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 fees and penalties for non-compliance related to the EHDS regulation

Sebastian C. Semler, TMF e. V. &
Pia Brinkmann, Bundesinstitut für Arzneimittel und Medizinprodukte BfArM

October 1st, 2025 | 8 a.m. to 9 a.m.

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

Download guidelines for public consultations:
https://tehdas.eu/public-consultations/

Disclaimer Recording of the online workshop

This workshop will be recorded for internal purposes.

The recording is used exclusively for **internal quality assurance, evaluation, and further development** of our workshop offerings. It will not be published or passed on to third parties.

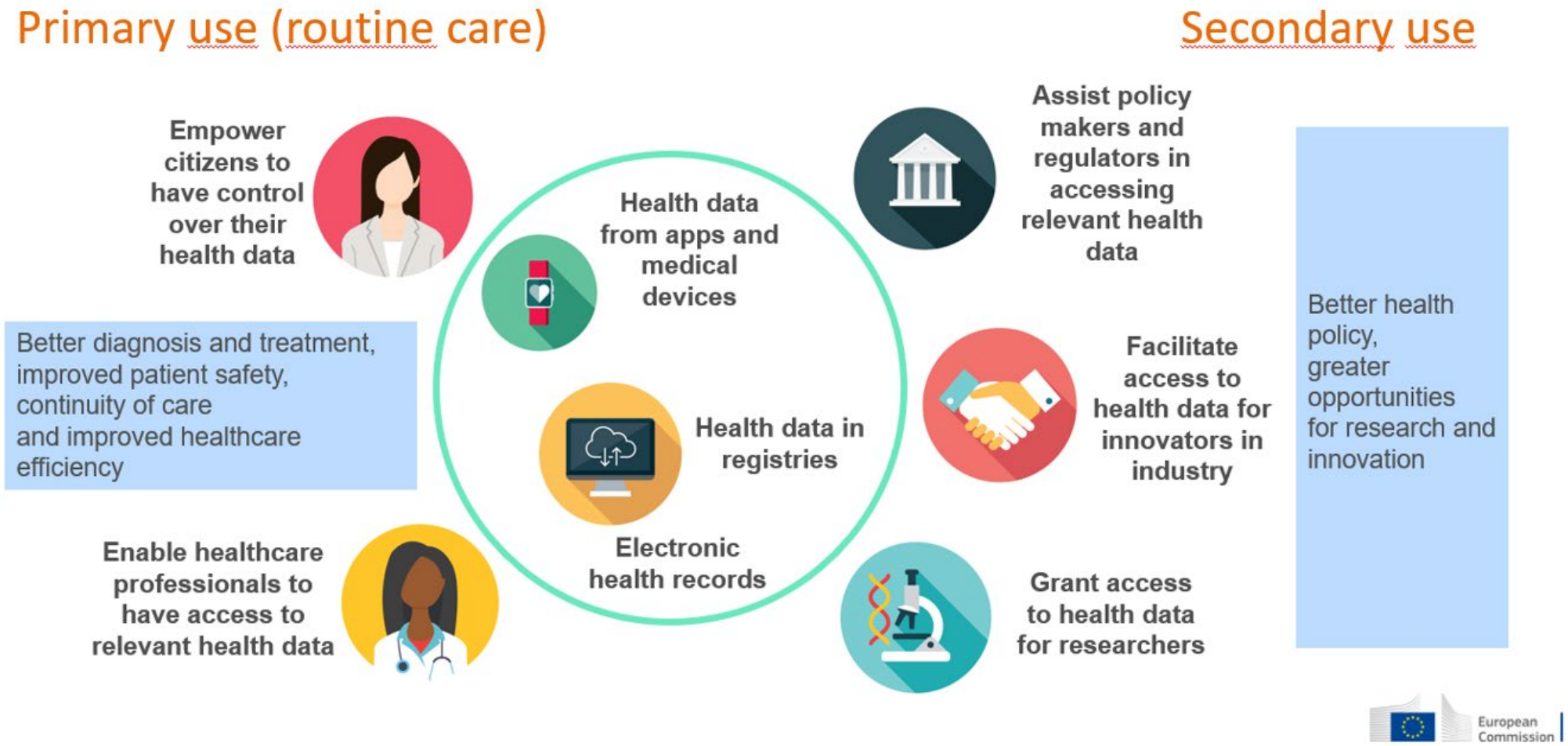
By participating, you consent to the recording.

Agenda

1. EHDS and TEHDAS2 in a nutshell
2. TEHDAS2 Documents for public consultation on September 30th, 2025
3. Presenting today‘s document:
   Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation
   - 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

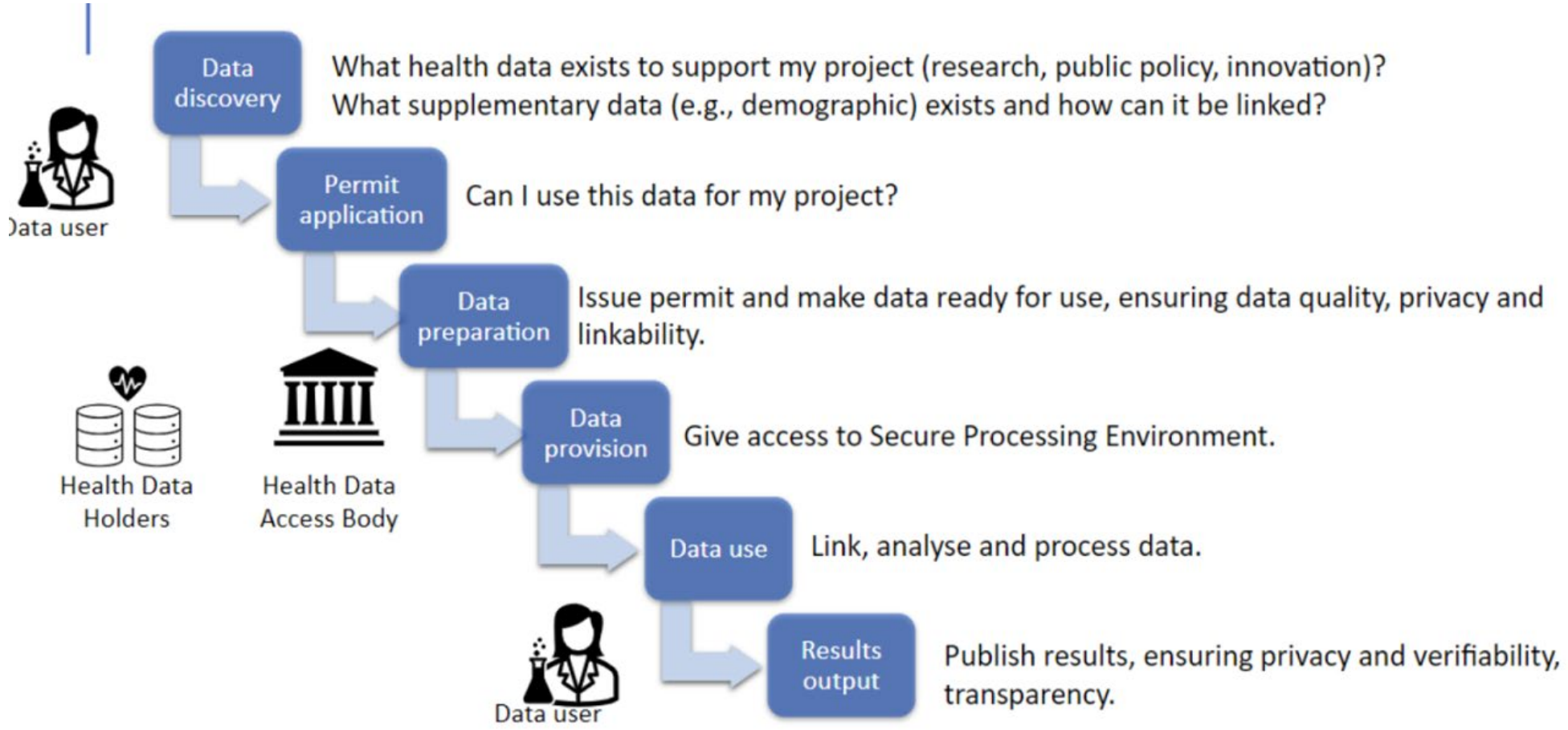
1. EHDS and TEHDAS2 in a nutshell

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

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.

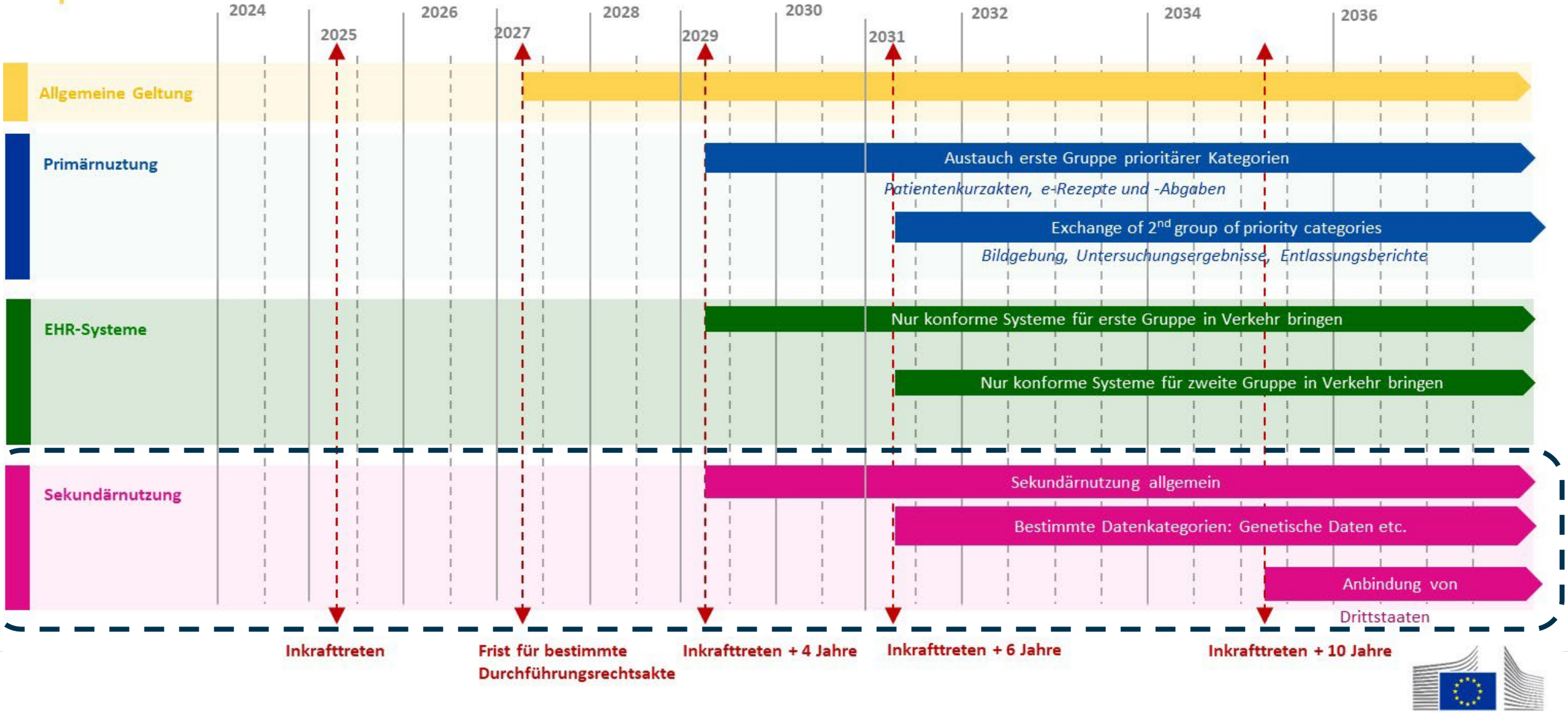
(3) The COVID-19 crisis strongly cemented the work of the eHealth Network, a voluntary network of authorities responsible for digital health, as the main pillar for the development of contact-tracing and contact-warning

[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



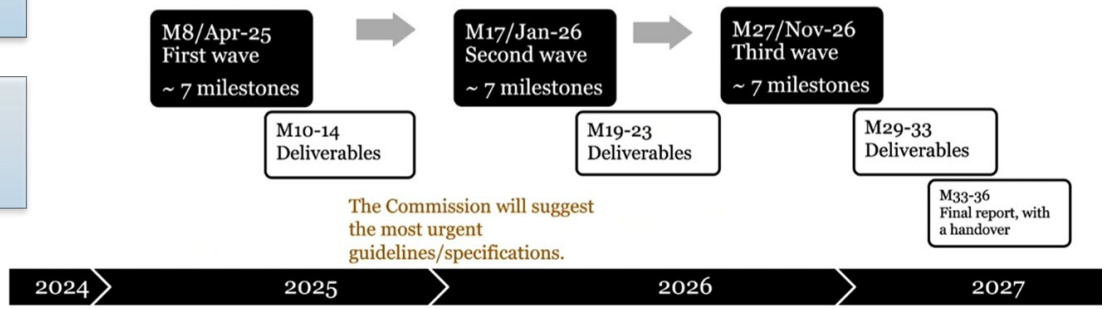
1. TEHDAS2 in a nutshell

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 fees and penalties for non-compliance related to the EHDS regulation (4.1)**

Part 1: Fees

Example → HDL in Germany

Gebührenverordnung

Die Datentransparenz-Gebührenverordnung (DaTraGebV) legt fest, welche Gebühren das FDZ Gesundheit erheben muss. Beispielhaft werden sie hier für den Demo-Antrag berechnet:

Position	DaTraGebV	Einzelposition	Anzahl	Gebühr	Erläuterung
Grundgebühr	§ 5	4.000,00€	1	4.000,00€	
Zusatzgebühr für Jahrgänge	§ 6 Abs. 2	1.000,00€	10	10.000,00€	Zehn Berichtsjahre (2009-2018)
Bereitstellung Daten in gesicherter virtueller Umgebung	§ 6 Abs. 3 1000 € pro Tag	1.000,00€	8	8.000,00€	Allgemein gibt es kein Limit bei der Anzahl der Tage im Analyseraum (außer bei pEDs). Für das Beispiel hier wurde eine Fertigstellung des Skripts nach 8 Tagen angenommen.
Erstellung von Zwischenergebnissen	§ 7	109,00€	1	109,00€	Einmal wurden Zwischenergebnisse angefordert, um die Sinnhaftigkeit der Ergebnisse zu prüfen.
Zwischensumme				**22.109,00€**	
Rechnungsbetrag nach Gebührenermäßigung auf ein Zehntel	§11 Abs. 3 u. 4	Ermäßigung wurde beantragt und bewilligt		**2.210,90€**	Das RKI ist eine Institution der Gesundheitsberichterstattung des Bundes und ist für eine Gebührenermäßigung berechtigt. Dies gilt u.a. auch für Hochschulen und Hochschulkliniken. Liste der berechtigten Institutionen unter §11 DaTraGebV Abs. 3 (Link)

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation (4.1)**

Part 1: Fees

EHDS Article 62

Summary of Article 62:

- **(1) HDABs/Union health data services/Trusted data holders may charge fees.**
  - **Cover: assessing, issuing, refusing, amending, consolidation, preparation, pseudonyisation, provision, reduced fees**
- **(2) DH shall be reimbursed for compiling and preparation of data**
- **(3) fees shall be transparent and non-discriminatory**
- **(4) disgreement for DH and DU – HDAB sets proportionate fees**
- **(5) DU shall be informed about the fee and the conditions of withdrawal**
- **(6) Fee policies will be an implementing act.**

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation (4.1)**

Part 1: Fees

Disclaimer: This guidance is non-binding and may be updated as further implementing acts and delegated acts are adopted by the European Commission or guidelines by the EHDS Board.

Content:

- Which costs can be included in the fees (and which are excluded),
- To whom the fees should be paid, and
- When the fees should be paid by the data user.

Goal: The objective is to promote consistent financial practices across Member States in line with the principles of transparency, non-discrimination and competition neutrality set out in the EHDS regulation.

Target audience: HDABs, TDHs and DHs

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation (4.1)**

Part 1: Fees

Excluded costs:

- Data collection and processing realised for medical purposes
- Data discovery phase
- Information on significant findings

Included costs:

- 1) Receipt of a Data Access Application/ Data Request
- 2) Data permit/Data request approval
- 3) Data preparation for the request
- 4) Provision of the data
- 5) Use of the data

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation (4.1)**

Part 1: Fees

1) Receipt of a Data Access Application/ Data Request

Included costs → HDAB:

- the management of the application (application check process),
- the running and updating of the public information system,
- the regulatory feasibility,
- the assessment of the datasets to be requested to DHs
- the preparation of the quote to respond to the request.
- related administrative overheads directly linked to the request (see Annex 3 for the list of proposed overheads)

Included costs → DH:

- the examination of the protocol and feasibility study to assess the capacity to provide the requested data based on the protocol
- the preparation of the quote to respond to the request.
- related administrative overheads directly linked to the request

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation (4.1)**

Part 1: Fees

2) Data permit/Data request approval

- the assessment of the application against the criteria in EHDS (Article 68.1), including the ethical evaluation where required (Article 68.1.f)
- the risk mitigation analysis for IP and trade secrets (Article 52),
- Etc.

3) Data preparation for the request

- Database constitution and data collection upon request
- Strategy-dependent costs

4) Provision of the data (note: Data request vs data permit)

- project monitoring
- data quality, linkage and consolidation
- pseudonymisation or anonymisation
- data treatment to preserve protection of intellectual property and trade secrets
- Etc.

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation (4.1)**

Part 1: Fees

5) Use of the data

- project closure, activities, including final reporting, data archiving, and controlled data destruction
- long-term storage of metadata or audit logs, where required under national law

To whom the fees are paid:

- Scenario 1) Centralised model (recommended)
- Scenario 2) Decentralised model
- Scenario 3) Hybrid model

3. Presenting today's document: **Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation (4.1)**

Part 1: Fees

Data application/ data request/ both	Eligible to be considered for fees?	TOPICS CATEGORY	Marginal/ Fixed	TOPICS	ACTIVITY	Task related to cost	Type of costs	HDAB	TDH	DH
Both	NO	Data discovery	Fixed	National Metadata catalogue	Quality and utility label	Implement provisions on data quality and utility label	HR			X
Both	NO	Data discovery	Fixed	National Metadata catalogue	Quality and utility label	Supervise DH to ensure implementation of the provisions on data quality a	HR	X		
Both	NO	Data discovery	Fixed	National Metadata catalogue	Implementation	Produce of database documentation	HR			X
Both	YES	Data discovery	Fixed	National Metadata catalogue	Implementation	Database update due to project-specific requirements	HR			X
Both	NO	Data discovery	Fixed	National Metadata catalogue	Administrative overheads	Communicate to HDAB a description of the database	HR			X
Both	NO	Data discovery	Fixed	National Metadata catalogue	Database accuracy	Check accuracy of database in the national dataset catalogue on annual ba	HR			X
Both	NO	Data discovery	Fixed	National Metadata catalogue	Implementation	Make and maintain a national dataset catalogue (internet site)	HR	X		
Both	NO	Data discovery	Fixed	National Metadata catalogue	Implementation	Develop tools to consolidate catalogs from DH	HR	X		
Both	NO	Data discovery	Fixed	National Metadata catalogue	Implementation	Integrate data and update in national catalogue	HR	X		
Both	NO	Data discovery	Fixed	National Metadata catalogue	Implementation	Server sizing and security costs	Infrastructure	X		
Both	NO	Data discovery	Fixed	European Metadata catalogue	Implementation	Synchronize at european level	HR	X		
Both	YES	Submission of Data Access application/request	marginal	Application/request management	Examination of the data application/re	Receive and analyse the file (details in M6.3)	HR	X		
Both	YES	Submission of Data Access application/request	marginal	Application/request management	Public information	Make publicaly available data application and request	HR	X		
Both	YES	Submission of Data Access application/request	Fixed	Application/request management	Public information	Run a management system to record and process health data access applic	Infrastructure	X		
Both	YES	Submission of Data Access application/request	marginal	Application/request management	Examination of the data application/re	Assessment of the datasets to be requested to data holders	HR	X		
Both	YES	Submission of Data Access application/request	marginal	Application/request management	Administrative overheads	Transmit the file to concerned data holders	HR	X		
Both	YES	Submission of Data Access application/request	marginal	Application/request management	Administrative overheads	Coordinate between HDAB at EU and national level	HR	X		
Both	YES	Submission of Data Access application/request	marginal	Project feasibility	Examination of the data application/re	Validate method and protocol	HR			X
Both	YES	Submission of Data Access application/request	marginal	Project feasibility	Feasibility study	Validate regulatory feasibility	HR	X		
Both	YES	Submission of Data Access application/request	marginal	Project feasibility	Feasibility study	Perform feasability study	HR			X
Both	YES	Submission of Data Access application/request	marginal	Fee estimate	Quoting	Draft the quote	HR	X		X
Both	YES	Submission of Data Access application/request	marginal	Fee estimate	Administrative overheads	Transmit the quote to HDAB	HR			X
Both	YES	Submission of Data Access application/request	marginal	Fee estimate	Administrative overheads	Compile and transmit the quote to data user	HR	X		
Data application	YES	Data permit/Data request approval	marginal	Data permit assessment	Permit management	Assess data application	HR	X	X	
Data application	YES	Data permit/Data request approval	marginal	Ethical assessment	Submission to ethical committee	Prepare file for ethical committee	HR	X		
Data application	YES	Data permit/Data request approval	marginal	Ethical assessment	Submission to ethical committee	Ethical committee assessment costs	HR	X		
Data application	YES	Data permit/Data request approval	marginal	Data permit	Permit management	Grant (or refuse) permit and justify	HR	X		
Data application	YES	Data permit/Data request approval	marginal	Data permit	Permit publication	Make publicaly available granted permit and refusal	HR	X		
Data request	YES	Data permit/Data request approval	marginal	Data request approval	Data request management	Assess data request (details in M6.3)	HR	X	X	
Data request	YES	Data permit/Data request approval	marginal	Data request approval	Data request management	Approve (or refuse) data request and justify	HR	X		
Data request	YES	Data permit/Data request approval	marginal	Data request approval	Data request publication	Make publicaly available data request approval/refusal	HR	X		
Both	YES	Data permit/Data request approval	marginal	Data request approval	Risk mitigation	Analyse risks for IP rights and trade secrets	HR	X		X
Both	YES	Data permit/Data request approval	marginal	Data request approval	Risk mitigation	Analyse risk for data protection GDPR	HR	X		
Both	YES	Data permit/Data request approval	marginal	Data request approval	Risk mitigation	Analyse risks for national defence, security, public security and public order	HR	X		
Both	YES	Data permit/Data request approval	marginal	Contracting	Contracting management	Prepare contract and signature	HR	X	X	
Both	YES	Database constitution, infrastructure and quality	Fixed	Compiling	Data extraction	Perform data collection to feed datawarehouse for secondary use	HR			X
Both	YES	Database constitution, infrastructure and quality	Fixed	Compiling	Data extraction	Create of new data pipeline for datawarehouse	HR			X
Both	YES	Database constitution, infrastructure and quality	Fixed	Compiling	Data quality	Monitor data (quality control on data collection)	HR			X
Both	YES	Database constitution, infrastructure and quality	Fixed	Compiling	Data quality	Align terminology (protocol + mapping)	HR			X
Both	YES	Database constitution, infrastructure and quality	Fixed	Compiling	Data quality	improve data quality (accuracy, completeness, format,...)	HR			X
Both	YES	Database constitution, infrastructure and quality	Fixed	Compiling	Data linkage	Perform internal data linkage	HR			X
Both	YES	Database constitution, infrastructure and quality	Fixed	Compiling	Infrastructure	Depreciation cost of investment for secondary use infrastructure	Infrastructure			X
Both	YES	Database constitution, infrastructure and quality	Fixed	Compiling	Data storage	Disk space and infrastructure costs (running+maintaining+update)	Infrastructure			X
Both	YES	Database constitution, infrastructure and quality	Fixed	Regulatory obligation	Patient information	Drafting and validation of patient information	HR			X
Both	YES	Database constitution, infrastructure and quality	Fixed	Regulatory obligation	Patient information	Dissemination of patient information	HR			X
Both	YES	Database constitution, infrastructure and quality	Fixed	Regulatory obligation	Patient information	Maintain a public information system to comply regulatory obligations	HR	X		
Both	YES	Database constitution, infrastructure and quality	Fixed	Regulatory obligation	Patient information	Run a public information system to comply regulatory obligations	Infrastructure	X		
Both	YES	Data preparation for the request	marginal	Regulatory obligation	Patient information	Draft and validate of patient information	HR			X
Both	YES	Data preparation for the request	marginal	Regulatory obligation	Patient information	Disseminate patient information	HR			X
Both	YES	Data preparation for the request	marginal	Data preparation DH	Data preparation follow up	Monitor project	HR			X
Both	YES	Data preparation for the request	marginal	Data preparation DH	Data selection	Check inclusion/exclusion criteria	HR			X
Both	YES	Data preparation for the request	marginal	Data preparation DH	Data extraction	Develop file/data extraction protocole	HR			X
Both	YES	Data preparation for the request	marginal	Data preparation DH	Data extraction	Extract file/data	HR			X
Both	YES	Data preparation for the request	marginal	Data preparation DH	Data treatment and consolidation	Perform pseudonymisation/ anonymisation	HR			X
Both	YES	Data preparation for the request	marginal	Data preparation DH	Data treatment and consolidation	Data minimisation	HR			X
Both	YES	Data preparation for the request	marginal	Data preparation DH	Data treatment and consolidation	Consolidate table	HR			X
Both	YES	Data preparation for the request	marginal	Data preparation DH	Data storage	Storage and computing resources preparation space	Infrastructure			X
Both	YES	Data preparation for the request	marginal	Data preparation DH	Data transmission	Export data to HDAB	HR			X
Both	YES	Provision of the data	marginal	Data preparation in SPE	Project space preparation	Monitor project	HR	X	X	
Both	YES	Provision of the data	marginal	Data preparation in SPE	Data transmission	Receive data and perform quality control	HR	X	X	
Both	YES	Provision of the data	marginal	Data preparation in SPE	Data quality	Align terminology (protocole + mapping)	HR	X	X	
Both	YES	Provision of the data	marginal	Data preparation in SPE	Data linkage	Define linkage strategy and implement	HR	X	X	
Both	YES	Provision of the data	marginal	Data preparation in SPE	Data linkage	Make linkage report	HR	X	X	
Data Application	YES	Provision of the data	marginal	Data preparation in SPE	Data treatment and consolidation	Perform pseudonymisation/ anonymisation	HR	X	X	
Both	YES	Provision of the data	marginal	Data preparation in SPE	Data treatment and consolidation	Take measures necessary to preserve the confidentiality of intellectual proj	HR	X	X	
Both	YES	Provision of the data	marginal	Data preparation in SPE	Dataset validation	Validate data set	HR	X	X	
Both	YES	Provision of the data	marginal	Data preparation in SPE	Run	Storage and computing resources preparation space	Infrastructure	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	Project space preparation follow up	Monitor project	HR	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	Project space preparation	Prepare project space SPE	HR	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	Project space preparation	Adapt existing tools/create new tools for project space	HR	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	Project space preparation	Validate project space	HR	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	Project space preparation	Licence for tool provision in project space	Licences	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	Project space preparation	Additional services from SPE providers and environment updates	HR	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	Project space preparation	Approve project space on security level	HR	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	Project space preparation	Approve data environment in project space SPE	HR	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	Project space preparation	Data export from preparation space to project space	HR	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	Project space preparation	Project space access	Infrastructure	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	SPE access	Project and analysis space provision (user training and support)	HR	X	X	
Data application	YES	Provision of the data	marginal	Project environment SPE	SPE access	Initial disk space in project space	Infrastructure	X	X	
Data request	YES	Provision of the data	marginal	Data request implementation	Data aggregation	Prepare and validate analysis plan	HR	X	X	
Data request	YES	Provision of the data	marginal	Data request implementation	Data aggregation	Develop analysis method	HR	X	X	
Data request	YES	Provision of the data	marginal	Data request implementation	Data aggregation	Generate aggregated statistical report	HR	X	X	
Data request	YES	Provision of the data	marginal	Data request implementation	Data aggregation	CPU for aggregation	Infrastructure	X	X	
Both	YES	Provision of the data	marginal	Invoice	Administrative overheads	Consolidate fee from contributors and send invoice	HR	X		
Both	YES	Provision of the data	marginal	Invoice	Administrative overheads	Reception of fees and redistribution to contributors	HR	X		
Both	YES	Use of the data	marginal	Regulatory obligation	Patient information	Maintain an information system to make public the results or output of sec	HR	X		
Both	YES	Use of the data	Fixed	Regulatory obligation	Patient information	Run an information system to make public the results or output of seconda	Infrastructure	X		
Data application	YES	Use of the data	marginal	Project running	Computation capacity	Computing resources in project space	Infrastructure	X	X	
Data application	YES	Use of the data	marginal	Project running	Disk space capacity	Disk space in project space	Infrastructure	X	X	
Data application	YES	Use of the data	marginal	Project running	Project extension	Infrastructure costs related to an extension of the data permit	Infrastructure	X	X	
Data application	YES	Use of the data	marginal	Project running	Project extension	HR costs related to an extension of the data permit	HR	X	X	
Both	YES	Use of the data	marginal	Project Closure	Project closure and archiving	Monitor project closure and database archiving	HR	X	X	
Both	YES	Use of the data	marginal	Project Closure	Project closure and archiving	Provide technical support for project closure and database archiving	HR	X	X	
Both	YES	Use of the data	marginal	Project Closure	Project closure and archiving	Perform all task for data archiving	HR	X	X	
Both	YES	Use of the data	marginal	Project Closure	Project closure and archiving	Data storage and archiving	Infrastructure	X	X	
Both	YES	Use of the data	marginal	Project Closure	Project closure and archiving	Close the project space	HR	X	X	
Both	YES	Use of the data	marginal	Project Closure	Project closure and archiving	Perform data destruction	HR	X	X	
Both	YES		Fixed	Overhead		Administration		X		X
Both	YES		Fixed	Overhead		Electricty bill		X		
Both	YES		Fixed	Overhead		Location costs		X		
Both	YES		Fixed	Overhead		Employer's social insurance contributions		X		
Both	YES		Fixed	Overhead		Equipment (PC, Telephone,...)		X		
Both	YES		Fixed	Overhead		Infrastructure		X		
Both	YES		Fixed	Overhead		Back office activities		X		

3. Presenting today‘s document: **Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation (4.1)**

Part 2: Penalties

EHDS Articles 63 & 64

- **Target audience:** HDABs
- **HDABs supervisory powers (Article 63):**
  - Investigative and monitoring mandate
  - Notification obligations and the right to be heard
  - Enforcement measures against data users: revocation, suspension and exclusion
  - Enforcement measures against DH
  - Communication of enforcement measures and compliance deadlines
  - Notification and transparency of enforcement measures through the HealthData@EU infrastructure
- **Implementing act** → principles for the fee policies and fee structures (Article 62(6). EHDS)

3.4 Who should comment?

HDABs
TDHs
DHs
Everyone interested….

4. Q&A

5. Overview 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

Contact

TMF e. V.
Charlottenstraße 42/Dorotheenstraße
10117 Berlin

www.tmf-ev.de | @TMF_eV

Dr. Pia Brinkmann
+49 228 99 307 4499 | pia.brinkmann@bfarm.de

Dr. Anna Niemeyer
+49 30 22 00 24 764 | anna.niemeyer@tmf-ev.de

Irene Schlünder
+49 30 22 00 24 742 | irene.schluender@tmf-ev.de