
EHDS – Be prepared for public consultations in TEHDAS2:
**Draft guideline for Health Data Access Bodies on implementing opt-out
from the secondary use of health data**

Sebastian C. Semler, TMF e. V. &
Irene Schlünder, TMF e. V.
September 16th, 2025 | 8 a.m. to 9 a.m.

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



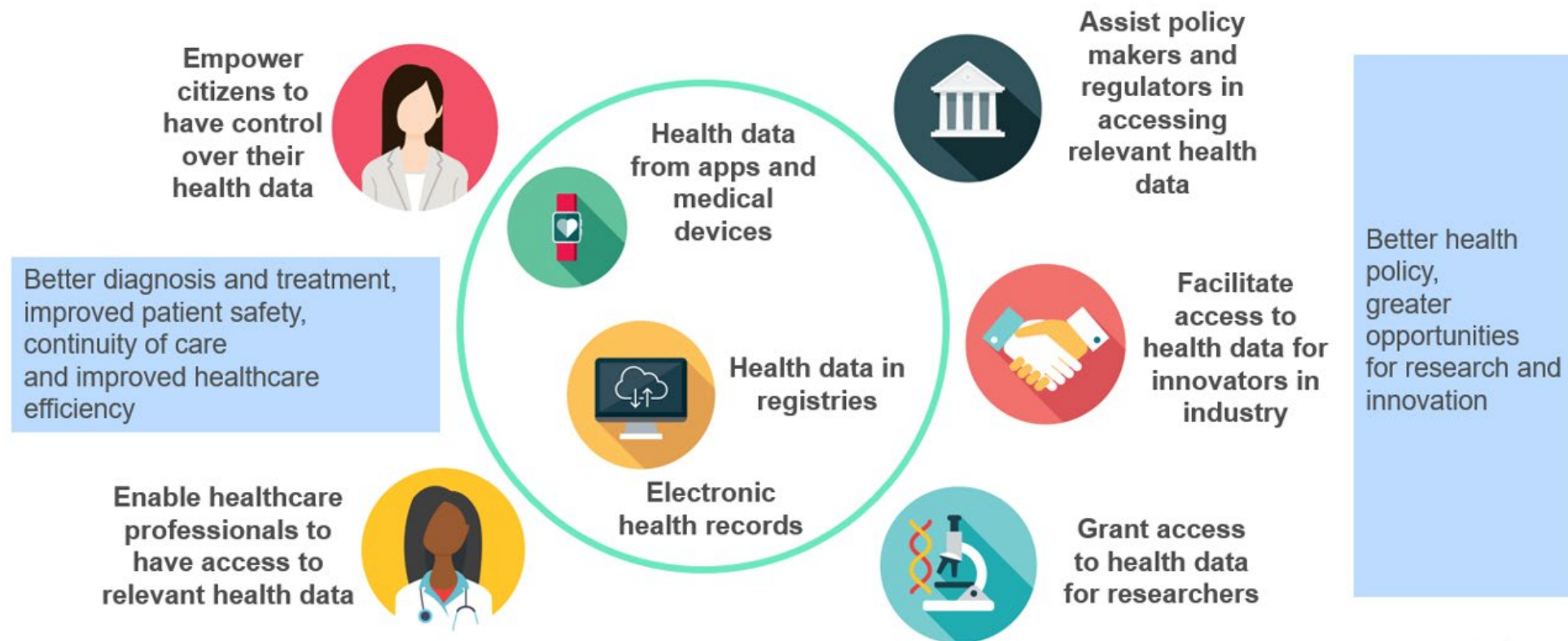
1. EHDS and TEHDAS2 in a nutshell
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3. Presenting today's document:
Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data
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1. EHDS and TEHDAS2 in a nutshell

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

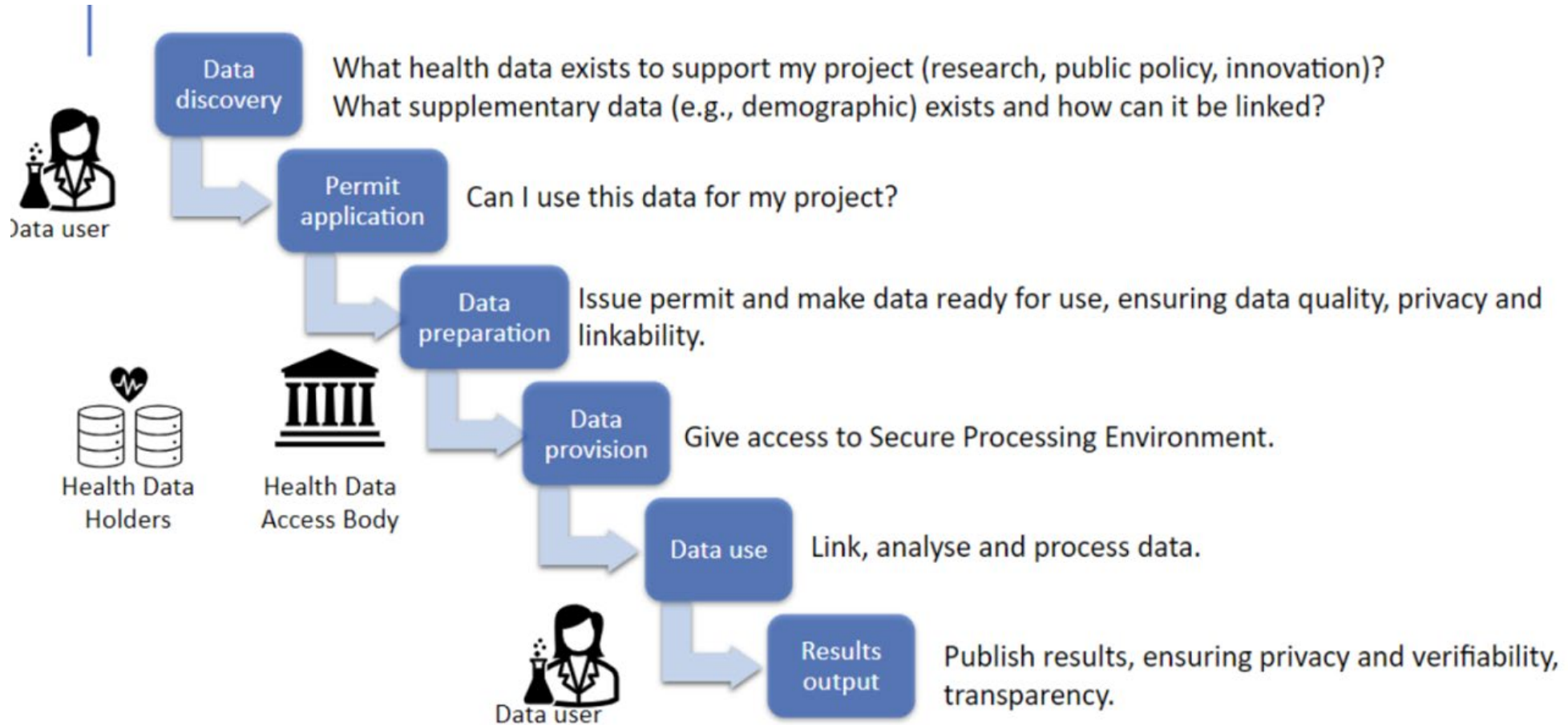
Primary use (routine care)

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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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)

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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 Gesundheitsaufzeichnungen (electronic health records (EHR) (im folgenden „EHR-Systeme“) festgelegt wird. Der EHDS wird ein zentralisiertes, interoperables System sein, das den Austausch von Gesundheitsdaten zwischen Mitgliedstaaten ermöglicht, um die Versorgung der Patienten zu verbessern und die Gesundheit der Bevölkerung zu schützen. Die COVID-19-Pandemie hat deutlich gemacht, dass ein zeitnahe Zugang zu hochwertigen elektronischen Gesundheitsdaten für die Prävention und Bewältigung von Pandemien und für die Patientenversorgung von entscheidender Bedeutung ist. Ein einheitlicher Rechtsrahmen und technischer Rahmen für die Entwicklung, Vermarktung und Verwendung von EHR-Systemen wird es ermöglichen, die Versorgung der Patienten zu verbessern und die Gesundheit der Bevölkerung zu schützen. Die COVID-19-Pandemie hat deutlich gemacht, dass ein zeitnahe Zugang zu hochwertigen elektronischen Gesundheitsdaten für die Prävention und Bewältigung von Pandemien und für die Patientenversorgung von entscheidender Bedeutung ist. Ein einheitlicher Rechtsrahmen und technischer Rahmen für die Entwicklung, Vermarktung und Verwendung von EHR-Systemen wird es ermöglichen, die Versorgung der Patienten zu verbessern und die Gesundheit der Bevölkerung zu schützen.
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- (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).

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 health data systems, and to ensure that such systems are interoperable and can be used across the EU. The EHDS will be a centralised, interoperable system that will enable the exchange of health data between Member States, thereby improving the quality of care and the health of the population. The COVID-19 pandemic has clearly shown that timely access to high-quality electronic health data is essential for the prevention and management of pandemics and for patient care. A uniform legal and technical framework for the development, marketing and use of electronic health data systems will enable the exchange of health data between Member States, thereby improving the quality of care and the health of the population.
- (2) The COVID-19 pandemic has clearly shown that timely access to high-quality electronic health data is essential for the prevention and management of pandemics and for patient care. A uniform legal and technical framework for the development, marketing and use of electronic health data systems will enable the exchange of health data between Member States, thereby improving the quality of care and the health of the population.
- (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.

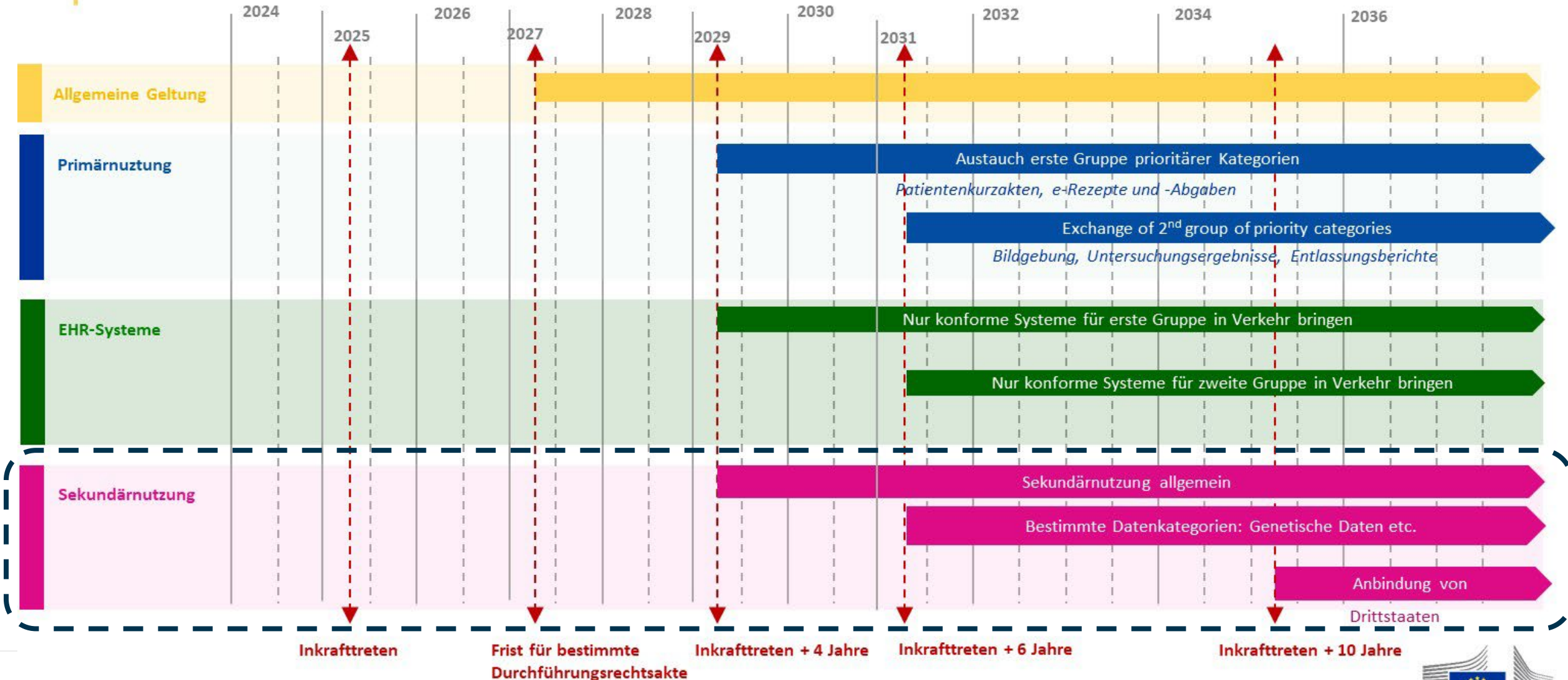
⁽²⁾ OJ C 157, 3.5.2023, p. 64.

⁽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).



EHDS – Inkrafttreten und Geltung



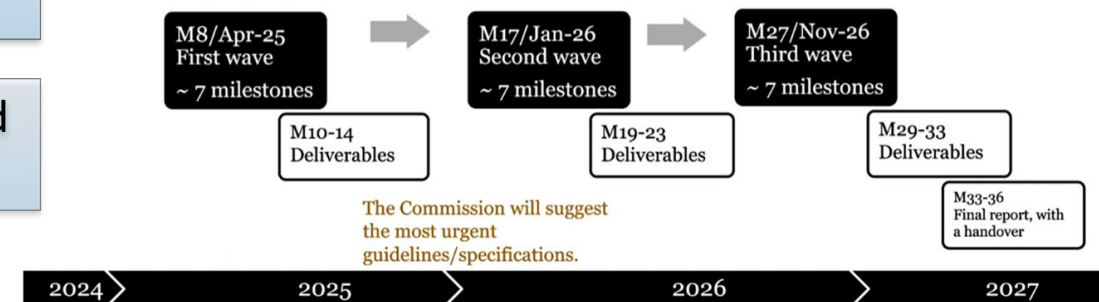
1. TEHDAS2 in a nutshell

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>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 Jutii (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, Ph.D (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 guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data (8.1)**



3.1 Legal background

Article 71 of the EHDS Regulation establishes a clear and enforceable right for all natural persons to opt out of the processing of their personal electronic health data for secondary use. This right applies across the Union and can be exercised at any time, without justification. It is reversible and must be made accessible and easily understandable.

While the right itself is established at EU level, its practical implementation is delegated to the Member States (*"2. Member States shall provide for ..."*). This includes the responsibility to define the technical and procedural modalities of the opt-out mechanism and, where relevant, the conditions for narrowly defined exceptions as set out in Article 71(4).

There will be no Implementing Act to harmonise the implementation across Member States.

3. Presenting today's document: **Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data (8.1)**



3.2 Summary of the document

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3. Presenting today's document: **Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data (8.1)**



3.3 Critical points

- National implementation can lead to fragmentation across Member States
- Opt-out in one Member State does not automatically lead to opt-out across EU
- Implementation needs to be GDPR compliant oversight by (DPAs)
- Relation to existing consent still a bit unclear
- The implementation effort increases with the options you want to offer citizens
- Transparency remains a key topic: close connection to other guidelines, e.g. on information portal (8.2, 3rd wave)

3. Presenting today's document: **Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data (8.1)**



3.4 Who should comment?

- National Ministries/Legislators
- HDABs
- Data Protection Authorities
- Individuals/Patient Organisations
- Research Organisation from the perspective as data holders

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

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