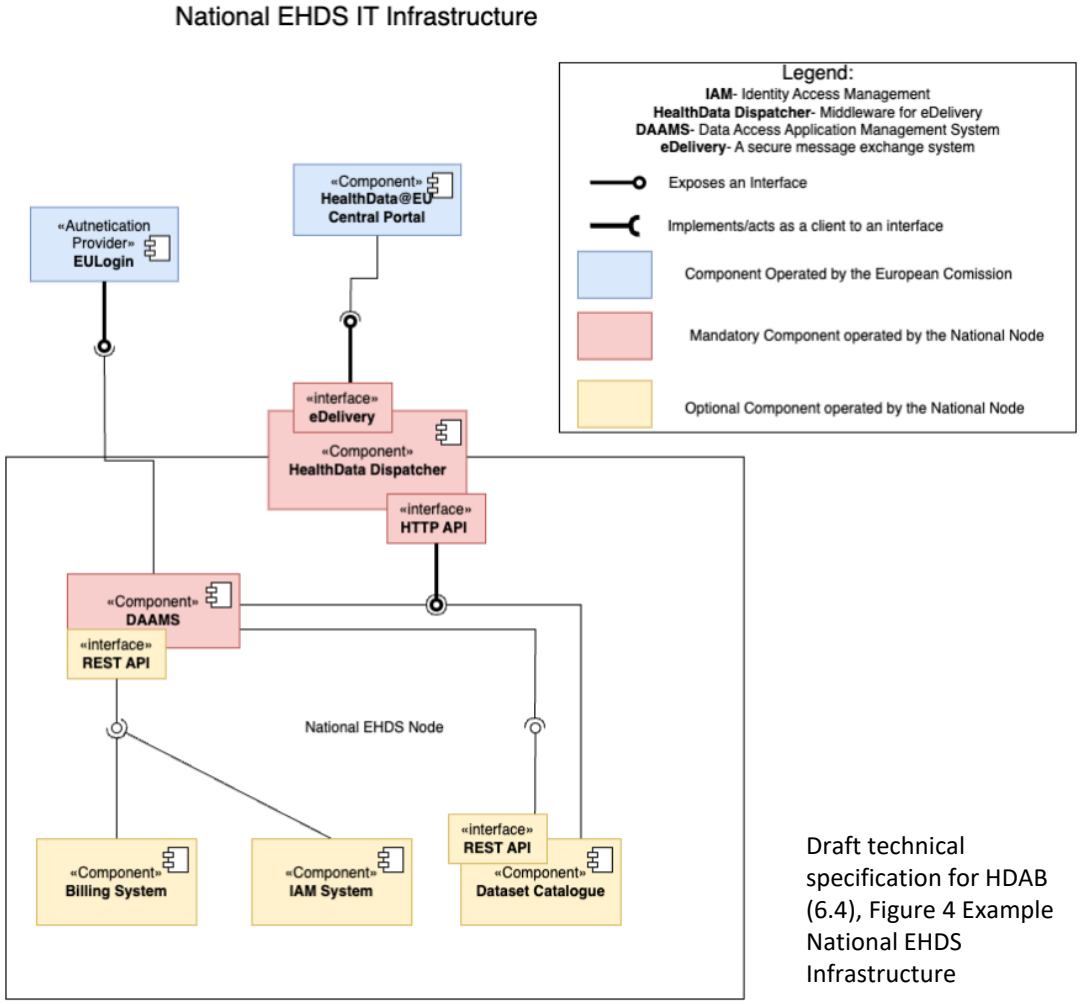
- Define the **functional and non-functional requirements** for the development and operation of the Data Access Application Management System (DAAMS)
  - in accordance with the European Health Data Space (EHDS) Regulation
  - ensuring interoperability with EU-level infrastructure through clearly defined APIs and integration patterns
  - supporting transparency and accountability by specifying mechanisms for audit logging, access control, and user notification
  - **allowing for national customisation**, enabling each Member State to extend or adapt the system in accordance with its legal and organisational frameworks, while maintaining compliance with shared EU-level standards.

- Out of scope
  - national-level implementation details
  - operation of secure processing environments
  - Opt-out Management
  - Helpdesk
  - Fees and invoicing Management

3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.4 Summary of the document

- Differentiation between MUST/MUST NOT/SHOULD / SHOULD NOT / MAY requirements
- DAAMS two main functions:
  - Submission and management of national data access applications and data requests originating within the Member State;
  - Reception and processing of data access applications and data requests submitted via the HealthData@EU Central Platform.
- If Member State designates multiple HDABs, a coordinating HDAB (or the NCP) is expected to take responsibility for receiving applications (which are always received via the NCP) and distributing them to the appropriate HDAB and DAAMS instance within the Member State.



Draft technical specification for HDAB (6.4), Figure 4 Example National EHDS Infrastructure

3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.4 Summary of the document

Chapter 6: Submitting Applications – DAAMS Front Office

- Requirements related to the
  - Graphical User Interface for applicant
  - Applicant User Space for managing and tracking applications
  - Application form
  - Communication between applicant and HDAB

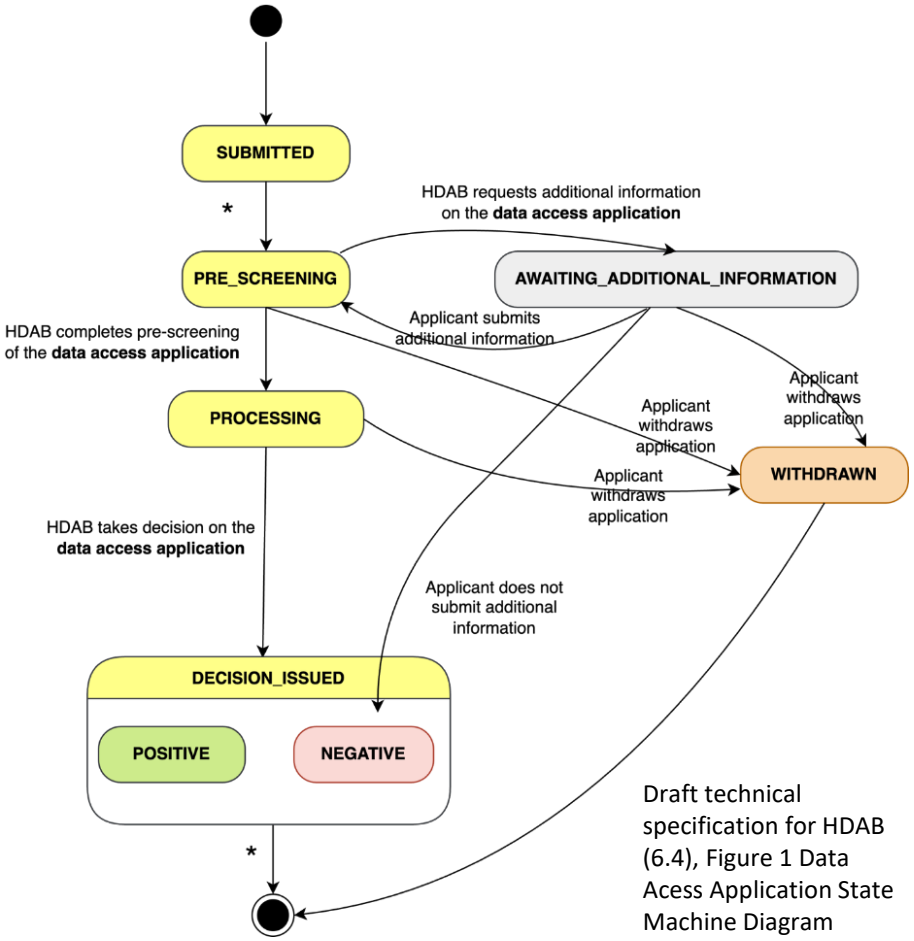
3. Presenting today's document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.4 Summary of the document

Chapter 7: Processing Applications- DAAMS Back Office

- Requirements related to:
  - Communication with HealthData@EU Central Platform
  - Pre Screening - Data access applications / Health Data Request
  - Application assessment - Data Access Applications / Health Data Request
  - Requesting additional information for a submitted application
  - Updating the status of Data Access Application / Data Request

- Includes Messages structure for all communication steps
  - HealthData@EU Central Platform → NCP → DAAMS
  - DAAMS → NCP → HealthData@EU Central Platform



Draft technical specification for HDAB (6.4), Figure 1 Data Acess Application State Machine Diagram

3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.4 Summary of the document

Chapter 8: Setting due dates

- Requirements related to
  - Setting due dates
  - Updating due dates
  - monitoring and informing about Deadlines

- Includes Messages structure for Assessment Extension
  - DAAMS → NCP → HealthData@EU Central Platform

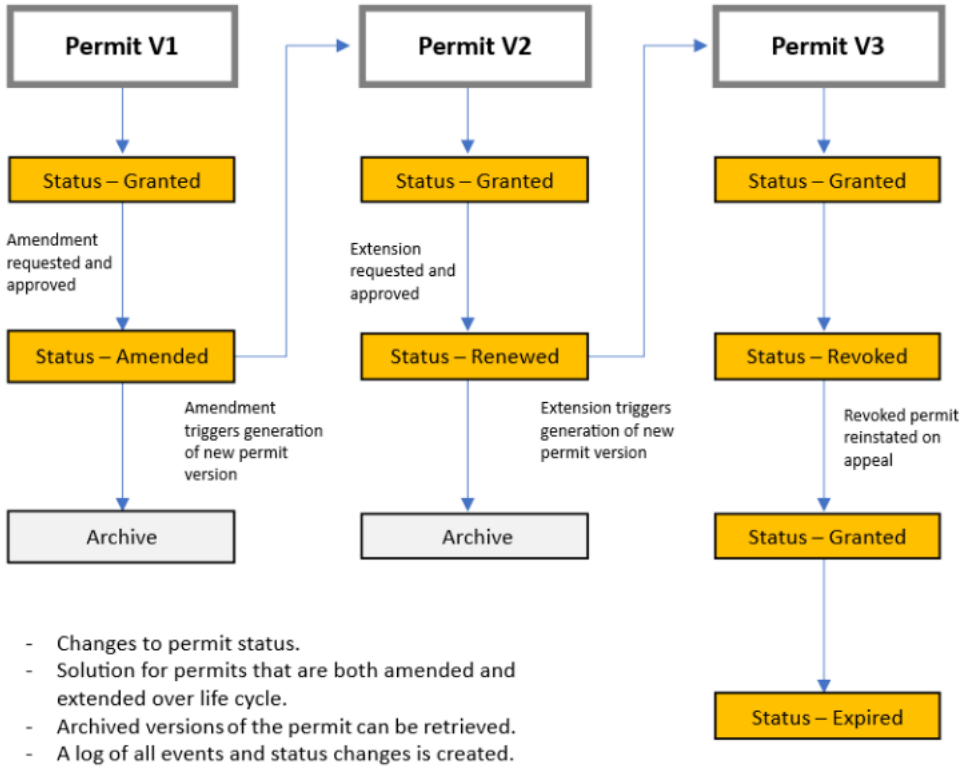
3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.4 Summary of the document

Chapter 9: Issuing a decision for Application

- Requirements related to:
  - issuing a decision
  - Permit pending acceptance
  - Data Permit status (Life Cycle)

- Includes Messages structure for all communication steps
  - DAAMS → NCP → HealthData@EU Central Platform
  - HealthData@EU Central Platform → NCP → DAAMS



Draft technical specification for HDAB (6.4), Figure 3: Life cycle of permit that is amended, renewed and revoked over its life cycle.

3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.4 Summary of the document

Chapter 10: Processing decision appeals for Application

- Requirements related to the decision appeals
- Includes Messages structure for the communication with HealthData@EU Central Platform when appeal refers to a decision made on an application originating from the HealthData@EU Central Platform
  - HealthData@EU Central Platform → NCP → DAAMS
  - DAAMS → NCP → HealthData@EU Central Platform

Chapter 11: Fetching related Data Permits for Mutual Recognition

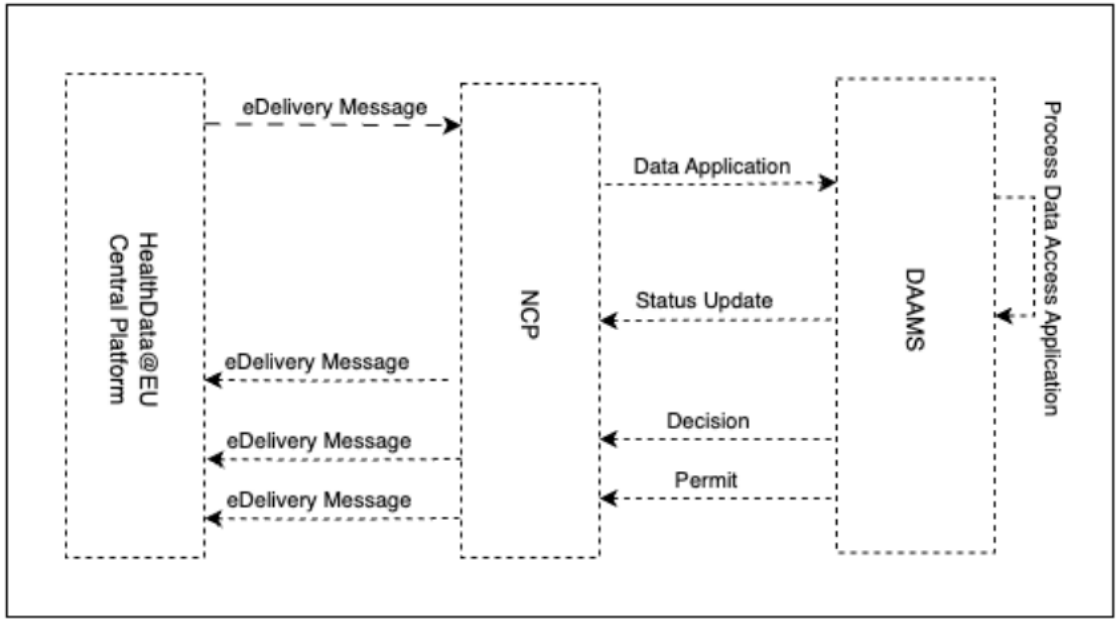
Chapter 12: Support for Trusted Data Holders

3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.4 Summary of the document

Chapter 13: DAAMS within National EHDS IT Infrastructure

- Requirements related to Communication between HealthData@EU Central Platform, NCP and DAAMS
  - ‘DAAMS MUST NOT communicate directly with the HealthData@EU Central Platform. All cross-border communication must flow through the National Contact Point which acts as the sole interface between national infrastructure and HealthData@EU Central Platform.”
  - ‘All messages exchanged between the NCP and the Central Platform, MUST follow the standard message formats defined under the HealthData@EU infrastructure. ’



Draft technical specification for HDAB (6.4) Figure 5 Message Sequence Diagram depicting the communication between DAAMS, NCP and HealthData@EU Central Platform. Note that not all messages are illustrated.

3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.4 Summary of the document

Chapter 14: Non-functional Requirements

- Requirements related to
  - Time zone/Timestamps
  - GUI
  - System load
  - Auditing
  - Authentication and Authorization Management
  - API

Chapter 15: Security Considerations

3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.5 Critical points - Questions from the public consultation

- Chapter 16: Open questions and unresolved issues
  - Digital Representation of a data permit
  - Questions regarding withdrawal:
    - Does withdrawal require decision?
    - Withdrawal due to non-acceptance of conditions and fees
      - Is a negative decision required for such withdrawal?
      - Can someone appeal upon such decision?

- What kind of input is expected?
  - Form with questions regarding
    - Document quality in general (completeness, comprehensivness, feasibility of the document)
    - Specific to each requirement group: How well does the specification cover the requirements

3. Presenting today‘s document: **Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies (6.4)**

3.6 Who should comment?

- The relevance of this document for different stakeholders largely depends on the national EHDS infrastructure.
  However, public consultations aim to gather diverse perspectives from a broad range of stakeholders (End User(Applicant), End User (HDAB Staff), Solution Architect, Developer, Operator, Other)
  - Increase comprehensiveness and feasibility
  - Identify potential issues or gaps

→ **Those who currently work with similar applications and have experience of similar systems and processes.**

4. Q&A

5. Save the date: Next workshops

Date	Workshop
Sep 15th, 2025	5.2 Draft guideline for Health Data Access Bodies on **minimum categories and limitations on the reuse of health data**
Sep 16th, 2025	8.1.1: Draft guideline for Health Data Access Bodies on **implementing opt-out** from the secondary use of health data
Sep 17th, 2025	7.2: Draft guideline for Health Data Access Bodies on data **minimisation, pseudonymisation, anonymisation and synthetic data**
Sep 18th, 2025	6.1: Draft guideline for data holders on **making personal and non-personal electronic health data available for reuse**
Sep 24th, 2025	6.3: Draft guideline for Health Data Access Bodies on the **procedures and formats for data access**
Sep 25th, 2025	6.4: Draft Data Access **Application Management System (DAAMS)** – Draft technical specification for health data access bodies
Sep 26th, 2025	7.3: Draft technical specification for Health Data Access Bodies on the **implementation of the common IT infrastructure**
Sep 29th, 2025	7.4: Draft technical specification for Health Data Access Bodies on the **implementation of secure processing environments**
Sep 30th, 2025	8.1.2: Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a **significant finding** from the secondary use of health data
Oct 1st, 2025	4.1: Draft guideline for Health Data Access Bodies on **fees and penalties for non-compliance** related to the EHDS regulation

2. TEHDAS2 Online-Workshop-Serie 15.09.-01.10.2025

Date	Workshop
Sep 15th, 2025	5.2 Draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data, *Dr. Anna Niemeyer (TMF e. V., Germany)*
Sep 16th, 2025	8.1.1: Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data, *Irene Schlünder (TMF e. V., Germany)*
Sep 17th, 2025	7.2: Draft guideline for Health Data Access Bodies on data minimisation, pseudonymisation, anonymisation and synthetic data, *Pia Brinkmann (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)*
Sep 18th, 2025	6.1: Draft guideline for data holders on making personal and non-personal electronic health data available for reuse, *Dr. Marije van Melle (Nictiz, Netherlands)*
Sep 24th, 2025	6.3: Draft guideline for Health Data Access Bodies on the procedures and formats for data access, *Rosa Jutii (Findata, Finland)*
Sep 25th, 2025	6.4: Draft Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies, *Dr. Ana Mužinić (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)*
Sep 26th, 2025	7.3: Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure, *Amélie Schäfer (Health Data Hub, France)*
Sep 29th, 2025	7.4: Draft technical specification for Health Data Access Bodies on the implementation of secure processing environments, *Heikki Lehväslaih (CSC - IT Center for Science, Finland)*
Sep 30th, 2025	8.1.2: Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data, *Dr. Gergely Mikesy (Semmelweis University Health Services Management Training Centre, Hungary)*
Oct 1st, 2025	4.1: Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation, *Pia Brinkmann (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)*

More information & registration: https://www.tmf-ev.de/news/ehds-oeffentliche-konsultationen-starten-im-herbst

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