

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

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

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

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

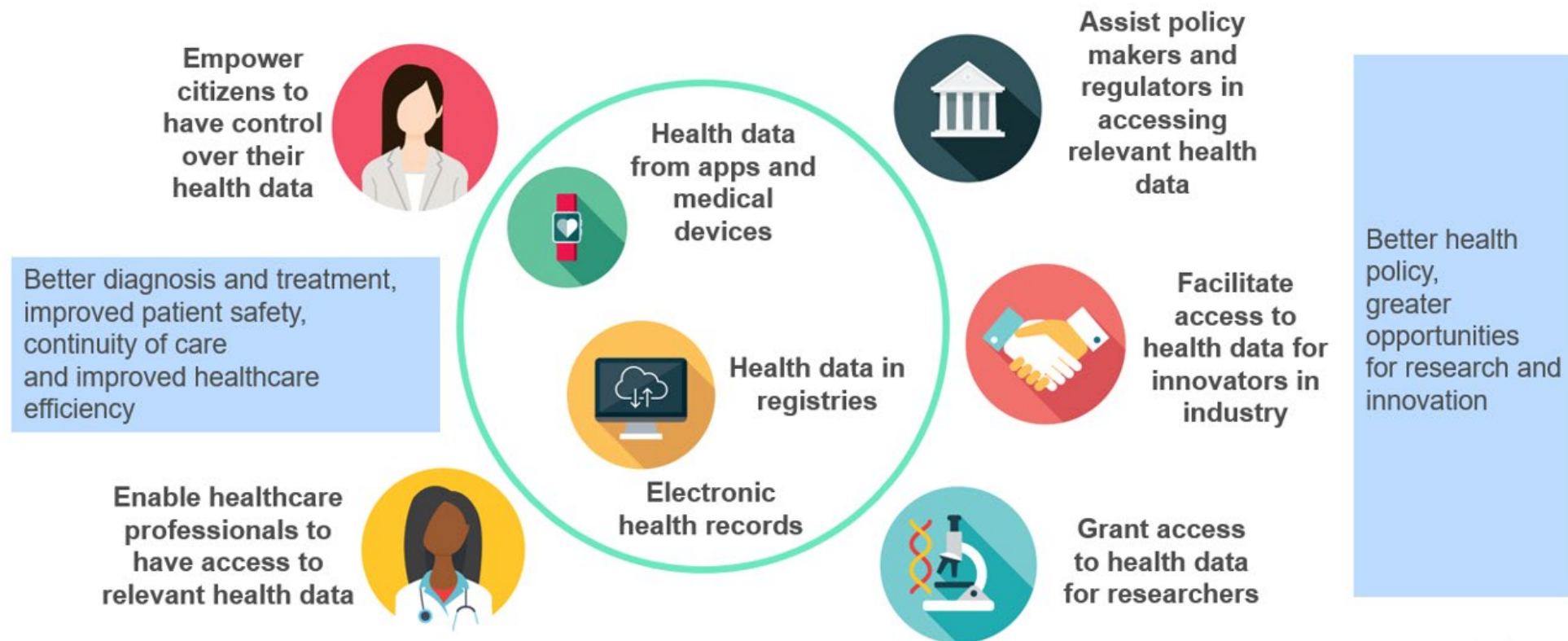
1. EHDS and TEHDAS2 in a nutshell
2. TEHDAS2 Documents for public consultation on September 30th, 2025
3. Presenting today's document:
Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data
 - 3.1 Legal background
 - 3.2 Summary of the document
 - 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

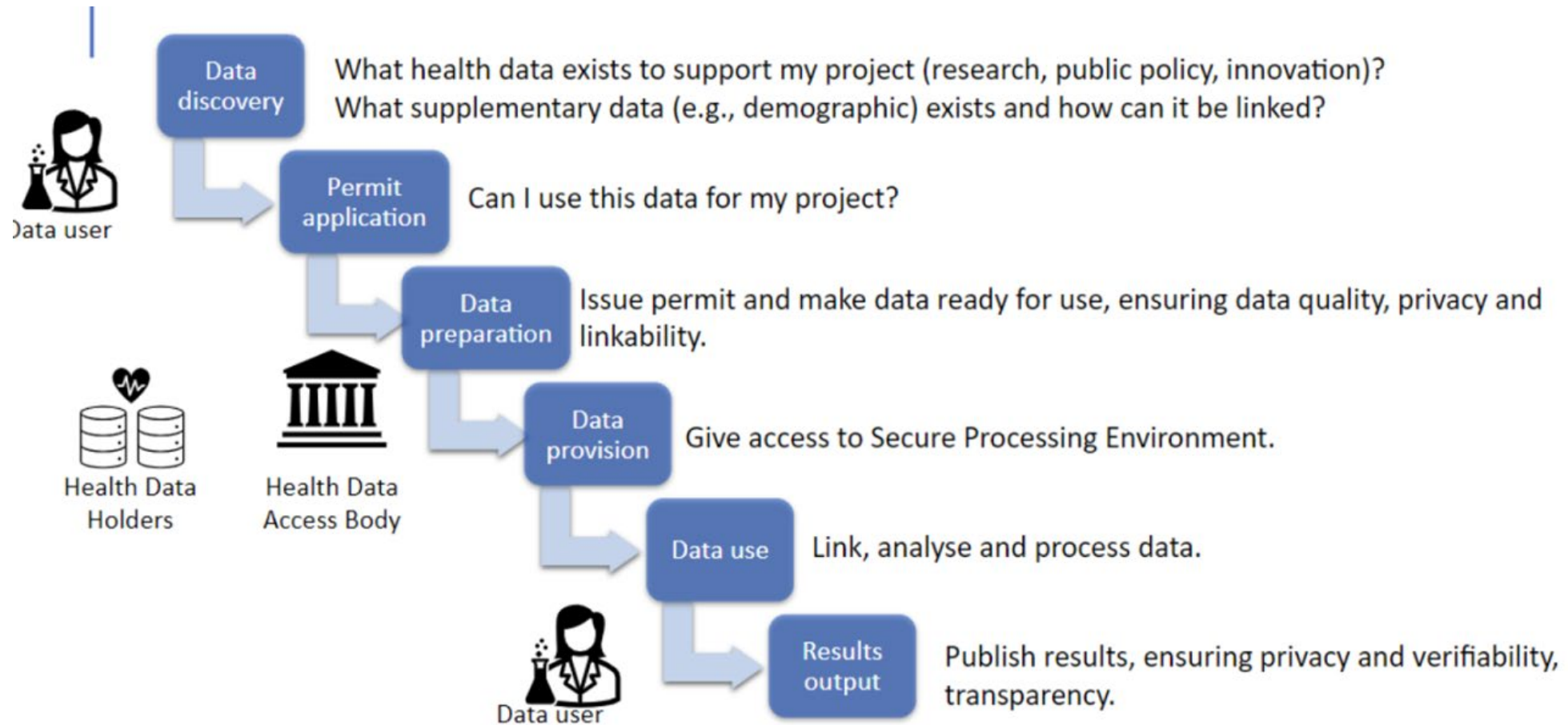
Primary use (routine care)

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



European
Union

EUR-Lex

Access to European Union law

<https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX%3A32025R0327&qid=1741704307107>



My EUR-Lex



English



Experimental features



EUROPA > EUR-Lex home > Verordnung - EU - 2025/327 - EN - EUR-Lex

Help

Print

Share

MENU

QUICK SEARCH



Search tips

Need more search options? Use the [Advanced search](#)

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)

In force

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

Expand all Collapse all

Languages, formats and authentic version

	BG	ES	CS	DA	DE	ET	EL	EN	FR	GA	HR	IT	LV	LT	HU	MT	NL	PL	PT	RO	SK	SL	FI	SV
HTML																								
PDF - authentic OJ																								
e-signature																								

How to verify the authenticity of the Official Journal

Multilingual display

English (en) ▾

Please choose ▾

Please choose ▾

Display

Text

Text

Document information

Procedure

Up-to-date link

Permanent link

Download notice

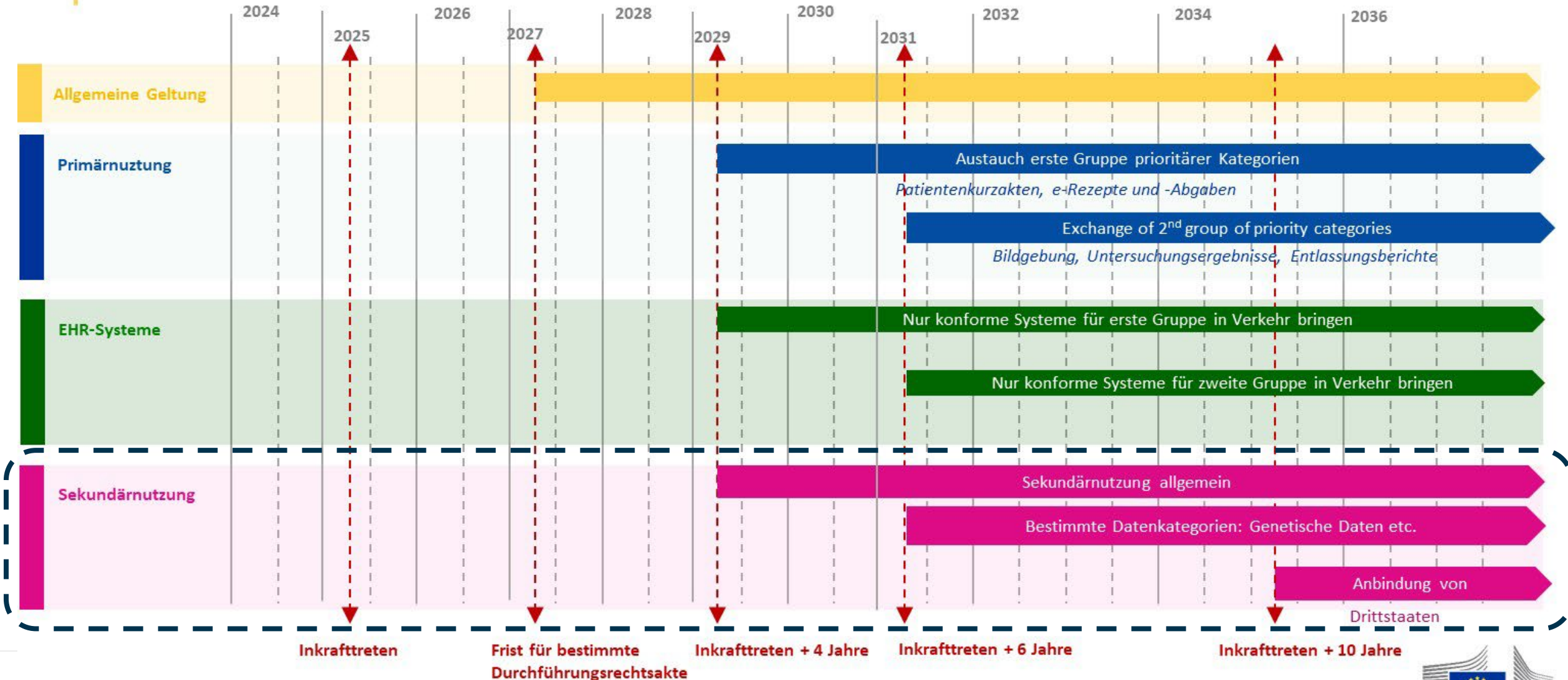
Save to My items

Create an email alert

Create an RSS alert

Table of contents

EHDS – Inkrafttreten und Geltung



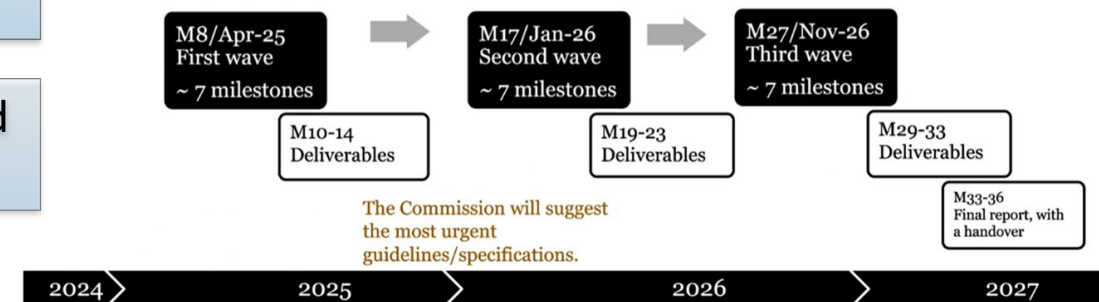
1. TEHDAS2 in a nutshell

TEHDAS2 in a nutshell

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

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

- ▶ TEHDAS2 bereitet die Durchsetzungsrechtsakte der EU zum EHDS II durch **Guidelines** vor.
- ▶ (Für EHDS I entsprechend: xt-EHR)
- ▶ in 3 „Wellen“ (1. bereits erfolgt)
- ▶ Die Guidelines werden vor Verabschiedung und Annahme durch die EU öffentlich zur Kommentierung gestellt. Beginn: 30. Sept. 2025 (2 Monate)



2. TEHDAS2 Guidelines



Upcoming public consultations

SEP-OCT 2025

TOPIC: Processes to manage permits or data pseudonymisation

Documents scheduled for public consultation(Click to view)

1. Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance regulated to the EHDS regulation
2. Draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data
3. Draft guideline for data holders on making personal and non-personal electronic health data available for reuse
4. Draft guideline for Health Data Access Bodies on the procedures and formats for data access
5. Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies
6. Draft technical specification for Health Data Access Bodies on data minimisation and de-identification
7. Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure
8. Draft technical specification for Health Data Access Bodies on the implementation of secure processing environments
9. Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data
10. Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data

<https://tehdas.eu/>



MAY-JUN 2026

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

Documents scheduled for public consultation(Click to view)

1. Draft guideline for Health Data Access Bodies on collaboration with other parties
2. Draft guideline for Health Data Access Bodies on international and third country access and transfer of electronic health data
3. Draft guideline for Health Data Access Bodies on enrichment of health datasets
4. Draft guideline for Health Data Access Bodies on linkage of health datasets
5. Draft guideline for Health Data Access Bodies on informing natural persons about the use of health data – “Citizen Information Point”
6. Draft guideline for data users on handling research outcomes

2. TEHDAS2 Participate in the public consultations



TEHDAS2 develops guidelines and technical specifications to enable seamless secondary use of electronic health data across Europe under the European Health Data Space (EHDS).



→ The next wave of public consultations will be in **Sept-Oct 2025**

2. TEHDAS2 Documents for public consultation on September 30th, 2025



2nd Wave: Processes to manage permits or data pseudonymisation | SEP-OKT 2025

MS/D	Description
4.1	Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation
5.2	Draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data
6.1	Draft guideline for data holders on making personal and non-personal electronic health data available for reuse
6.3	Draft guideline for Health Data Access Bodies on the procedures and formats for data access
6.4	Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies
7.2	Guideline for Health Data Access Bodies on data minimisation, pseudonymisation, anonymisation and synthetic data
7.3	Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure
7.4	Draft technical specification for Health Data Access Bodies on the implementation of secure processing environments
8.1	Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data
8.1	Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data

2. TEHDAS2 Online-Workshop-Serie 15.09.-01.10.2025



Date	Workshop
Sep 15th, 2025	5.2 Draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data, <i>Dr. Anna Niemeyer (TMF e. V., Germany)</i>
Sep 16th, 2025	8.1.1: Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data, <i>Irene Schlünder (TMF e. V., Germany)</i>
Sep 17th, 2025	7.2: Draft guideline for Health Data Access Bodies on data minimisation, pseudonymisation, anonymisation and synthetic data, <i>Pia Brinkmann (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)</i>
Sep 18th, 2025	6.1: Draft guideline for data holders on making personal and non-personal electronic health data available for reuse, <i>Marije van Melle (Nictiz, Netherlands)</i>
Sep 24th, 2025	6.3: Draft guideline for Health Data Access Bodies on the procedures and formats for data access, <i>Rosa Juuti (Findata, Finland)</i>
Sep 25th, 2025	6.4: Draft Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies, <i>Dr. Ana Mužinić, Ph.D (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)</i>
Sep 26th, 2025	7.3: Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure, <i>Amélie Schäfer (Health Data Hub, France)</i>
Sep 29th, 2025	7.4: Draft technical specification for Health Data Access Bodies on the implementation of secure processing environments, <i>Heikki Lehväslaihi (CSC - IT Center for Science, Finland)</i>
Sep 30th, 2025	8.1.2: Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data, <i>Dr. Gergely Mikešy (Semmelweis University Health Services Management Training Centre, Hungary)</i>
Oct 1st, 2025	4.1: Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation, <i>Pia Brinkmann (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)</i>

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

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



3.1 Legal background

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

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

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

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



3.2 Summary of the document

Table of Contents

Executive summary	4
Introduction	5
Scope and aim of the guideline	6
Audience	6
Legal framework	6
Right to opt out from the processing of personal electronic health data for secondary use	9
1. What is opt-out? Definition.	9
Legal definition	9
Opt-out from secondary use in contrast to opt out from primary use	9
Difference between EHDS opt-out, and GDPR informed consent and right to object	9
Citizen engagement and empowerment as regards the opt-out	10
2. Opt-out from what	14
Characteristics of data falling under the opt-out	14
Does opt-out block anonymisation?	14
Are there different levels of opt-out available in EHDS?	15
3. Where to declare opt-out	17
Role of the HDABs and the opt-out	17
4. How to declare opt-out	18
Data protection aspects of declaring and reversing opt-out	19
5. How to implement opt-out with regard to citizens' rights	21
How to inform citizens about their right to opt out?	21
Information to be communicated to citizens regarding the right to opt out	22
6. Data use before opt-out	23
7. Data use after opt-out	24
8. Data use after the revocation of opt-out	25
9. Reaction to opt-out?	25
Annex I Glossary	26
Annex II EHDS User Journey	31

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



3.3 Critical points

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

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



3.4 Who should comment?

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

4. Q&A



5. Save the date: Next workshops



Date	Workshop
Sep 15th, 2025	5.2 Draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data
Sep 16th, 2025	8.1.1: Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data
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, <i>Dr. Anna Niemeyer (TMF e. V., Germany)</i>
Sep 16th, 2025	8.1.1: Draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data, <i>Irene Schlünder (TMF e. V., Germany)</i>
Sep 17th, 2025	7.2: Draft guideline for Health Data Access Bodies on data minimisation, pseudonymisation, anonymisation and synthetic data, <i>Pia Brinkmann (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)</i>
Sep 18th, 2025	6.1: Draft guideline for data holders on making personal and non-personal electronic health data available for reuse, <i>Marije van Melle (Nictiz, Netherlands)</i>
Sep 24th, 2025	6.3: Draft guideline for Health Data Access Bodies on the procedures and formats for data access, <i>Rosa Juuti (Findata, Finland)</i>
Sep 25th, 2025	6.4: Draft Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies, <i>Dr. Ana Mužinić, Ph.D (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)</i>
Sep 26th, 2025	7.3: Draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure, <i>Amélie Schäfer (Health Data Hub, France)</i>
Sep 29th, 2025	7.4: Draft technical specification for Health Data Access Bodies on the implementation of secure processing environments, <i>Heikki Lehväslaihi (CSC - IT Center for Science, Finland)</i>
Sep 30th, 2025	8.1.2: Draft guideline for Health Data Access Bodies on implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data, <i>Dr. Gergely Mikešy (Semmelweis University Health Services Management Training Centre, Hungary)</i>
Oct 1st, 2025	4.1: Draft guideline for Health Data Access Bodies on fees and penalties for non-compliance related to the EHDS regulation, <i>Pia Brinkmann (Bundesinstitut für Arzneimittel und Medizinprodukte BfArM, Germany)</i>

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

Contact

TMF e. V.
Charlottenstraße 42/Dorotheenstraße
10117 Berlin

www.tmf-ev.de | [@TMF_eV](https://www.instagram.com/TMF_eV)

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