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 implementing the obligation of notifying the natural person on a significant finding from the secondary use of health data

Sebastian C. Semler, TMF e. V. &
Dr. Gergely Mikesy, National Directorate General for Hospitals, Hungary

September 30th, 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 It will not be published or passed on to third parties.

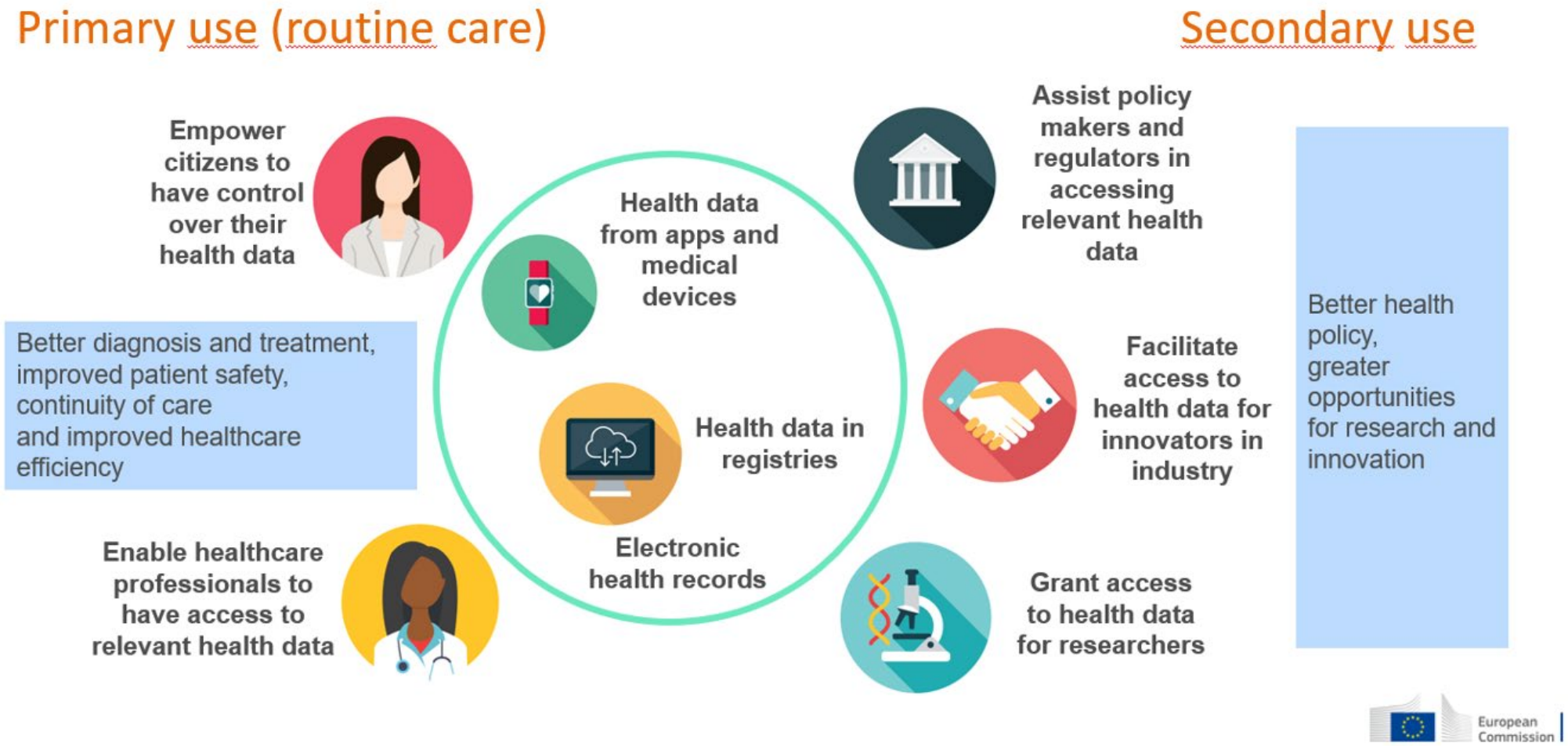
By participating, you consent to the recording.

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 implementing the obligation of notifying the natural person on a significant finding 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

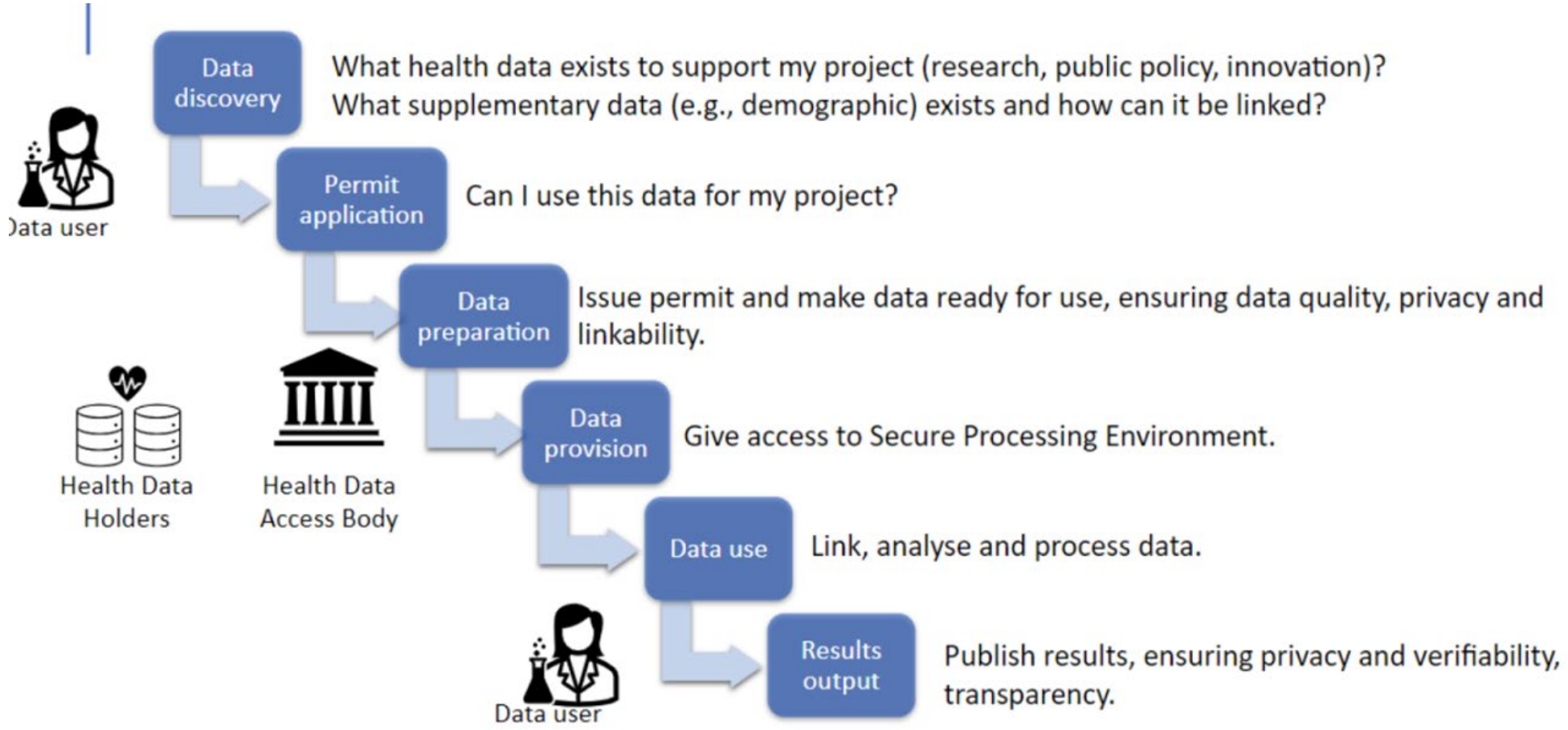
1. EHDS and TEHDAS2 in a nutshell

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



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.

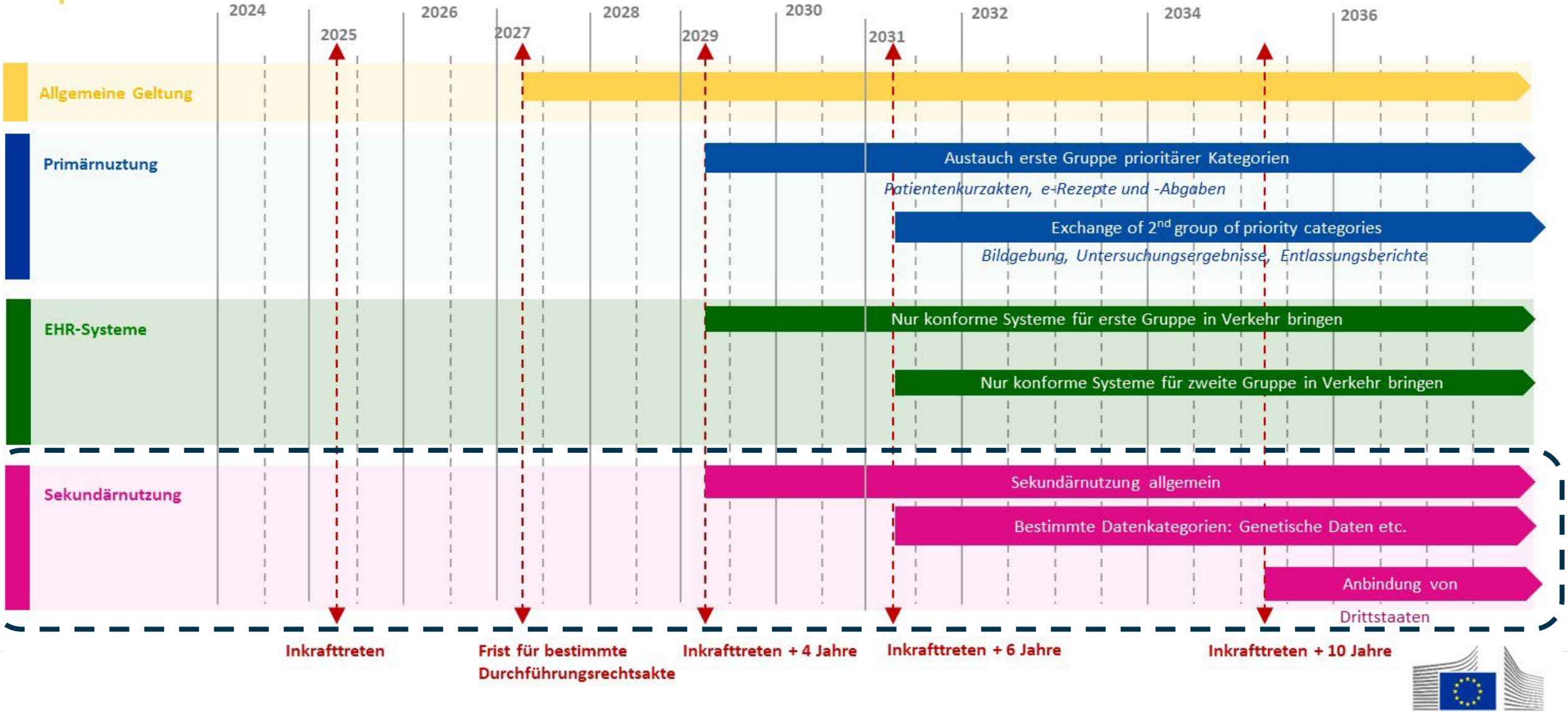
(3) The COVID-19 crisis strongly cemented the work of the eHealth Network, a voluntary network of authorities responsible for digital health, as the main pillar for the development of contact-tracing and contact-warning

[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



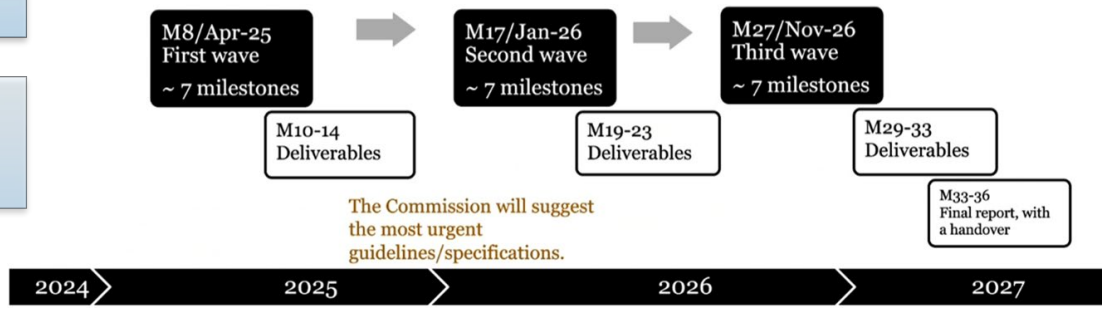
1. TEHDAS2 in a nutshell

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

3.1 Legal background

The term (Significant Findings) is not specifically defined in the EHDS Regulation.

- First step: clarifying the concept of Significant Findings

Recital 67 refers: *„Natural persons should be informed by the health data holders about significant findings related to their health made by health data users.”*

3.1 Legal background

Explanation:

Clinically Significant Findings are observations that have **a direct impact on patient care, diagnosis, treatment, or prognosis**. These findings play a crucial role in medical decision-making and are essential for guiding therapeutic interventions. A finding is considered clinically significant if it influences patient management, treatment options, or health outcomes. To be classified as clinically significant, findings must be relevant to the patient’s condition **(directly associated with the reason for the test or clinical evaluation)**.

Conversely, findings that lack scientific validity, clinical relevance, or personal specificity would not meet the threshold of significance.

3.1 Legal background

It is important to make a distinction between primary care significant findings and significant findings which are retrieved from secondary use of data. If the sampling process is aimed at information about certain conditions, in such cases the findings from the secondary use are not considered as a significant finding.

Incidental Findings refer to **unexpected** observations identified during a diagnostic test, medical examination, or research study that are **unrelated** to the primary reason for conducting the test.

3.1 Legal background

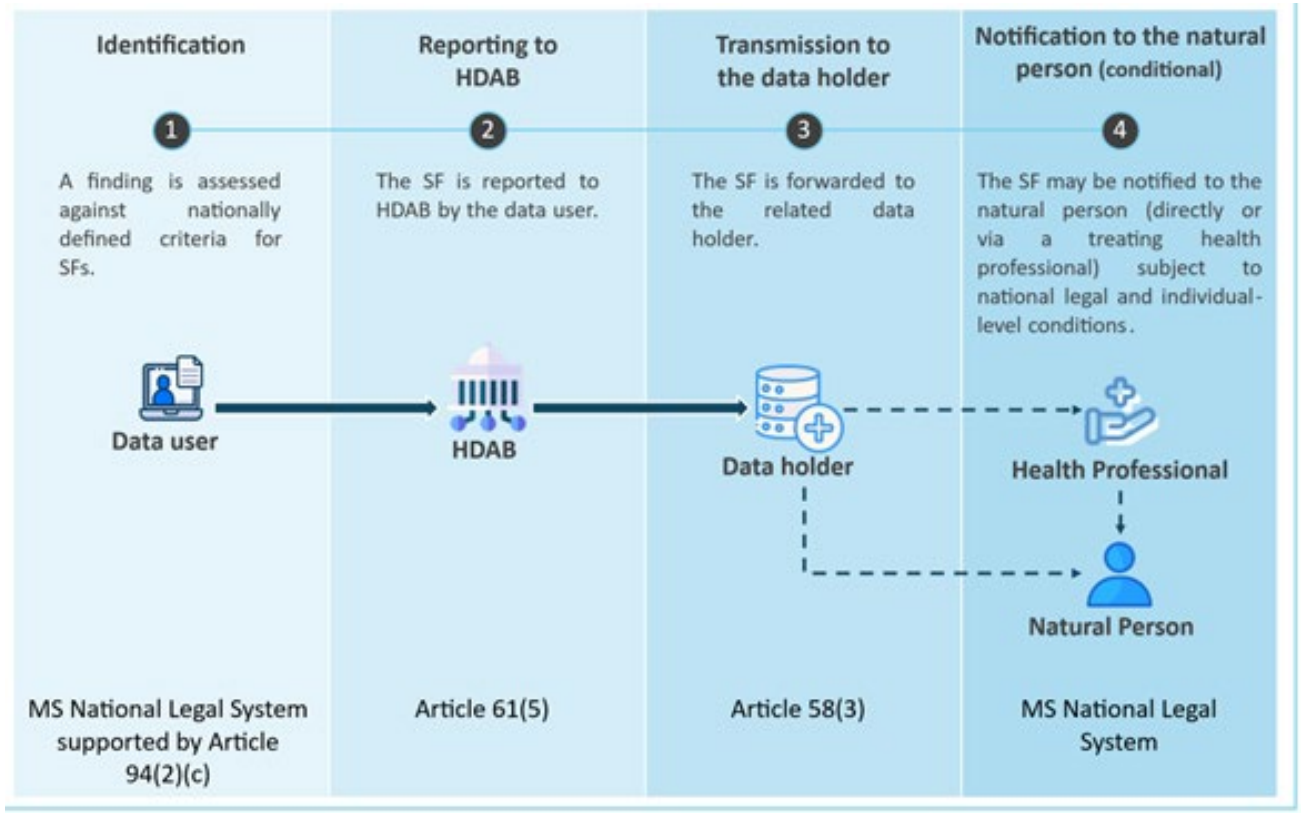
Related articles:

Article 61 (Duties of health data users) states, that health data users shall inform the health data access body of any significant finding related to the health of the natural person whose data are included in the dataset, while safeguarding privacy.

Article 58 (Obligations of health data access bodies towards natural persons), para. 3 confirms the roles and duties of the actors in such a way that where a health data access body is informed by a health data user of a significant finding related to the health of a natural person, the health data access body shall inform the health data holder about that finding.

Article 94 (Tasks of the EHDS Board), para. 2 point (c): the EHDS Board help health data users to fulfil their duties under Article 61(5), and in particular to determine whether their findings are clinically significant

3.1 Legal background



3.2 Summary of the document

1. Explaining Significant Findings

    1.1 Clarifying the term (detailed previously)

    1.2 Legal framework (detailed previously)

    1.3 **Typical examples – Idea behind the concept!**

2. General aspects (Identification, Quality, Communication, Data-sharing, etc.)

3. Responsibilities of the key actors (summary)

4. **Guidance on the responsibilities of HDABs as regards significant findings**

Annexes

3.3 Critical points

1. Explaining Significant Findings

    1.1 Clarifying the term

    1.2 Legal framework (Rules prescribed by the EHDS Regulation)

    1.3 **Typical examples**

        Reflects on the participants professions, and experience – we would like to see different approaches!

3.3 Critical points

2. General aspects (defines the standards)

3. Responsibilities of the key actors (summary)

4. **Guidance on the responsibilities of HDABs as regards significant findings**

Basically, the HDABs responsibilities are just to communicate the considered significant findings to the Data Holders from the Data Users!

It is up to the Member States to regulate what specific tasks they assign to HDABs within the EHDS framework, e.g., a possible filtering role in the assessment of significant findings!

3.3 Critical points

Just a few words (aspects), where the HDABs can help about the Significant Findings (if a MS delegate these tasks).

- HDAB may help to interpret and put the significant findings into context?
  - Filtering, and avoiding the burden of irrelevant details and information
- The HDAB may participate in the re-identification process (pseudonymization too!)?
- The HDAB may register the natural persons’ requests?
- Disclosure, and communication to national authorities?

3.4 Who should comment?

Anyone, and everyone!

- Data Holder candidates (hospitals, and other data controllers, etc.)
- Data User candidates (researchers, innovators, etc.)
- National authority members

4. Q&A

5. Save the date: Next workshops

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

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