EHDS – Be prepared for public consultations in TEHDAS2:

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

Sebastian C. Semler, TMF e. V. & 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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Agenda



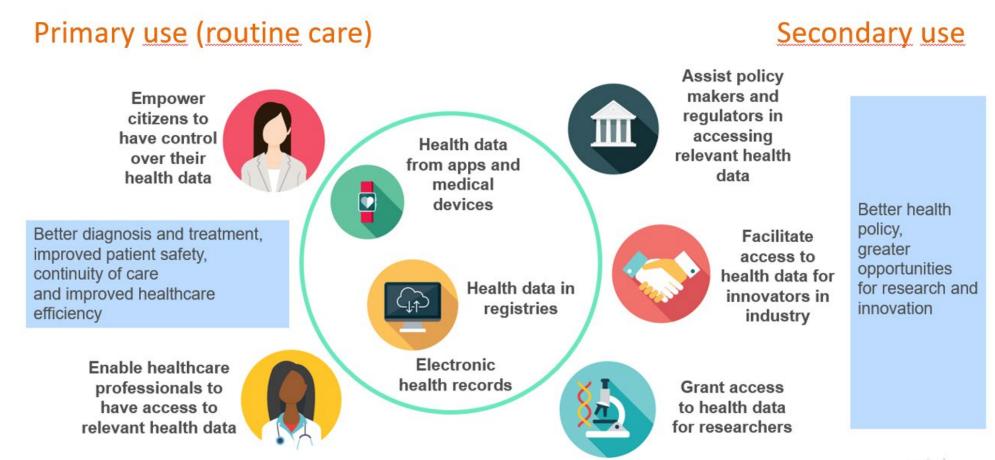
- EHDS and TEHDAS2 in a nutshell
- 2. TEHDAS2 Documents for public consultation on September 30th, 2025
- 3. Presenting today's document:

 Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure
 - 3.1 Legal background
 - 3.2 Summary of the document
 - 3.3 Critical points
 - 3.4 Who should comment?
- 4. Q&A
- 5. Save the date: Next workshops

1. EHDS and TEHDAS2 in a nutshell



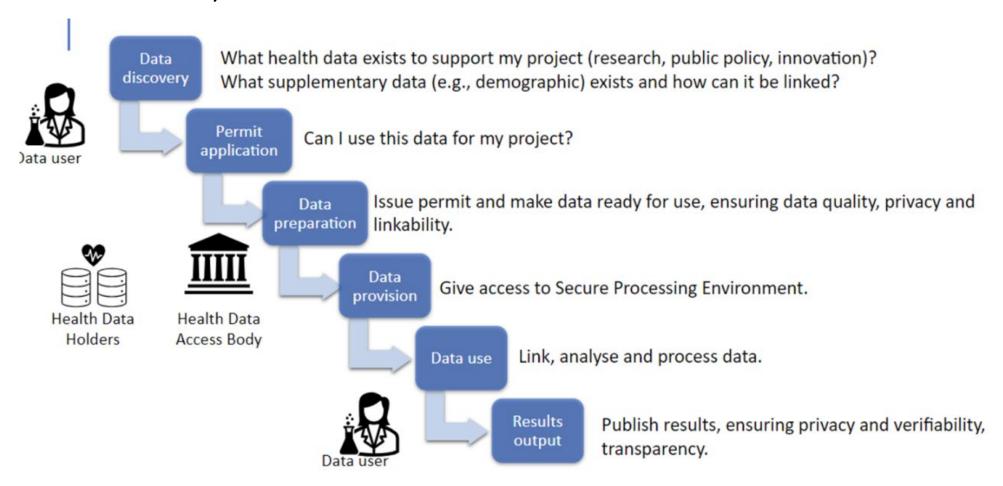
European Health Data Space (EHDS) – AIMS FROM User perspectives



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

∨ Text



<u>https://eur-lex.europa.eu/legal-</u> <u>content/DE/TXT/?uri=CELEX%3A32025R0327&qid=17417</u> <u>04307107</u>



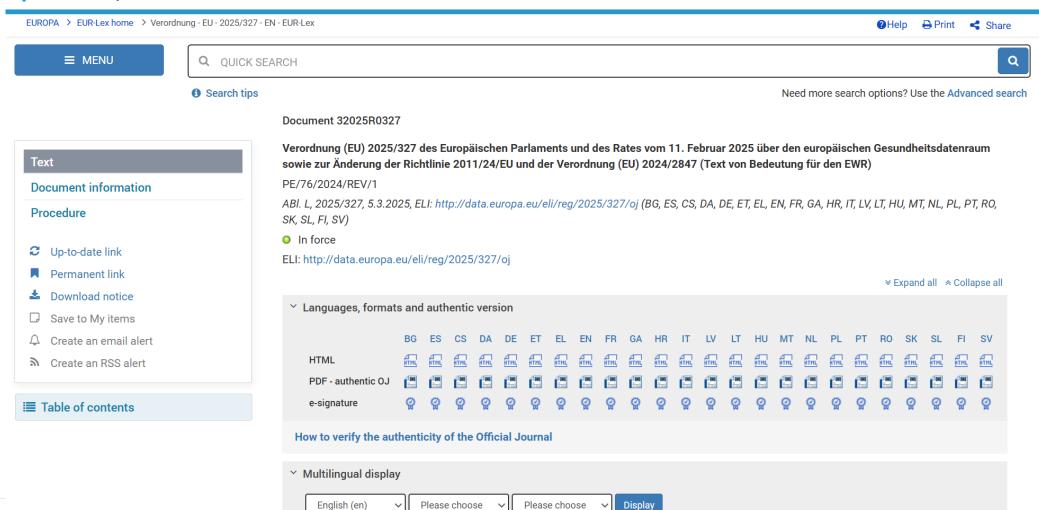
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Experimental features



EUR-Lex

Access to European Union law



Reihe I

5.3.2025

2025/327

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-



2025/327

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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)

(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:

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 involving the use of electronic health data in the healthcare and care sectors that

Finale Fassung (05.03.2025 veröffentlicht) – deutsch / englisch:

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r 1st, 202

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

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

urgently adapted its Clinical Patient Management System, established by Commission Implementing Decision (EU) 2019/1269 (*), 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.

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

Frequently Asked Questions on the European Health Data Space

https://health.ec.e uropa.eu/documen t/download/4dd47 ec2-71dd-49fcb036ad7c14f6ed68 en? filename=ehealth ehds ga en.pdf

Seite 8

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

ABl. C 486 vom 21.12.2022, S. 123.

ABl. C 157 vom 3.5.2023, S. 64.

Standpunkt des Europäischen Parlaments vom 24. April 2024 (noch nicht im Amtsblatt veröffentlicht) und Beschluss des Rates vom

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. I. 200 vom 29.7.2019, S. 35).

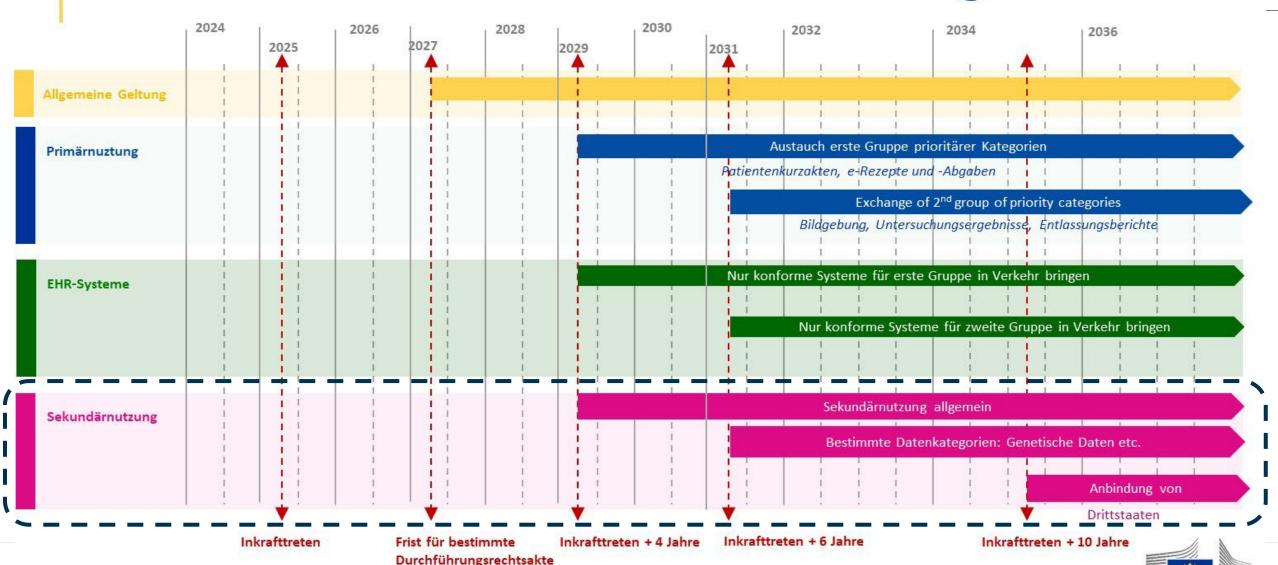
OJ C 486, 21.12.2022, p. 123.

OJ C 157, 3.5.2023, p. 64.

Position of the European Parliament of 24 April 2024 (not yet published in the Official Journal) and decision of the Council of

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).

EHDS – Inkrafttreten und Geltung



1. TEHDAS2 in a nutshell

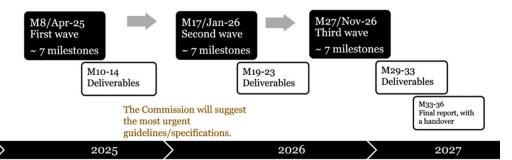


TEHDAS2 in a nutshell

- A joint action with clear scope, timeline and budget
- Structured in independent work packages but common working methods
- Aims for harmonised implementation of EHDS secondary use of health data
- Produces tangible results in the form of guidelines and technical specifications
- 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-0CT 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 noncompliance 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

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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

Seite 11

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



3.1 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.



3.1 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



3.2 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.



3.2 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



3.2 Summary of the document

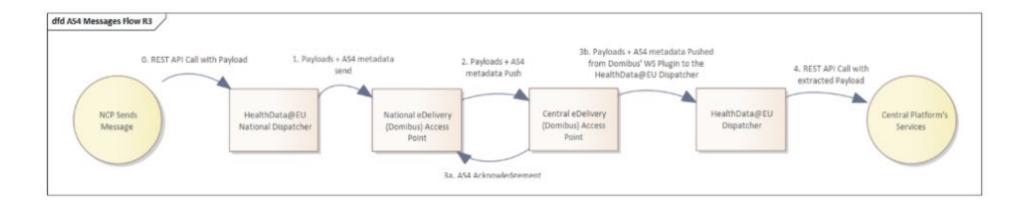
Key focus areas

- 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



3.2 Summary of the document

Example of HealthData@EU infrastructure messaging flow





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 HealthData@EU infrastructure.
Cross-border data access mechanisms	HealthData@EU Central Platform is responsible for distributing such requests to relevant NCPs of Member State.



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



3.3 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.



3.3 Critical points:

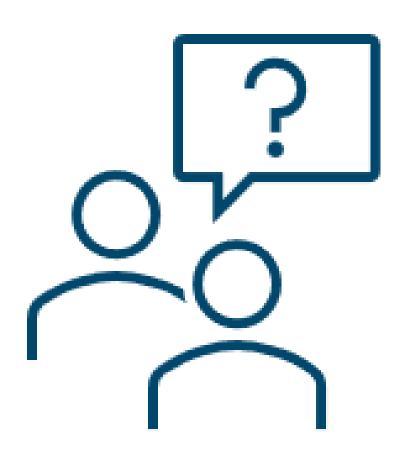
Key differences in concepts

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



- 3.4 Who should comment?
- Future NCPs
- Future HDABs as they will interact with the NCPs or will be designated NCP





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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