TMF – Technologie- und Methodenplattform
für die vernetzte medizinische Forschung e.V.

EHDS – Be prepared for public consultations in TEHDAS2:

Draft guideline for Health Data Access Bodies on the procedures and formats for data access

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September 24th, 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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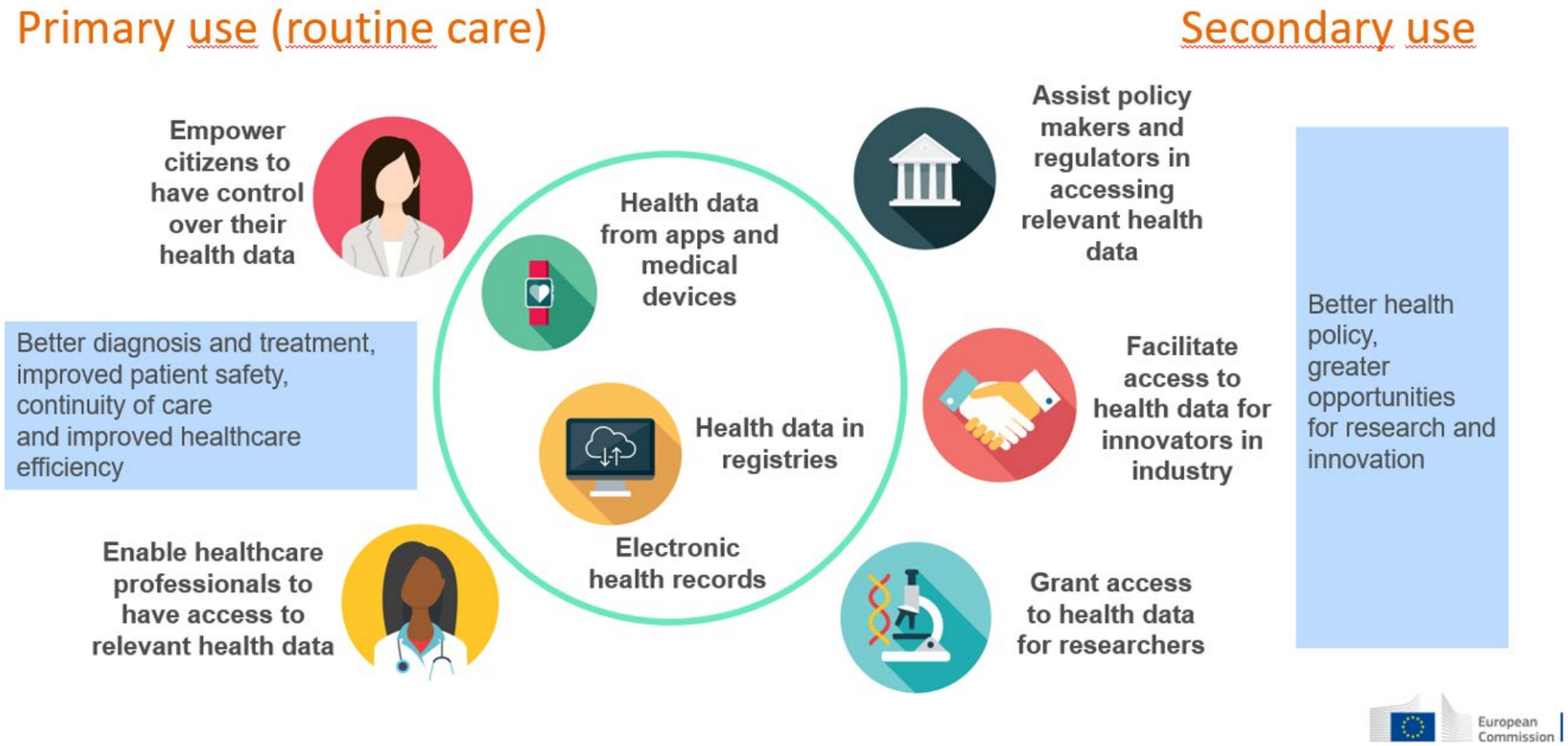
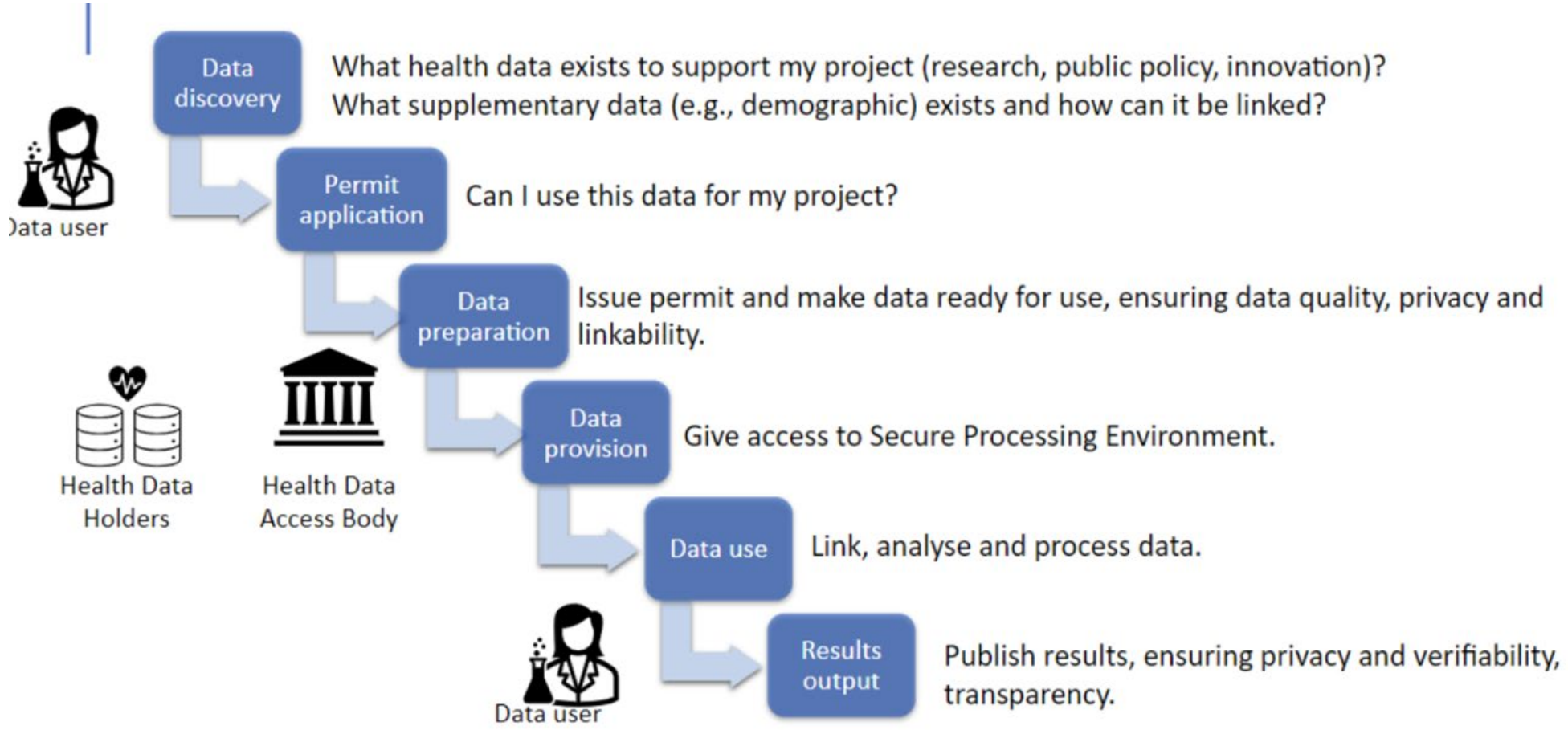
1. EHDS and TEHDAS2 in a nutshell

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

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

ABl. 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

Amtsblatt
der Europäischen Union

DE
Reihe L

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 Gesundheits-aufzeichnungen (electronic health records, EHR) (im Folgenden „EHR-Systeme") festgelegt wird. Der EHDS wird ein

(2) Die COVID-19-Pandemie hat deutlich gemacht, dass ein zeitnaher Zugang zu hochwertigen elektronischen [illegible] möglicherweise zu einer wirksameren Bewältigung künftiger Pandemien, geringeren Kosten und einer besseren [illegible] System für das klinische Patientenmanagement im Eilverfahren an, um es den Mitgliedstaaten zu ermöglichen, elektronische Gesundheitsdaten von COVID-19-Patienten auszutauschen, die während des Höhepunkts dieser Pandemie den Gesundheitsdienstleister wechselten oder sich von einem Mitgliedstaat in einen anderen begaben. 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 beizutragen.

(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).

Official Journal
of the European Union

EN
L series

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 [illegible] of such electronic health data. Such timely access could potentially contribute, through efficient public health surveillance and monitoring, to more effective management of future pandemics, to a reduction of costs and to improving the response to health threats, and ultimately could help to save more lives. In 2020, the Commission urgently adapted its Clinical Patient Management System, established by Commission Implementing Decision (EU) 2019/1269 [4], 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.

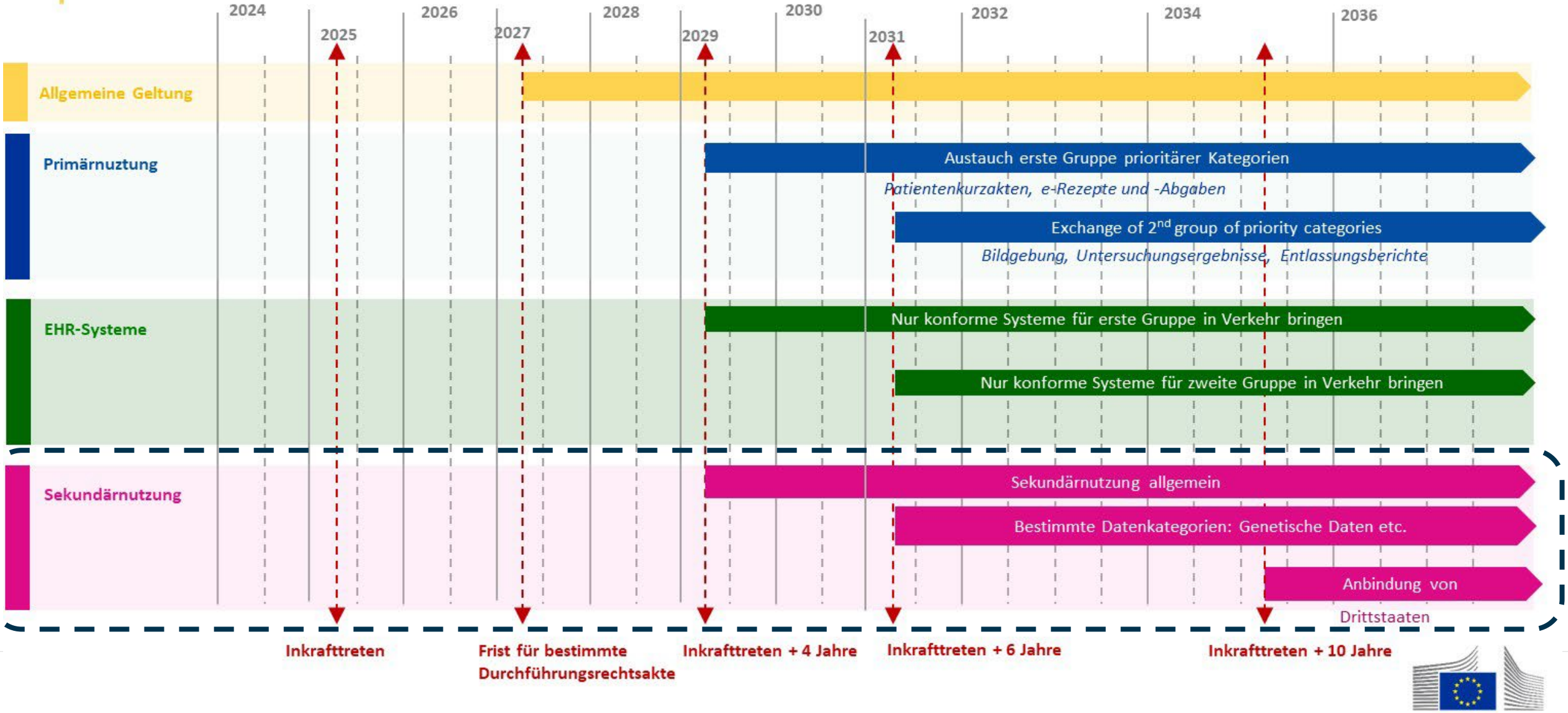
(3) The COVID-19 crisis strongly cemented the work of the eHealth Network, a voluntary network of authorities responsible for digital health, as the main pillar for the development of contact-tracing and contact-warning

[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).

Finale Fassung (05.03.2025 veröffentlicht) – deutsch / englisch:
https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=OJ:L_202500327&qid=1741704307107
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202500327&qid=1741704307107

https://health.ec.europa.eu/document/download/4dd47ec2-71dd-49fc-b036-ad7c14f6ed68_en?filename=ehealth_ehds_qa_en.pdf

EHDS – Inkrafttreten und Geltung



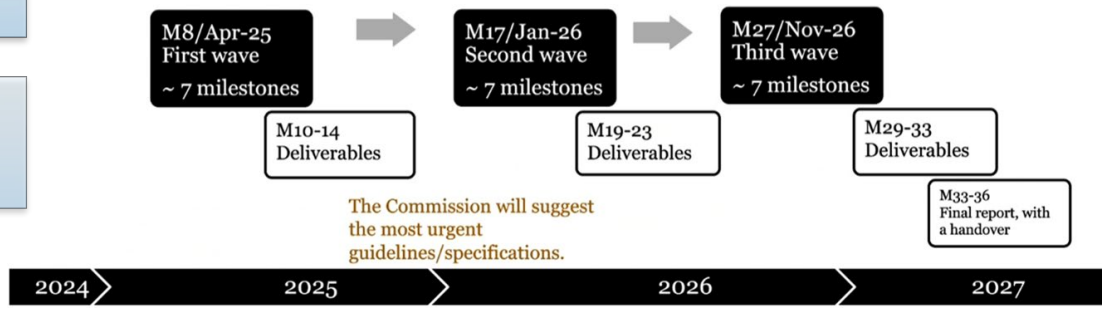
1. TEHDAS2 in a nutshell

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. 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

https://tehdas.eu/

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

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, *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. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on the procedures and formats for data access (6.3)**

3.1 Legal background

- EHDS articles 67-69 describe the requirements for Health Data Access Bodies (HDABs) for
  - assessing health data access applications (for individual-level data) and health data requests (for anonymised statistical data) and
  - issuing data permits and approvals
- Article 70 describes the requirement for the European Commission to adopt standardised templates for health data access applications, data permits and health data requests through implementing acts.
- Article 72 allows member states to designate certain health data holders as "trusted," provided they meet strict criteria
  - Applications or requests for data solely from these trusted holders follow a simplified process

→ **This guideline describes processes and templates needed to fulfill requirements in these articles**

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on the procedures and formats for data access (6.3)**

3.2 Summary of the document

- Focus on 3 distinct stages of the application/request lifecycle:

1. Completeness checks

- This step is not directly required in the EHDS
- However, only “complete” application shall be taken to processing
  - “Complete” application is not defined
  - Completeness aims for a minimum level of information provided in the application that enables assessment

- No assessment of response/attachment quality or scientific value at this stage
- Guideline includes concrete points to be checked and examples
  - Checklists provided as optional additional tool to help in this step – separately for health data access application and health data request

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on the procedures and formats for data access (6.3)**

Publishing applications

- EHDS regulation requires that HDABs publish all applications and requests without undue delay after initial reception [article 57(1)(j)(ii)]
  - This should occur as soon as possible after the application is received, even if it is later found to be incomplete and requiring amendments.
  - → This means that the publication takes place prior to the completeness check
  - Updated versions or changes to the application introduced later during the completeness check and assessment phases can be published as updates to the same entry
  - → **Purpose is to provide transparency**
  - → **However, applications can include confidential information – question related to this included in the unresolved section**

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on the procedures and formats for data access (6.3)**

2. Assessment and evaluation of the applications / requests

- Thorough review and assessment of the application/request
- Guideline includes clear and concrete instructions in the format of “What to check” boxes, organised by sections of the application forms

- In addition, the following topics are discussed:
  - Simplified process with trusted health data holders
  - Contacting data holders during the assessment
  - Fee estimation
  - Issuing permit / approving a request or refusal
  - Specific points related to cross-border and multi-country cases

- It should be borne in mind that there may be additional national requirements on top of the EHDS requirements

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on the procedures and formats for data access (6.3)**

3. Steps after the decision

- Extraction requests for health data holders
- Data preparation, sharing and the secure processing environment (SPE)
- Monitoring activities
- Documentation
- Revocation of permits/approvals
- Appeal process
- Amendments to permits
- Publication of results and outputs
- Publishing information on decisions

→ Descriptions on these actions are kept quite short, as majority of them are in the scope of other TEHDAS2 documents → the relevant document is referred to

Annexes

→ not an exhaustive list, but incl. those with substance contents regarding the guideline scope

- Common templates for data access application and data request
  - These are based on the HealthData@EU central platform Release 4 version
  - Can be also accessed and reviewed at the central platform: https://acceptance.data.health.europa.eu/
    - Release 5 to be published in late September – stay tuned!

- Checklists for completeness check: separately for data access application and data request
- Data permit template
- Data request approval template
- Key recommendations for electronic contractual arrangements

3. Presenting today's document: **Draft guideline for Health Data Access Bodies on the procedures and formats for data access (6.3)**

3.3 Critical points – Part B questions for public consultation 1/3

1. What perspective best describes *your* role in the implementation of EHDS? Please choose one.

The perspective of a data user / The perspective of a data holder / The perspective of a HDAB / None of the above

Chapter 5 describes the application completeness check phase. This is recommended to ensure that an application is complete before entering the actual application assessment process.

2. Were the points to be checked presented clearly? Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand).

3. Do you consider the checklists for data access application and data request completeness check (annexes 7 ja 8) helpful in performing the completeness check? Please rate from 1 (not helpful) to 4 (very helpful).

4. Do you have suggestions for improving section 5? Was something missing or was something unnecessary? [Please provide feedback, max. 5000 characters].

Chapter 6 describes the application assessment process that begins after the application has been deemed complete in the completeness check phase. The application contents are reviewed, and it is evaluated whether a data permit can be granted, or a data request approved.

5. Were the different aspects to be reviewed presented clearly? Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand).

6. Were the *What to check* points helpful and concrete? Please rate from 1 (not helpful nor concrete) to 4 (very helpful and concrete).

7. Do you have suggestions for improving section 6? Was something missing or was something unnecessary? [Please provide feedback, max. 5000 characters].

8. Was the distinction between the completeness check phase and the application assessment phase clearly presented? Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand).

9. Would the distinction need to be clarified further? If yes, please provide suggestions. [Please provide feedback, max. 5000 characters].

10. Was the distinction between assessing data access applications and data requests clear? Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand).

11. Would the distinction need to be clarified further? If yes, please provide suggestions. [Please provide feedback, max. 5000 characters].

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on the procedures and formats for data access (6.3)**

3.3 Critical points – Part B questions for public consultation /3

Chapter 7 describes the steps after the decision and the actions the HDABs need to take. Many of the topics are described in detail in other TEHDAS2 guidelines.

12. Were the responsibilities and actions to be taken after the decision presented clearly and on a sufficient level? Please rate from 1 (neither clear nor on sufficient level) to 4 (very clear and on sufficient level).

13. Do you have suggestions for improving section 7? Was something missing or was something unnecessary? [Please provide feedback, max. 5000 characters].

Open questions and unresolved issues of Chapter 9.

14. Should the full applications, data permits and data request approvals be published in the transparency portal or only certain information from these?

If the full documents should be published, sensitive information related to e.g. the persons entitled to process the data, the detailed description of the granted data sets or other sensitive information might need to be transferred to a non-public annex or similar. The HDAB must justify all omissions.

15. EHDS Article 68(2) states that the HDAB shall take into account (a) risks for national defence, security, public security and public order and (b) the risk of undermining the confidentiality of data in governmental databases of regulatory authorities.

What specific points should be considered when assessing the aforementioned risks? On what level these should be assessed? [Please provide feedback, max. 5000 characters].

16. EHDS states that if a data permit needs to be amended, the health data user shall submit an amendment request. Further, EHDS separately mentions two topics that an amendment can concern: extending the data permit validity period once or modifying the authorised persons with access rights to the electronic health data in a secure processing environment.

Do you foresee some other points in the data permit that should be allowed to be subject to amendment requests? What kind of implications this would have in your member state? Potential options could include e.g. transferring the data to another secure operating environment, extracting additional variables from the datasets included in the original permit, and extending the period from which the data are extracted (i.e. extracting more data from the datasets included in the original permit). The original datasets and purpose of use should be maintained. [Please provide feedback, max. 5000 characters].

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on the procedures and formats for data access (6.3)**

3.3 Critical points – Part B questions for public consultation 3/3

Annexes 5-6 of this deliverable are templates for the common European data access application and data request, respectively, to be utilised when applying for data under the EHDS both through the HealthData@EU central platform and national HDABs.

17. Was annex 5 (the data access application template) clear and easy to understand? Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand).

18. Do you have any feedback related to annex 5 (the data access application template)? Please elaborate. [Please provide feedback, max. 5000 characters].

19. Was annex 6 (the data request template) clear and easy to understand? Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand).

20. Do you have any feedback related to annex 6 (the data request template)? Please elaborate. [Please provide feedback, max. 5000 characters].

Annexes 9-10 of this deliverable are templates for the data permit and data request approval, to be utilised by the HDABs or the European Commission when granting access to data.

21. Was annex 9 (the data permit template) clear and easy to understand? Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand).

22. Do you have any feedback related to annex 9 (the data permit template)? Please elaborate. [Please provide feedback, max. 5000 characters].

23. Was annex 10 (the data request approval template) clear and easy to understand? Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand).

24. Do you have any feedback related to annex 10 (the data request approval template)? Please elaborate. [Please provide feedback, max. 5000 characters].

Annex 11 describes the key recommendations for electronic contractual arrangements that may be used by health data holders and health data users for the sharing of data containing information or content protected by intellectual property rights or trade secrets.

25. Was annex 11 (the key recommendations for electronic contractual arrangements) clear and easy to understand? Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand).

26. Do you have any feedback related to annex 11 (the key recommendations for electronic contractual arrangements)? Please elaborate. [Please provide feedback, max. 5000 characters].

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on the procedures and formats for data access (6.3)**

3.4 Who should comment?

- Target audience for this guideline are:
  - **HDAB personnel** (or those going to be ones)
    - → Information on what is expected of you and what needs to be taken into account when assessing applications
  - **Health data applicants** (e.g. researchers, public authorities)
    - → Clarifying how different aspects of the applications are assessed and what to expect from the HDAB review process
  - **Health data holders and trusted health data holders**
    - → Clarifying their role during the application assessment process
  - **Public sector institutions and EU bodies**
    - → Support and clarifying their dual role as potential health data applicants or health data holders under the EHDS framework.

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
Sep 17th, 2025	7.2: Draft guideline for Health Data Access Bodies on data **minimisation, pseudonymisation, anonymisation and synthetic data**
Sep 18th, 2025	6.1: Draft guideline for data holders on **making personal and non-personal electronic health data available for reuse**
Sep 24th, 2025	6.3: Draft guideline for Health Data Access Bodies on the **procedures and formats for data access**
Sep 25th, 2025	6.4: Draft Data Access **Application Management System (DAAMS)** – Draft technical specification for health data access bodies
Sep 26th, 2025	7.3: Draft technical specification for Health Data Access Bodies on the **implementation of the common IT infrastructure**
Sep 29th, 2025	7.4: Draft technical specification for Health Data Access Bodies on the **implementation of secure processing environments**
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
Oct 1st, 2025	4.1: Draft guideline for Health Data Access Bodies on **fees and penalties for non-compliance** related to the EHDS regulation

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 Jutii (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)*

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

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