
EHDS – Be prepared for public consultations in TEHDAS2: Draft guideline for data enrichment (M5.4)

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May 11th, 2026 | 8 a.m. to 9 a.m.

online workshop series | May 11th to May 26th, 2026

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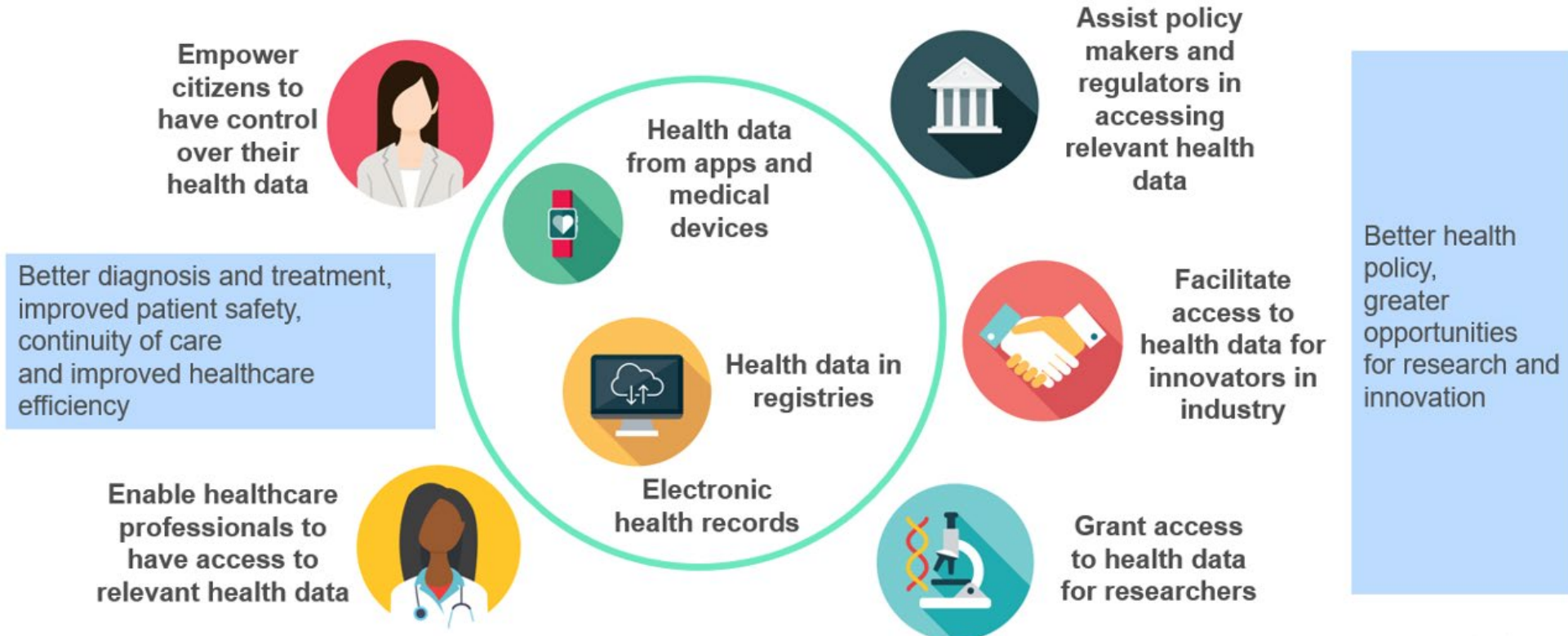
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1. EHDS and TEHDAS2 in a nutshell

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

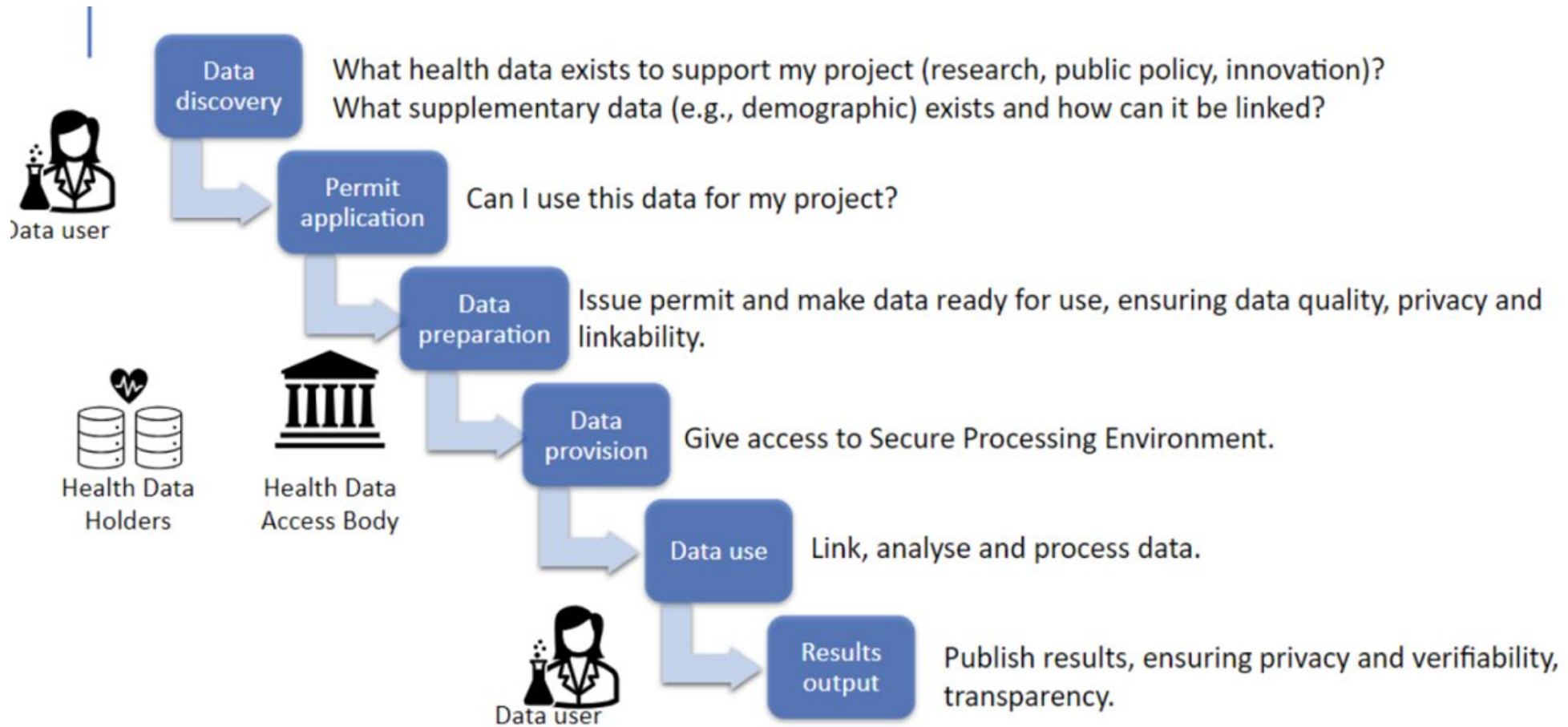
Primary use (routine care)

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



<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)

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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 zentraler Ort sein, an dem die Vorwahrung und die Kontrolle über Gesundheitsdaten für die Prävention, Diagnose, Behandlung und Überwachung von Krankheiten und die Unterstützung der öffentlichen Gesundheit sichergestellt werden können. Der EHDS wird es ermöglichen, die Gesundheitsversorgung zu verbessern und die Kosten zu senken, indem die Gesundheitsversorgung durch den Austausch von Gesundheitsdaten zwischen den Mitgliedstaaten erleichtert wird. Der EHDS wird es ermöglichen, die Gesundheitsversorgung zu verbessern und die Kosten zu senken, indem die Gesundheitsversorgung durch den Austausch von Gesundheitsdaten zwischen den Mitgliedstaaten erleichtert wird. Der EHDS wird es ermöglichen, die Gesundheitsversorgung zu verbessern und die Kosten zu senken, indem die Gesundheitsversorgung durch den Austausch von Gesundheitsdaten zwischen den Mitgliedstaaten erleichtert wird.
- (2) Die COVID-19-Pandemie hat deutlich gemacht, dass ein zeitnaher Zugang zu hochwertigen elektronischen Gesundheitsdaten für die Vorwahrung und die Kontrolle über Gesundheitsdaten für die Prävention, Diagnose, Behandlung und Überwachung von Krankheiten und die Unterstützung der öffentlichen Gesundheit sichergestellt werden können. Der EHDS wird es ermöglichen, die Gesundheitsversorgung zu verbessern und die Kosten zu senken, indem die Gesundheitsversorgung durch den Austausch von Gesundheitsdaten zwischen den Mitgliedstaaten erleichtert wird. Der EHDS wird es ermöglichen, die Gesundheitsversorgung zu verbessern und die Kosten zu senken, indem die Gesundheitsversorgung durch den Austausch von Gesundheitsdaten zwischen den Mitgliedstaaten erleichtert wird. Der EHDS wird es ermöglichen, die Gesundheitsversorgung zu verbessern und die Kosten zu senken, indem die Gesundheitsversorgung durch den Austausch von Gesundheitsdaten zwischen den Mitgliedstaaten erleichtert wird.
- (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).

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. The EHDS will be a central place where the control and ownership of health data for the prevention, diagnosis, treatment and monitoring of diseases and the support of public health can be guaranteed. The EHDS will enable the improvement of healthcare and the reduction of costs by facilitating the exchange of health data between Member States. The EHDS will enable the improvement of healthcare and the reduction of costs by facilitating the exchange of health data between Member States. The EHDS will enable the improvement of healthcare and the reduction of costs by facilitating the exchange of health data between Member States.
- (2) The COVID-19 pandemic has clearly shown that timely access to high-quality electronic health data is essential for the prevention, diagnosis, treatment and monitoring of diseases and the support of public health. The EHDS will enable the improvement of healthcare and the reduction of costs by facilitating the exchange of health data between Member States. The EHDS will enable the improvement of healthcare and the reduction of costs by facilitating the exchange of health data between Member States. The EHDS will enable the improvement of healthcare and the reduction of costs by facilitating the exchange of health data between Member States.
- (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).



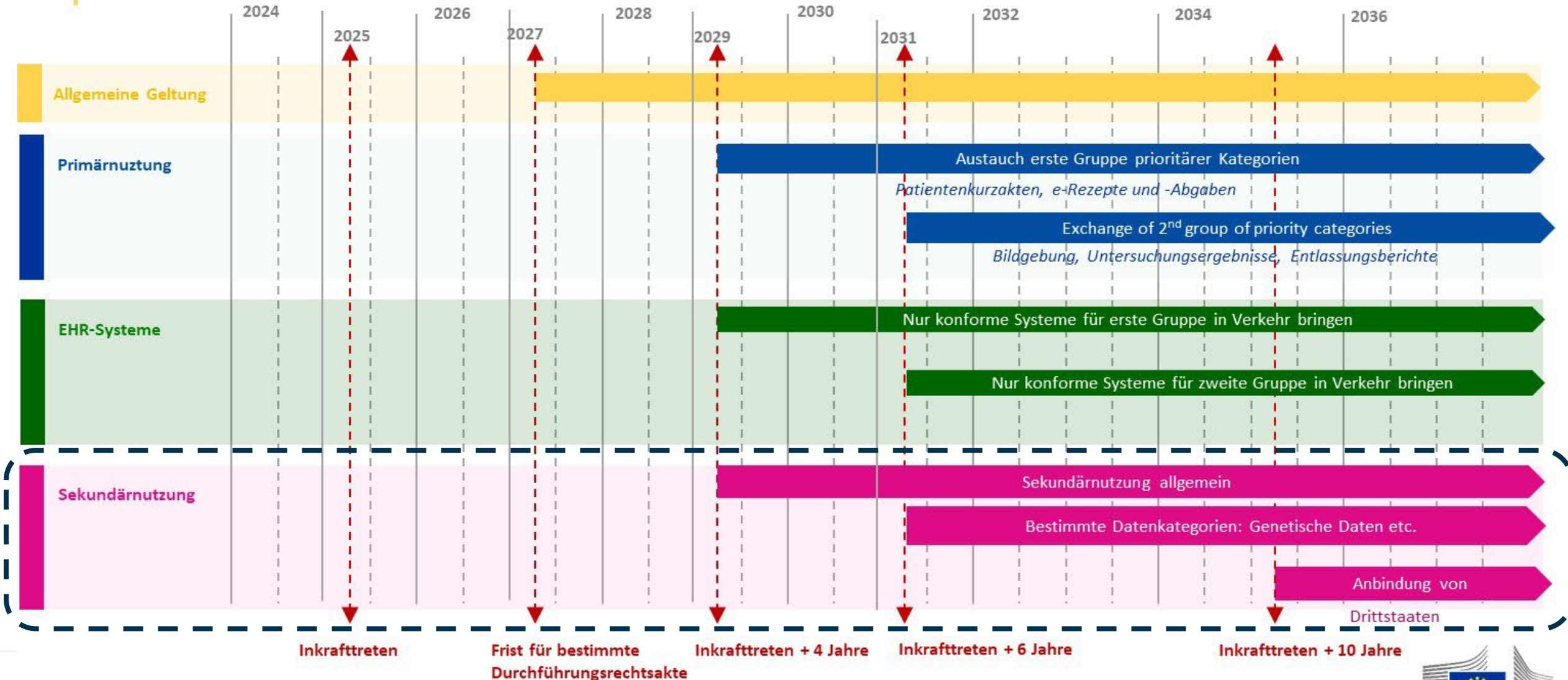
European Commission

Frequently Asked Questions on the European Health Data Space

Last updated 9 March 2025

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

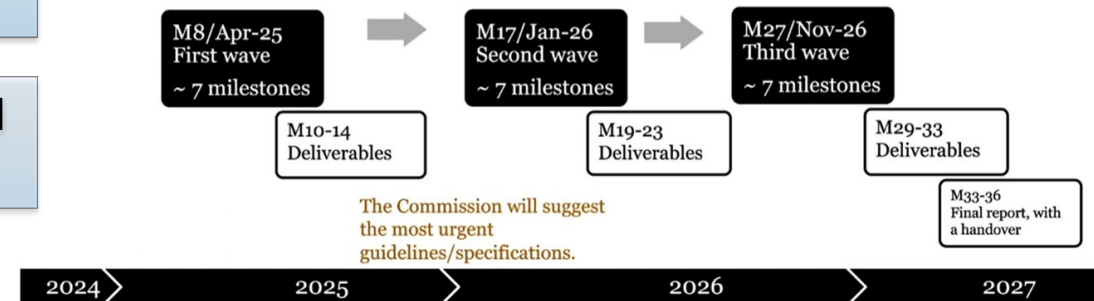


TEHDAS2 in a nutshell

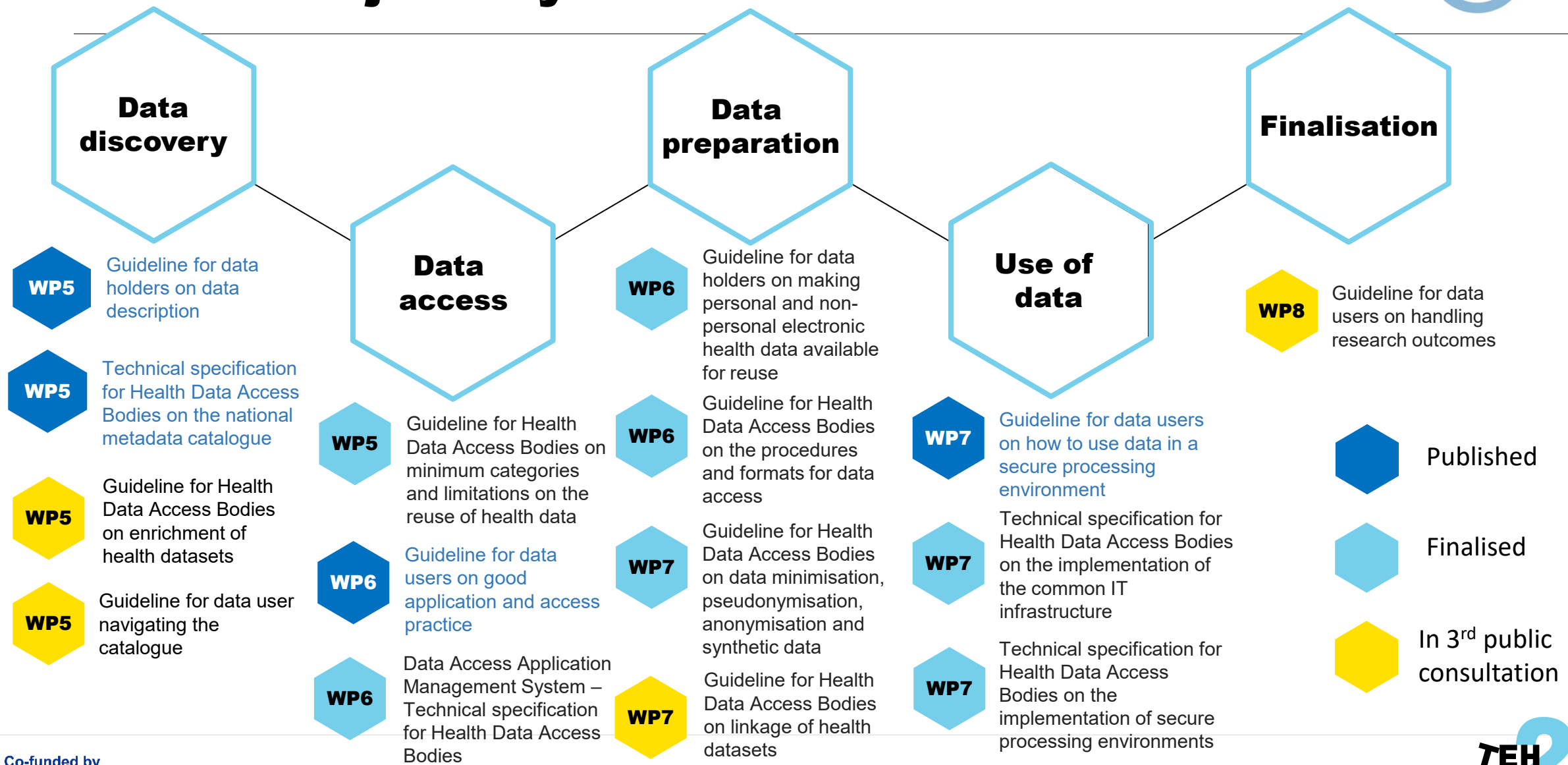
- 1 A joint action with clear scope, timeline and budget
- 2 Structured in independent work packages but common working methods
- 3 Aims for harmonised implementation of EHDS – secondary use of health data
- 4 Produces tangible results in the form of guidelines and technical specifications
- 5 High emphasis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

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

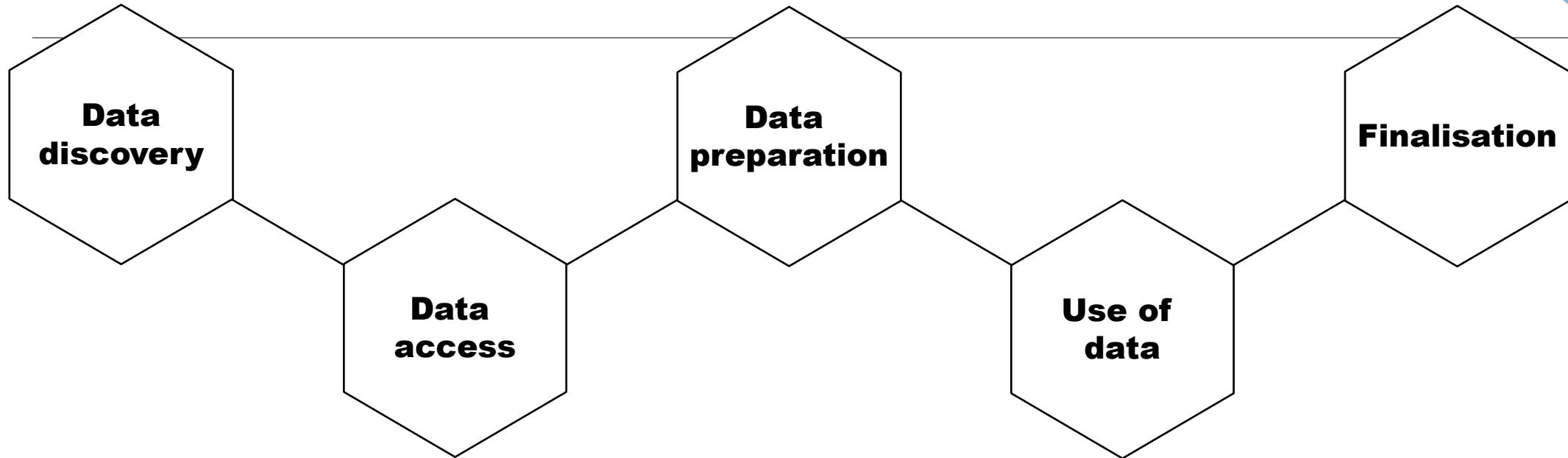
- ▶ TEHDAS2 bereitet die Durchsetzungsrechtsakte der EU zum EHDS II durch **Guidelines** vor.
- ▶ (Für EHDS I entsprechend: xt-EHR)
- ▶ in 3 „Wellen“ (1. und 2. bereits erfolgt)
- ▶ Die Guidelines werden vor Verabschiedung und Annahme durch die EU öffentlich zur Kommentierung gestellt. Beginn: 05.05. bis 28.06.2026 (2 Monate)



EHDS user journey and related WP deliverables 1/2



EHDS user journey and related WP deliverables 2/2



WP4 Guideline for Health Data Access Bodies on fees and penalties for non-compliance regulated to the EHDS regulation

WP4 Guideline for Health Data Access Bodies on collaboration with other parties

WP4 Guideline for Health Data Access Bodies on international and third country access and transfer of electronic health data

WP8 Guideline for Health Data Access Bodies on opt-out mechanism from the secondary use of health data

WP8 Guideline for Health Data Access Bodies on the obligation of notifying the natural person on a significant finding from the secondary use of health data

WP8 Guideline for Health Data Access Bodies on informing natural persons about the use of health data – "Citizen Information Point"

Public consultation results

- Summaries integrated as part of the final documents
- Common feature: more specific or operational guidance expected
- KPI: 30 replies for each guideline from at least 14 European countries
- **1st public consultation:**
 - **4 documents: 78–106 responses/guideline, 15–16 countries**
 - **Altogether around 350 responses**
- **2nd public consultation:**
 - **11 guidelines: 40–99 responses/guideline, 12–16 countries**
 - **Altogether around 760 replies (consolidated responses)**



2. TEHDAS2 Guidelines



Third public consultation

<https://tehdas.eu/>

5 MAY – 28 JUNE

TOPIC: Collaboration with third countries, data enrichment and informing citizens

Documents scheduled for public consultation:

1. Draft guideline on a framework for collaboration
2. Draft guideline for health data access bodies on international and third country access and transfer of electronic health data
3. Draft guideline for data enrichment
4. Draft guideline for data users navigating the catalogue
5. Draft guideline for health data access bodies on linkage of health datasets
6. Draft guideline for health data access bodies on informing natural persons about the use of health data – “Citizen Information Point”
7. 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).



2. TEHDAS2 Online-Workshop-Serie 11.05.-26.05.2026



Date	Workshop
May 11 th , 2026	Draft guideline for data enrichment (M5.4), <i>Dr. Anna Niemeyer (TMF e. V., Germany)</i>
May 12 th , 2026	Draft guideline for health data access bodies on international and third country access and transfer of electronic health data (M4.3), <i>Irene Schlünder (TMF e. V., Germany)</i>
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More information & registration: <https://www.tmf-ev.de/news/tehdas2-public-consultations-tmf-workshops-mai-2026>

3. Presenting today's document: **Draft guideline for data enrichment (M5.4)**



3.1 Legal background: **EHDS Regulation – Recital 57**

*“Health data users who benefit from access to datasets provided for under this Regulation **could enrich the data in those datasets with various corrections, annotations and other improvements**, for instance by supplementing missing or incomplete data, thus improving the accuracy, completeness or quality of the data in the datasets. Health data users should be encouraged to report critical errors in datasets to health data access bodies.*

*To support the improvement of the initial database and further use of the enriched dataset, Member States should be able to establish rules for the processing and the use of electronic health data containing improvements related to the processing of those data. The **improved dataset should be made available free of charge to the original health data holder** together with a description of the improvements. The health data holder should **make the new dataset available**, unless it provides a justified notification to the health data access body for not doing so, for instance in cases in which the enrichment by the health data user is of low quality.”*

3. Presenting today's document: **Draft guideline for data enrichment (M5.4)**



3.2 Summary of the document

1. Conceptual Framework of Data Enrichment

- *Definition & Typology*: The guideline establishes a distinction between internal enrichment (transforming data from within the provided dataset, e.g., feature derivation or clinical scoring) and external enrichment (appending authorised contextual data, such as socio-economic or environmental indicators, within the SPE).
- *Delineation from Linkage*: It clarifies that enrichment is a post-access, user-driven analytical operation, whereas data linkage is a pre-access, centralised process managed by HDABs

2. The Data Enrichment Journey

- *Operational Pathways*: To facilitate the voluntary feedback loop envisioned in EHDS Recital 57, the document proposes three pathways.
- *Priority on Methodology (Pathway B)*: Reflecting the technical constraints of data holder infrastructures, the guideline prioritises the sharing of well-documented methodologies, executable code, and algorithms over the transfer of enriched datasets.
- *Exceptional Dataset Transfer (Pathway C)*: Outlines the rare scenarios where dataset transfer may be justified, requiring formal controller-to-controller agreements and robust infrastructure

3. Considerations on Implementation Standards and Interoperability

- *Semantic Interoperability*: Use of international standards including SNOMED CT, LOINC, and HL7 FHIR to ensure enrichments are interpretable and reusable across the EHDS ecosystem.
- *Metadata Management*: Guidance on utilising HealthDCAT-AP versioning properties (e.g., *isVersionOf* and *versionNote*) to maintain traceability and link enriched datasets to their original versions

4. Considerations on Governance and Risk Mitigation

- *Privacy & Re-identification*: Provides a framework for re-evaluating re-identification risks, as enrichment increases data granularity. This is particularly critical for vulnerable cohorts like rare diseases or paediatric oncology, where derived clinical phenotypes can make individual profiles highly distinctive.
- *Legal Instruments*: Suggestions for integrating enrichment-related clauses into Data Permits or Data Use Agreements (DUAs) to clarify rights regarding transformations and output sharing.

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- *Legal Instruments*: Suggestions for integrating enrichment-related clauses into Data Permits or Data Use Agreements (DUAs) to clarify rights regarding transformations and output sharing.

Main elements of the draft guideline

Conceptual understanding of data enrichment

- ▶ What defines data enrichment and the types of operations it may include (internal vs external)

Data enrichment in the EHDS user journey

- ▶ Where enrichment may occur and identification of potential enrichment procedures and feedback loops

The feedback loop

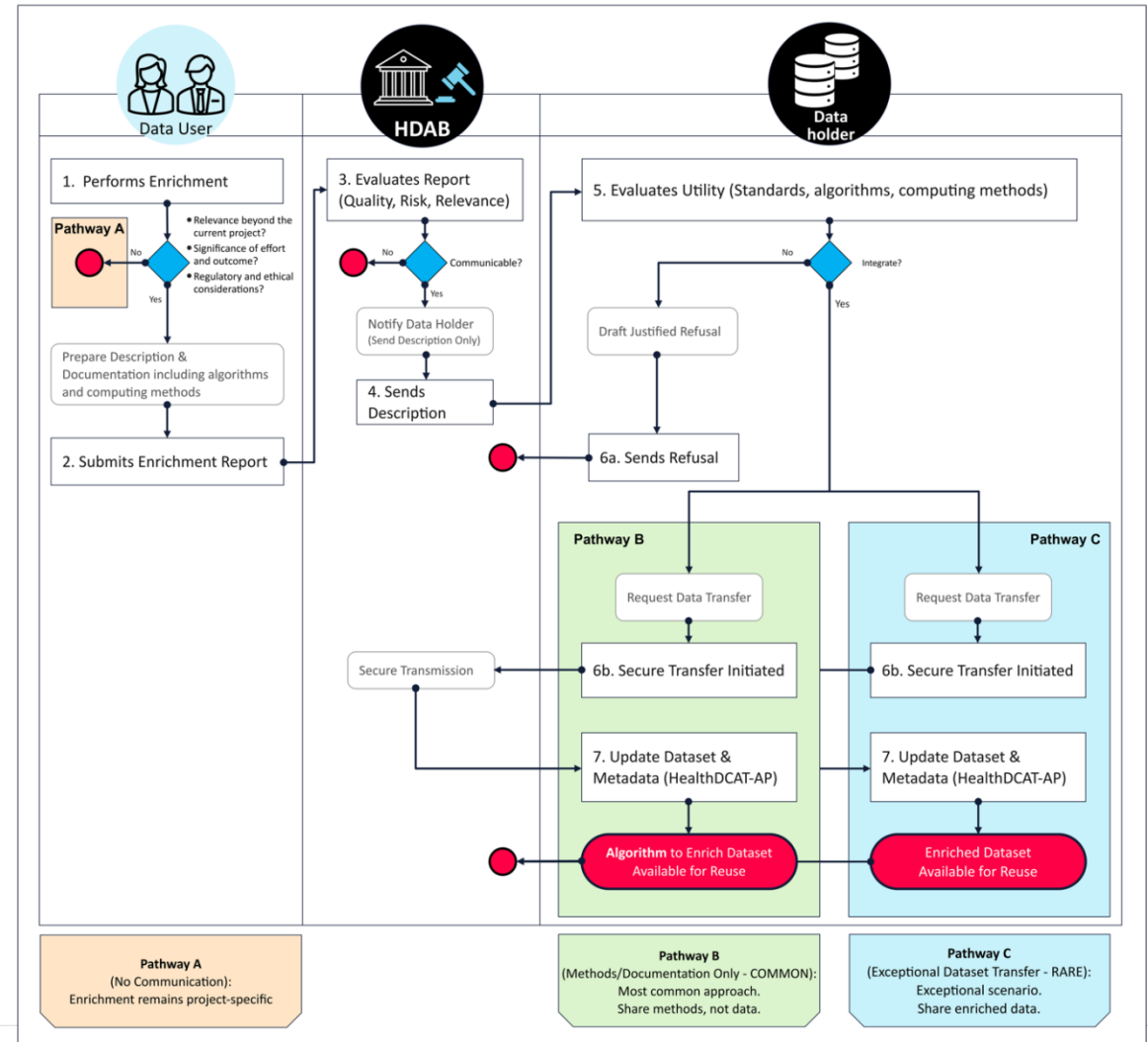
- ▶ Envisioning a process where users return descriptions of improvements, following the data user journey and roles of key actors (data users, HDABs, data holders)

Pathways:

- ▶ Emphasizing sharing methodologies, code, and algorithms, supporting reuse and reproducibility

Governance, legal and operational considerations

- ▶ How enrichment can be integrated into governance and technical frameworks, including key legal aspects of sharing outputs and practical operational elements such as documentation, standards, and infrastructure



3. Presenting today's document: **Draft guideline for data enrichment (M5.4)**



3.3 Critical points

Lack of binding force

- ▶ The non-binding nature of the recital makes it difficult to provide clear and unambiguous recommendations.

Standardisation of communication

- ▶ Exploring the options for standardising communication regarding enrichments with **fit-for-purpose mechanisms**, such as those being developed within the **QUANTUM** project.

Clarification of roles and incentives

- ▶ Gathering feedback on how to ensure appropriate recognition, incentives, and clear expectations for data users contributing enrichment.

Examples and governance approaches

- ▶ Identifying existing models, practices, or initiatives across Member States to enrich the guideline's practical examples and inform future approaches to data enrichment.

3. Presenting today's document: **Draft guideline for data enrichment (M5.4)**



3.4 Who should comment?

- ▶ Data user, data holder, HDABs

... and why?

- ▶ **Your expertise is essential** for refining the proposed approaches to data enrichment, including the relevance and scientific value of enrichment and how it is communicated within the EHDS framework.

... what are we looking for?

- ▶ We specifically seek feedback on the **proposed pathways**, as well as the **legal, organisational, and operational considerations**, including the role of **HDABs as intermediaries** and how to ensure feasible and efficient processes.

Public consultation

- The public consultation is open to all stakeholders from 5 May to 28 June.
- Draft documents, feedback forms and instructions can be found on tehdas.eu/public-consultations once the consultation opens.
- Submit your feedback via the provided forms.
- Your feedback is valuable input for the authors when they edit and finalise the documents!



4. Q&A



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