
EHDS – Be prepared for public consultations in TEHDAS2:
**Draft technical specification for Health Data Access Bodies on the
implementation of the common IT infrastructure**

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Amélie Schäfer, Health Data Hub
September 26th, 2025 | 8 a.m. to 9 a.m.

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



Disclaimer Recording of the online workshop



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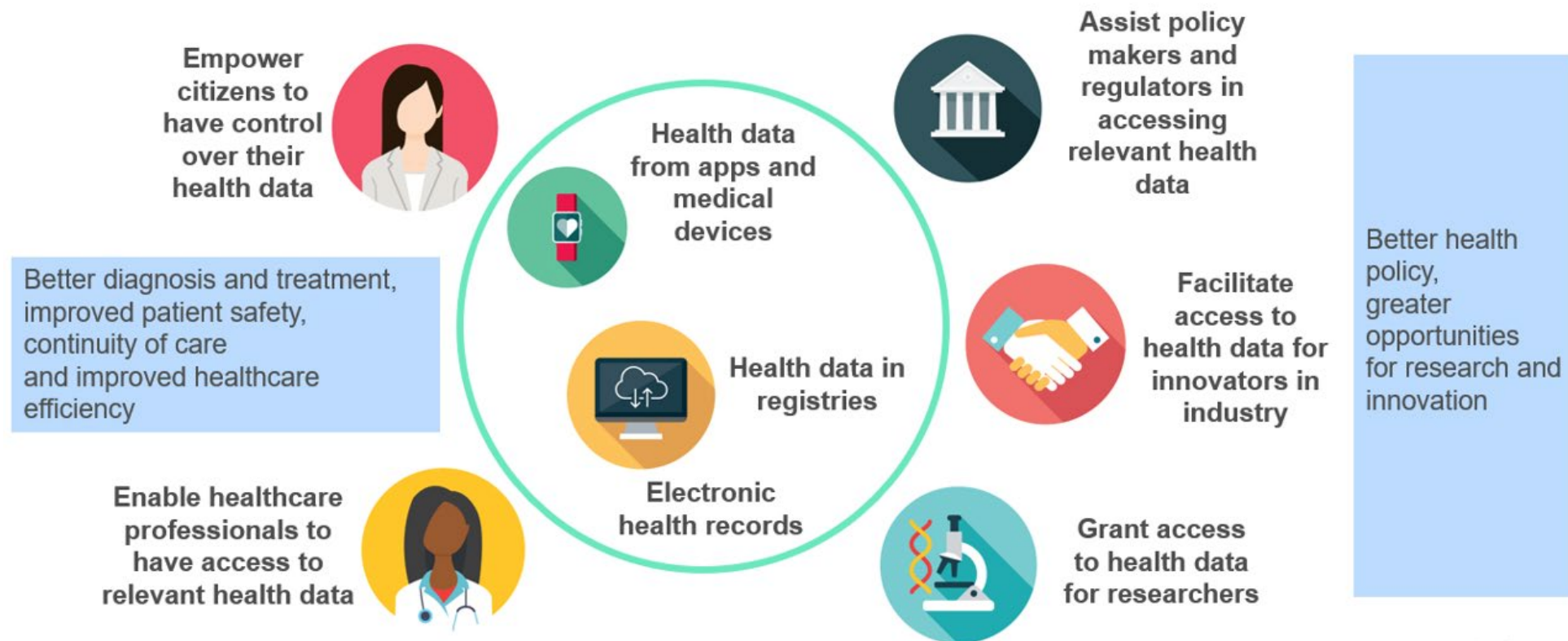
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1. EHDS and TEHDAS2 in a nutshell

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

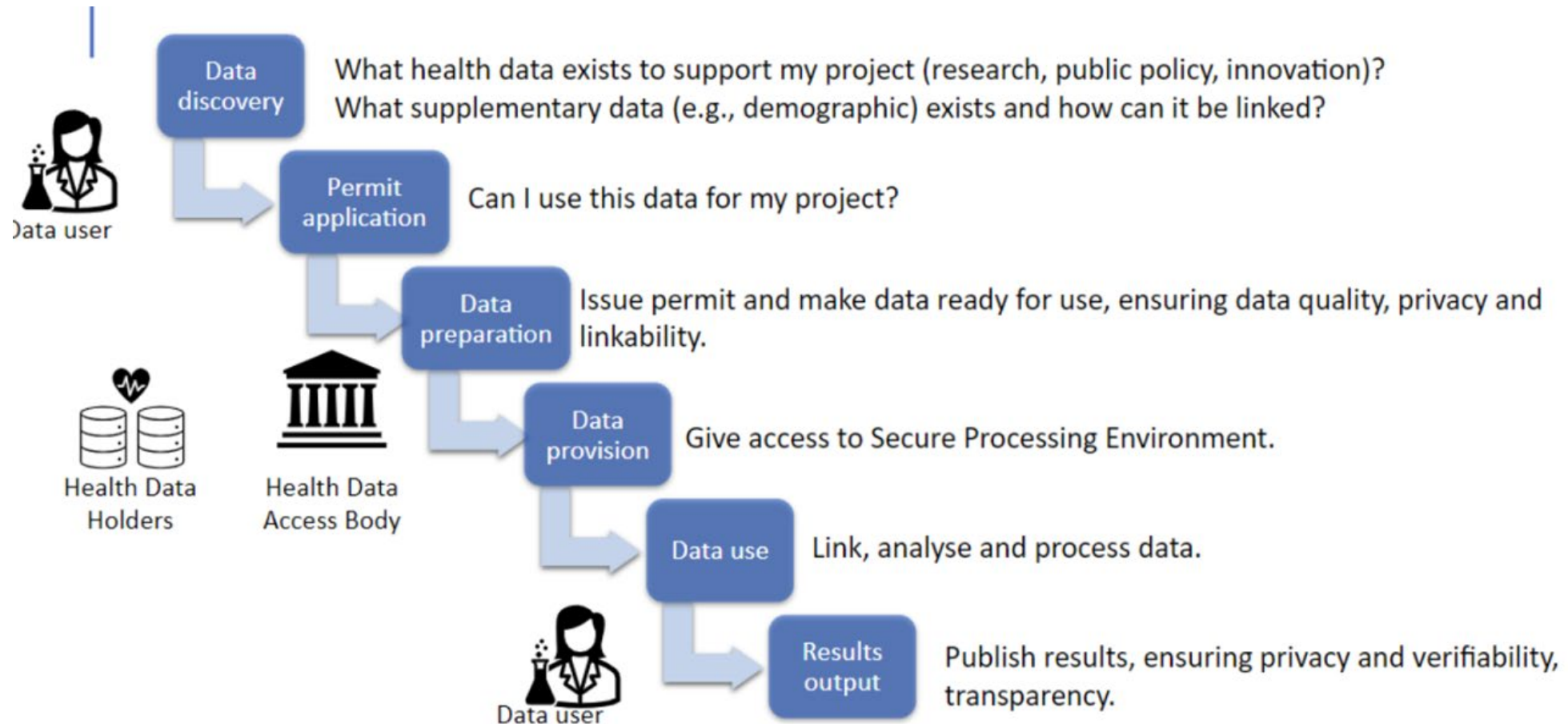
Primary use (routine care)

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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Access to European Union law

<https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32025R0327&qid=1741704307107>

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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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⌵ Languages, formats and authentic version

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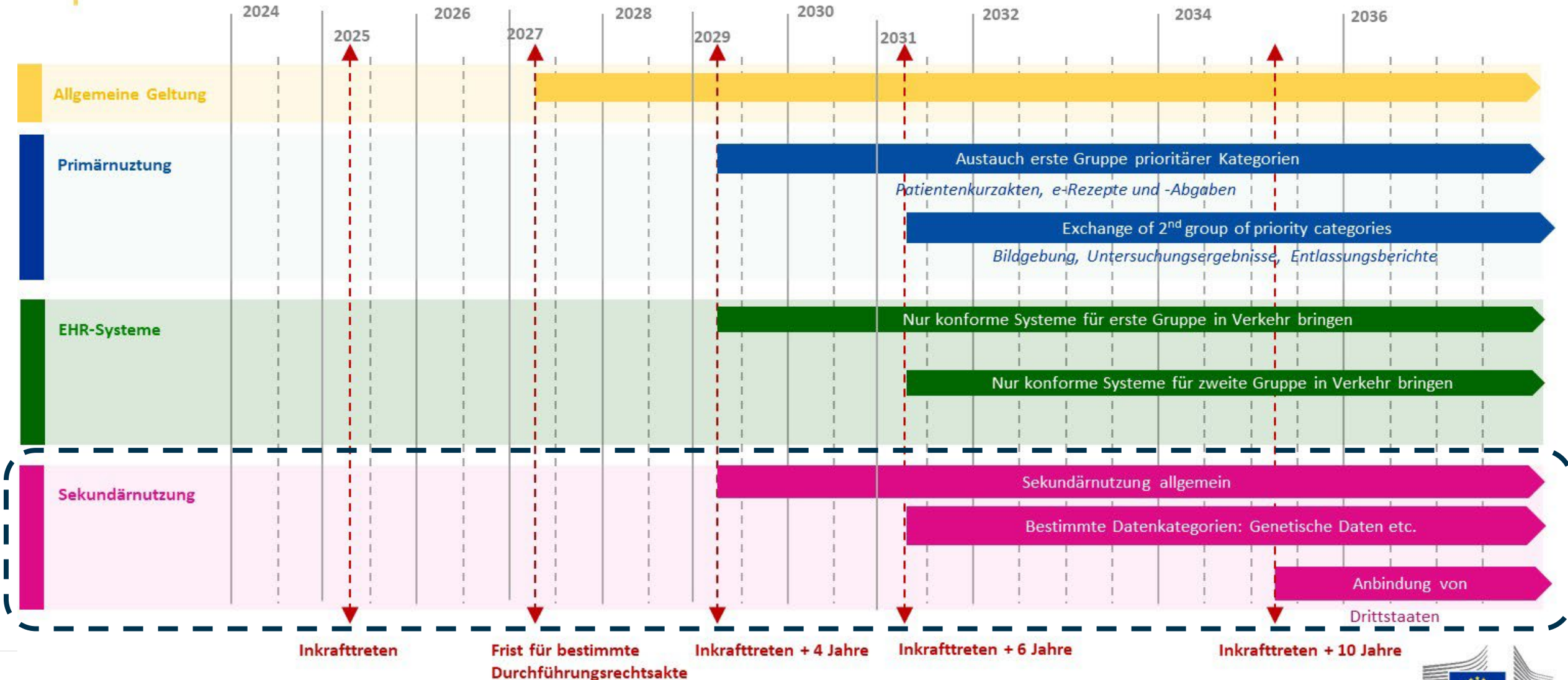
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⌵ Text

EHDS – Inkrafttreten und Geltung



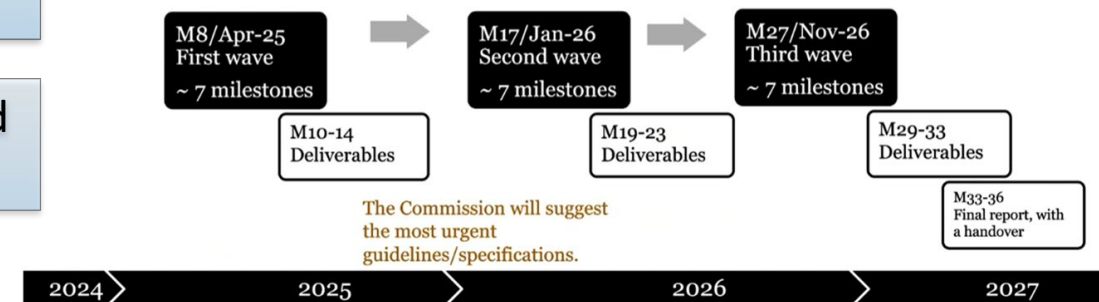
1. TEHDAS2 in a nutshell

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



| Date | Workshop |
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| 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> |
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| 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> |
| Sep 29th, 2025 | 7.4: Draft technical specification for Health Data Access Bodies on the implementation of secure processing environments, <i>Heikki Lehväslaihi (CSC - IT Center for Science, Finland)</i> |
| 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: **Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure (7.3)**



3.1 Legal background

Issue

- Technical fragmentation and varied national frameworks hinder efficient and secure cross-border access to health data for secondary purposes among EU Member States.

Solution: Common EU infrastructure HealthData@EU (Article 75 of the EHDS Regulation)

- **Definitions:**
 - **HealthData@EU infrastructure:** the infrastructure connecting national contact points for secondary use of electronic health data with the HealthData@EU Central Platform
 - **The HealthData@EU Central Platform for secondary use of electronic health data:** the interoperability platform established by the European Commission to support and facilitate the exchange of information between national contact points for secondary use of electronic health data.

3. Presenting today's document: **Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure (7.3)**



3.1 Legal background

EHDS technical requirements (Article 75(2) of the EHDS Regulation)

- The HealthData@EU infrastructure and central platform must be able to communicate securely with all authorised participants of HealthData@EU
- This communication is enabled by a specialised software that ensure secure exchange of information between HDABs (data is encrypted, access is authenticated and authorised, and compliance with GDPR is maintained)

Responsibilities (as specified in Article 75)

- **The European Commission** holds the primary responsibility for developing, maintaining, and continuously improving the HealthData@EU infrastructure: includes proposing robust interoperability standards, consistent data exchange protocols, secure data-sharing mechanisms
- **At the national level, Member States** contribute by deploying and managing NCPs, acting as connectors between their national data environments and the HealthData@EU infrastructure

3. Presenting today's document: **Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure (7.3)**



3.2 Summary of the document

Main objective

- Provide a policy-level overview of the proposed common IT infrastructure to support the development of the HealthData@EU infrastructure (based on Release 4)

Scope

- The EHDS regulation, especially Article 75, explains that our focus is only on the shared infrastructure. It does not try to prescribe how Member States should build their national solutions - it just sets the baseline for interoperability.

3. Presenting today's document: **Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure (7.3)**



3.2 Summary of the document

Key focus areas

Technical infrastructure stakeholders

- NCP (operated by each Member State): acts as the interface between national services and the cross-border HealthData@EU infrastructure. Must deploy the following components:
 - the HealthData@EU **National Dispatcher**
 - the National eDelivery **Access Point**
- For the HealthData@EU Central Platform (operated by EC) to be able to exchange the information with NCPs, the Commission must deploy:
 - the HealthData@EU **Central Dispatcher**
 - the Central eDelivery **Access Point**

3. Presenting today's document: **Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure (7.3)**



3.2 Summary of the document

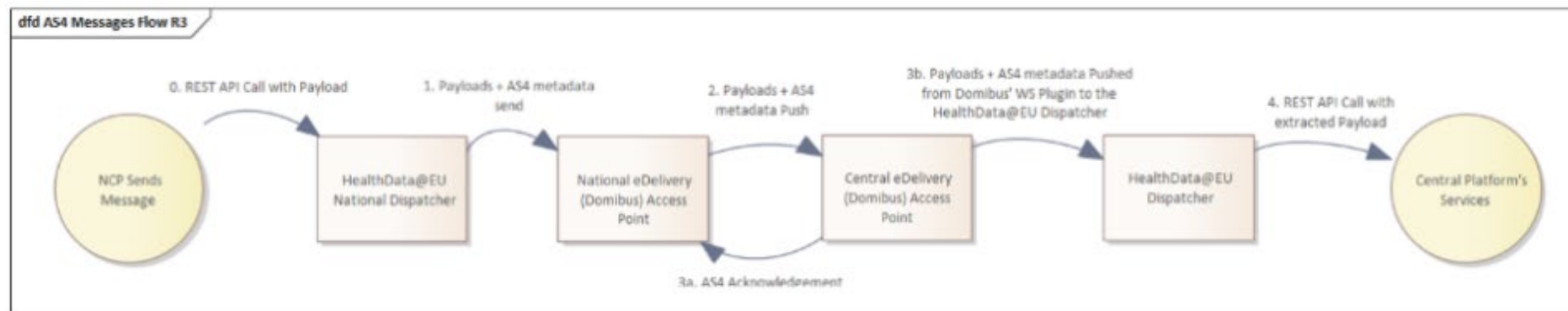
Key focus areas

- **Components** with 2 messaging layers:
 - **Dispatcher** (Business layer): ensures that the data exchanged between national and central system comply with the HealthData@EU business and technical requirements (handles validation, routing, dataset creation, and application logic)
 - **Access point** (Messaging/transport layer): relies on AS4/eDelivery to provide secure message transport.
- Components together enable point-to-point connections between each Member State and the HealthData@EU Central Platform, in line with the requirements of **Article 75** of the EHDS Regulation, which mandates each Member State to designate a National Contact Point for secondary use

3. Presenting today's document: **Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure (7.3)**

3.2 Summary of the document

Example of HealthData@EU infrastructure messaging flow



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3.2 Summary of the document

EHDS provision related to message exchange (Article 75 & 76 of the EHDS Regulation)

| Regulation | HealthData@EU Central Platform functions/support |
|---|---|
| Secure communication infrastructure | Implementing eDelivery Access Point as Messaging layer |
| Interoperability and standardisation | Implementing HealthData@EU Dispatcher as Business layer |
| EU Dataset Catalogue synchronisation | HealthData@EU Central Platform is responsible for receiving dataset metadata from Member State via <u>HealthData@EU</u> infrastructure. |
| Cross-border data access mechanisms | HealthData@EU Central Platform is responsible for distributing such requests to relevant NCPs of Member State. |

3. Presenting today's document: **Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure (7.3)**



3.2 Summary of the document

Key focus areas

- **Use cases** : grouped around practical activities like dataset management, handling of applications, decisions on permits, and appeals or reporting.
- **System interoperability**: provides optional but highly recommended self-service tests for catalogue publication, application routing, and response handling
 - Commission-hosted tool for voluntary conformance testing
 - Not legally required under the EHDS regulation
 - Facilitates implementation of technical and organisational requirements under Article 75
 - Supports Member States and authorised actors in verifying: Messaging protocols, API behaviours, Data structures

3. Presenting today's document: **Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure (7.3)**

3.3 Critical points: **Key differences in concepts**

Health Data@EU infrastructure

The network that connects national contact points with the EU's Central Platform.

Uses eDelivery/Domibus (AS4 messaging) to send messages and metadata securely.

Works as the transport layer, ensuring information moves reliably across countries and the EU platform.

Can be updated or changed without affecting how national business processes run.

HealthData@EU Central Platform

The software system managed by the European Commission.

Brings together and connects national catalogues of datasets using HealthDCAT-AP.

Offers services such as: searching and finding datasets, managing data access applications and requests, validating, routing and tracking requests, providing statistics, reports, and user interfaces.

Built with open-source components like Piveau Hub, Search, Store, and Dispatcher.

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3.3 Critical points:

Key differences in concepts

- Split between
 - Business layer (core principles → Stable across implementation)
 - Messaging layer (Messaging technologies → Flexible for Member State)

3. Presenting today's document: **Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure (7.3)**



3.4 Who should comment?

- Future NCPs
- Future HDABs as they will interact with the NCPs or will be designated NCP

4. Q&A



5. Save the date: Next workshops



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