

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

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



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Agenda



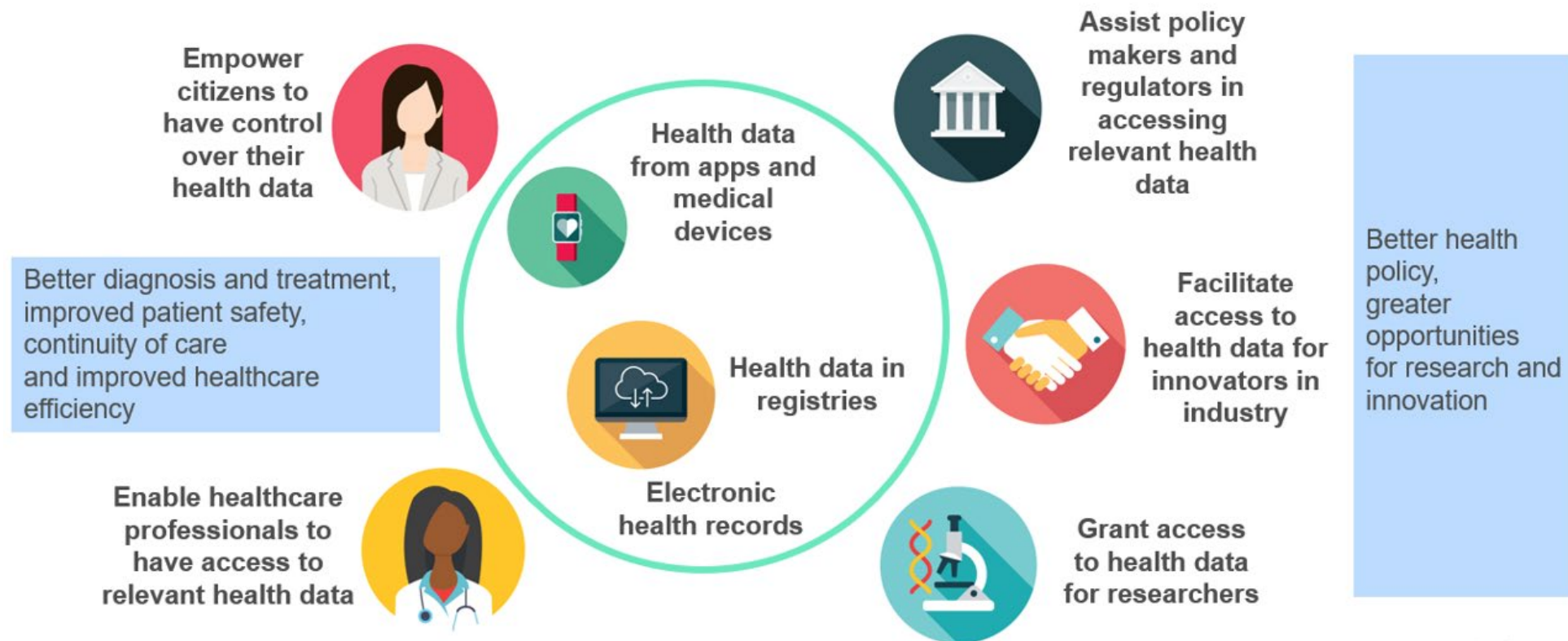
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1. EHDS and TEHDAS2 in a nutshell

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

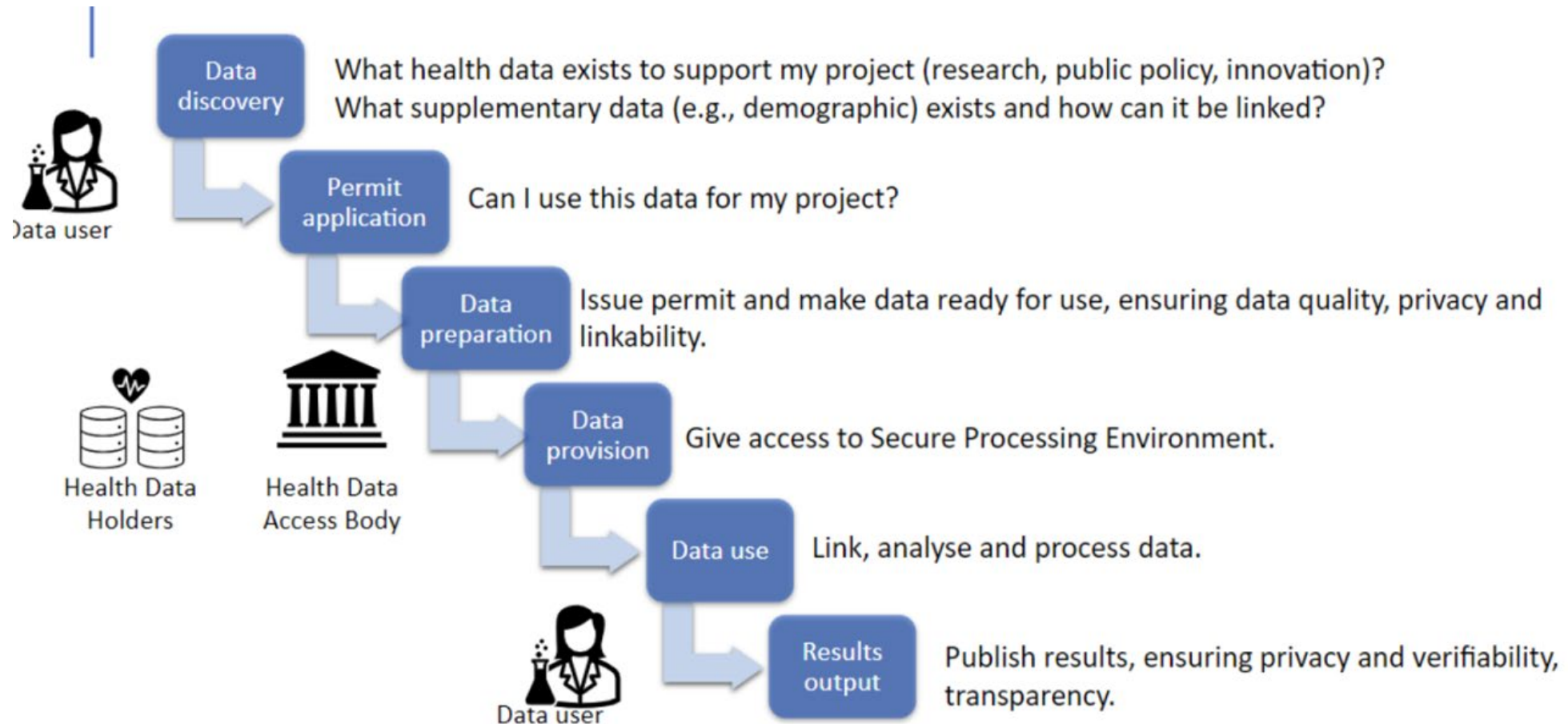
Primary use (routine care)

Secondary use



1. EHDS and TEHDAS2 in a nutshell

EHDS2: Secondary Use of Electronic Health Data



- ▶ 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



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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

Abi. 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>

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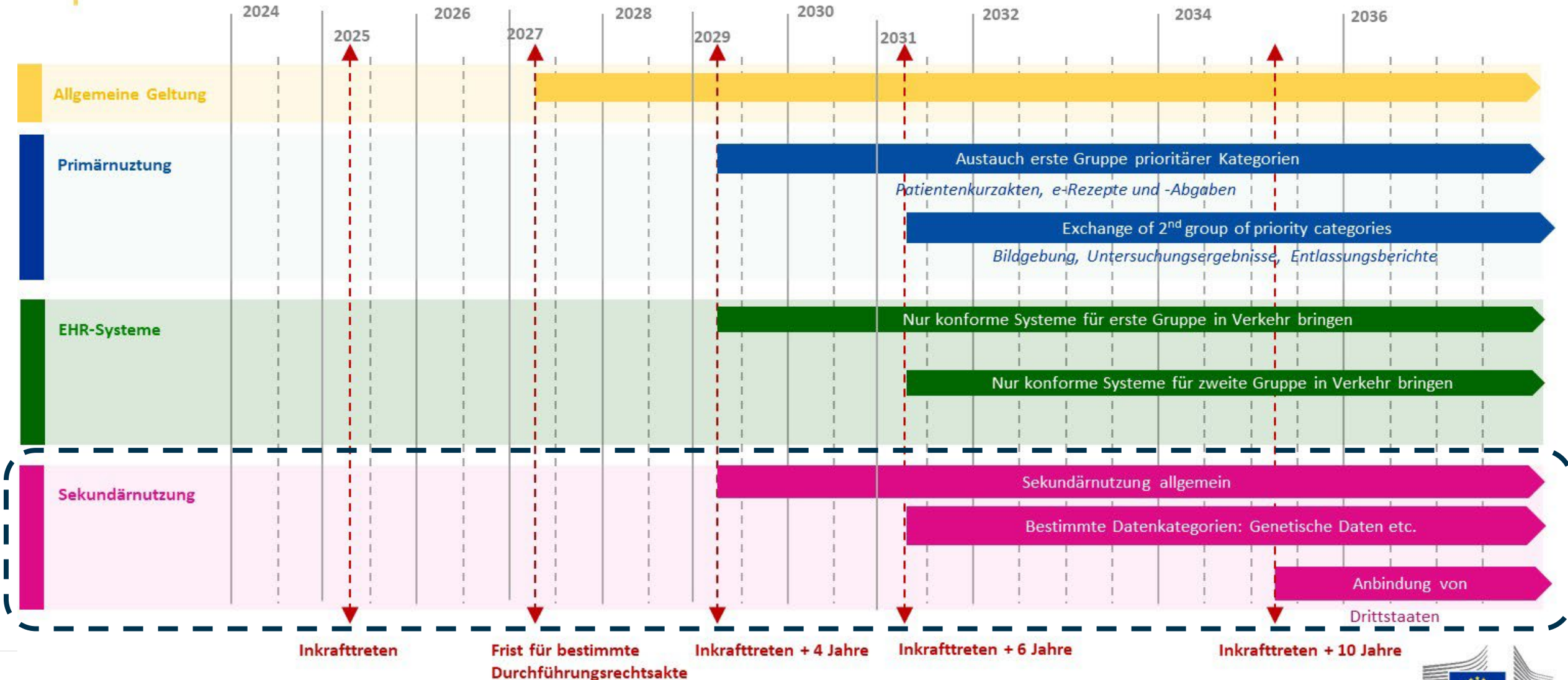
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EHDS – Inkrafttreten und Geltung



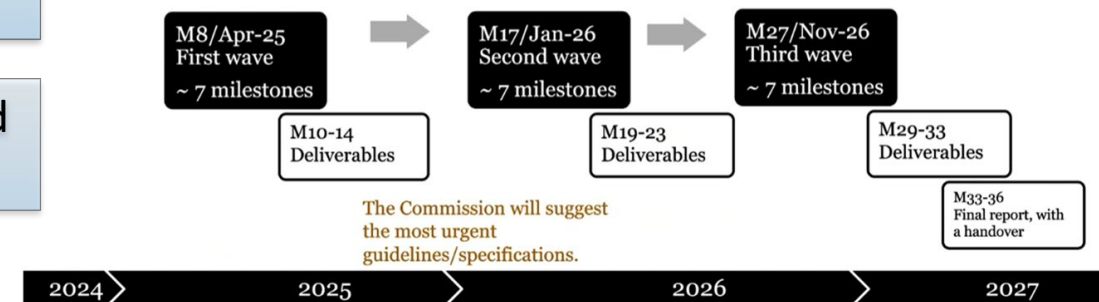
1. TEHDAS2 in a nutshell

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

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

<https://tehdas.eu/>



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, <i>Dr. Anna Niemeyer (TMF e. V., Germany)</i>
Sep 16th, 2025	8.1.1: Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data, <i>Irene Schlünder (TMF e. V., Germany)</i>
Sep 17th, 2025	7.2: Draft guideline for Health Data Access Bodies on data minimisation, pseudonymisation, anonymisation and synthetic data, <i>Pia Brinkmann (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)</i>
Sep 18th, 2025	6.1: Draft guideline for data holders on making personal and non-personal electronic health data available for reuse, <i>Dr. Marije van Melle (Nictiz, Netherlands)</i>
Sep 24th, 2025	6.3: Draft guideline for Health Data Access Bodies on the procedures and formats for data access, <i>Rosa Juuti (Findata, Finland)</i>
Sep 25th, 2025	6.4: Draft Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies, <i>Dr. Ana Mužinić (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)</i>
Sep 26th, 2025	7.3: Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure, <i>Amélie Schäfer (Health Data Hub, France)</i>
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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, <i>Dr. Gergely Mikešy (Semmelweis University Health Services Management Training Centre, Hungary)</i>
Oct 1st, 2025	4.1: Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation, <i>Pia Brinkmann (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)</i>

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.'

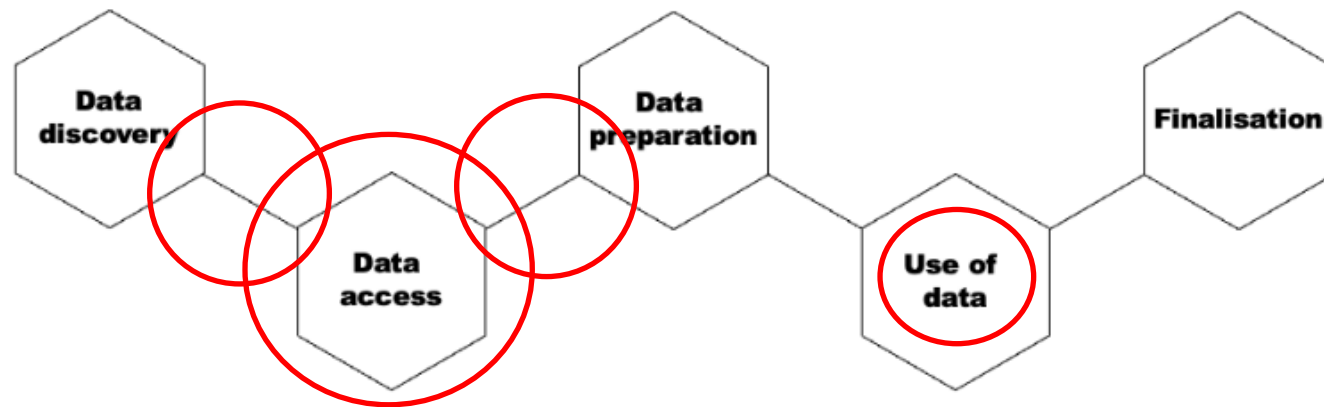
- The term '**Data Access Application Management System**' (DAAMS)

- 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

Chapter 6: Submitting Applications – DAAMS Front Office

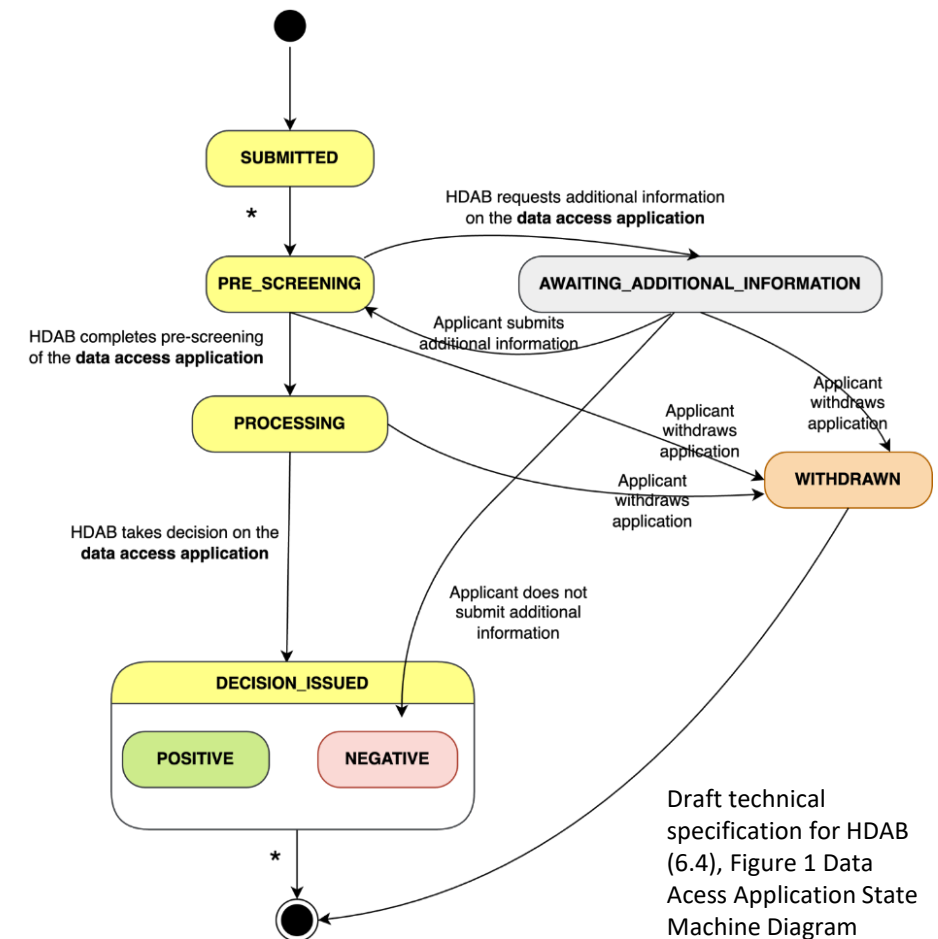
- Requirements related to the
 - Graphical User Interface for applicant
 - Applicant User Space for managing and tracking applications
 - Application form
 - Communication between applicant and HDAB

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



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

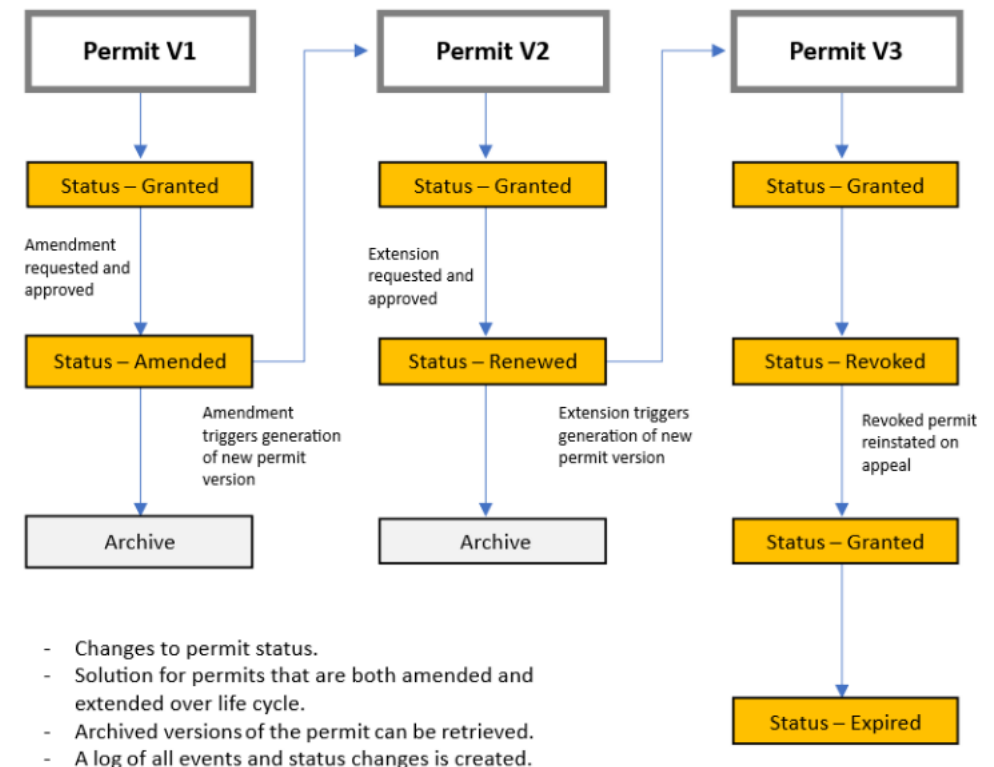
- Requirements related to
 - Setting due dates
 - Updating due dates
 - monitoring and informing about Deadlines
- Includes Messages structure for Assessment Extension
 - DAAMS → NCP → HealthData@EU Central Platform

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

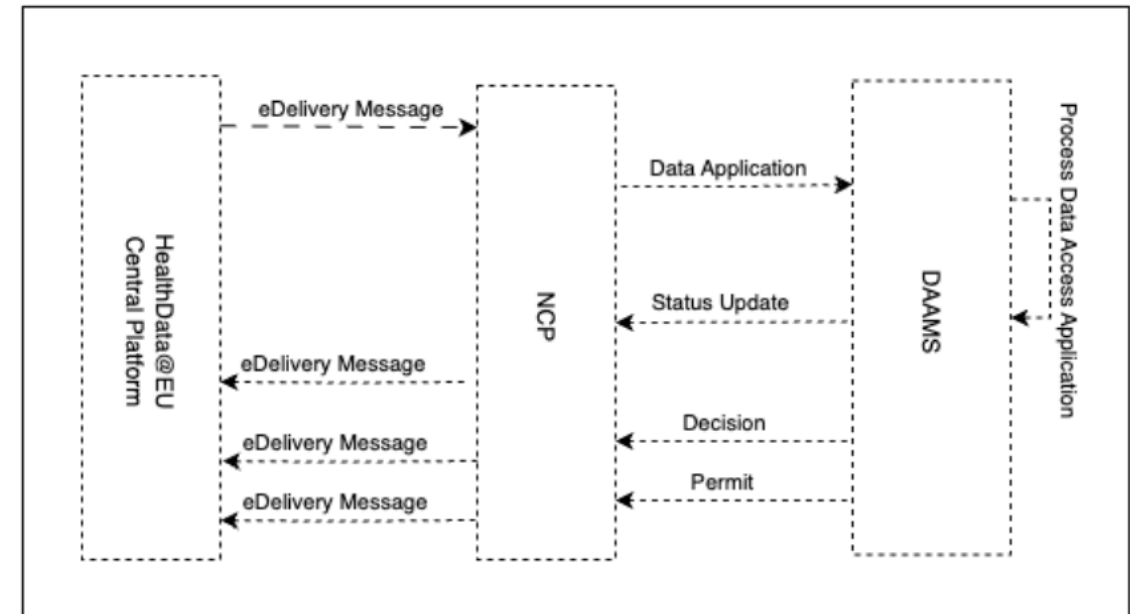
Chapter 12: Support for Trusted Data Holders

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, comprehensiveness, 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



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

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