

PLENARY 6

Secondary use of health data: insights from

**TEH
DAS** Towards
European
Health
Data
Space

Introduction to TEHDAS2

Elina Drakvik, Senior Lead & Project Lead,
Sitra, the Finnish Innovation Fund





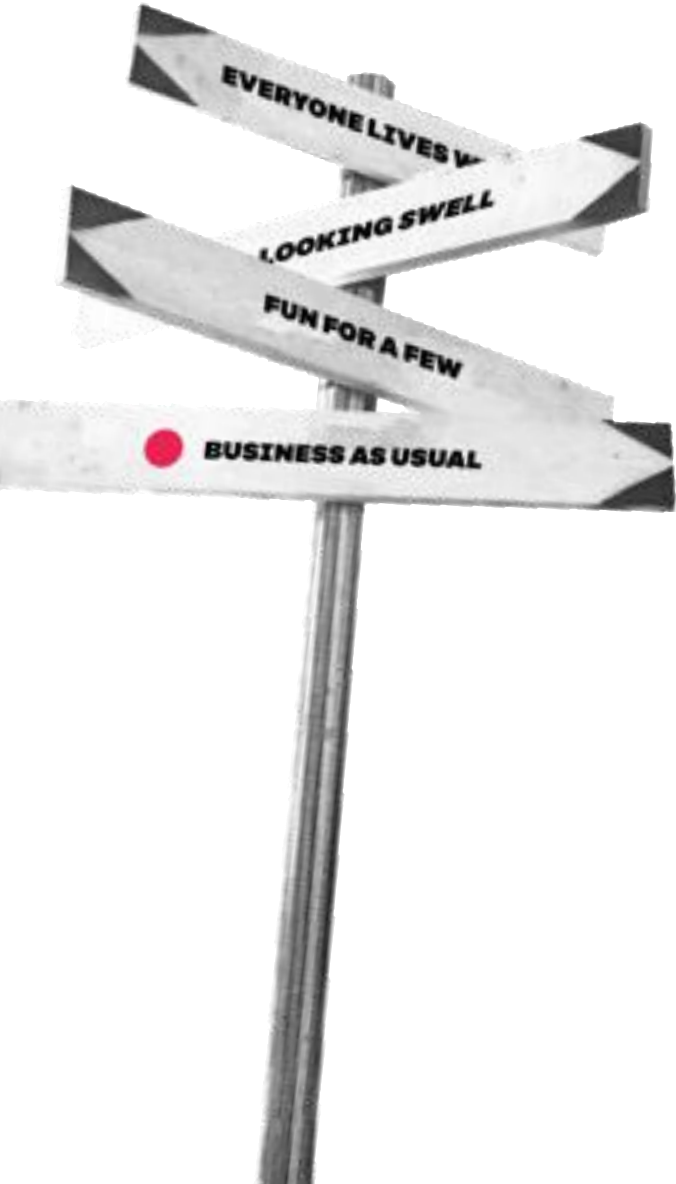
Introduction to TEHDAS2

Limassol, 30 April 2026

Elina Drakvik, Senior Lead & Project Lead

Sitra – TEHDAS2 Coordination

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Timeline

May 2024

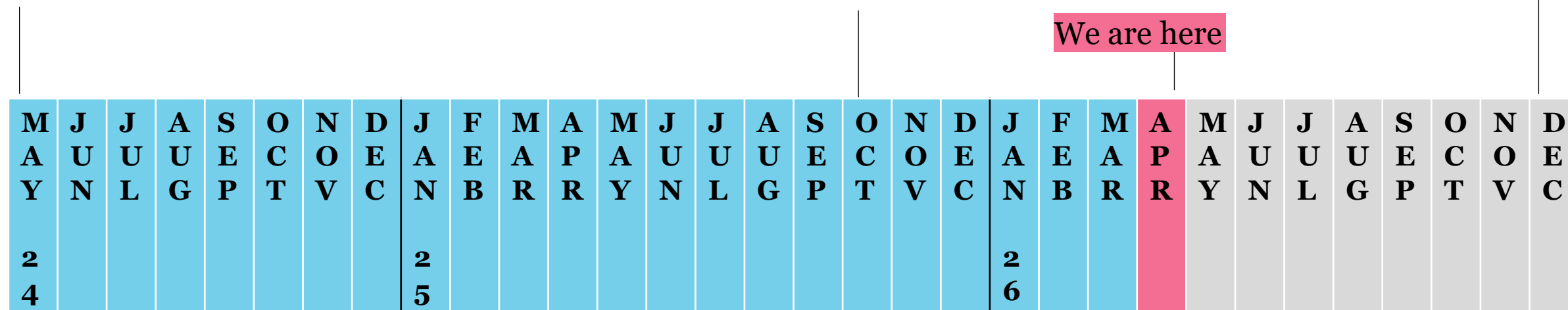
TEHDAS2 started

September–November 2025

2nd stakeholder forum &
11 documents in public consultation

December 2026

TEHDAS2 ends



We are here

January 2025

1st stakeholder forum &
4 documents in public consultation

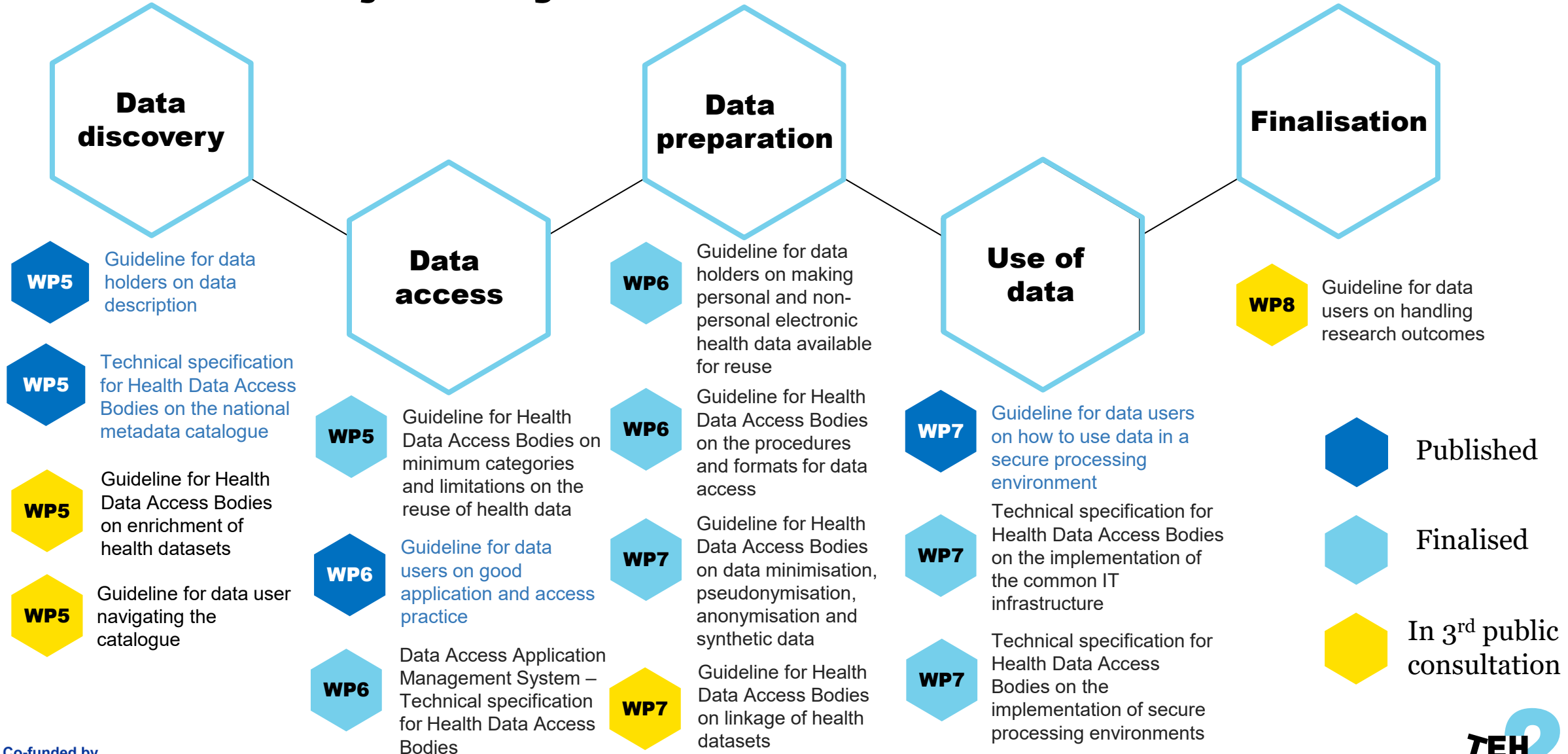
April 2026

3rd stakeholder forum
as part of Cyprus EU
Presidency conference

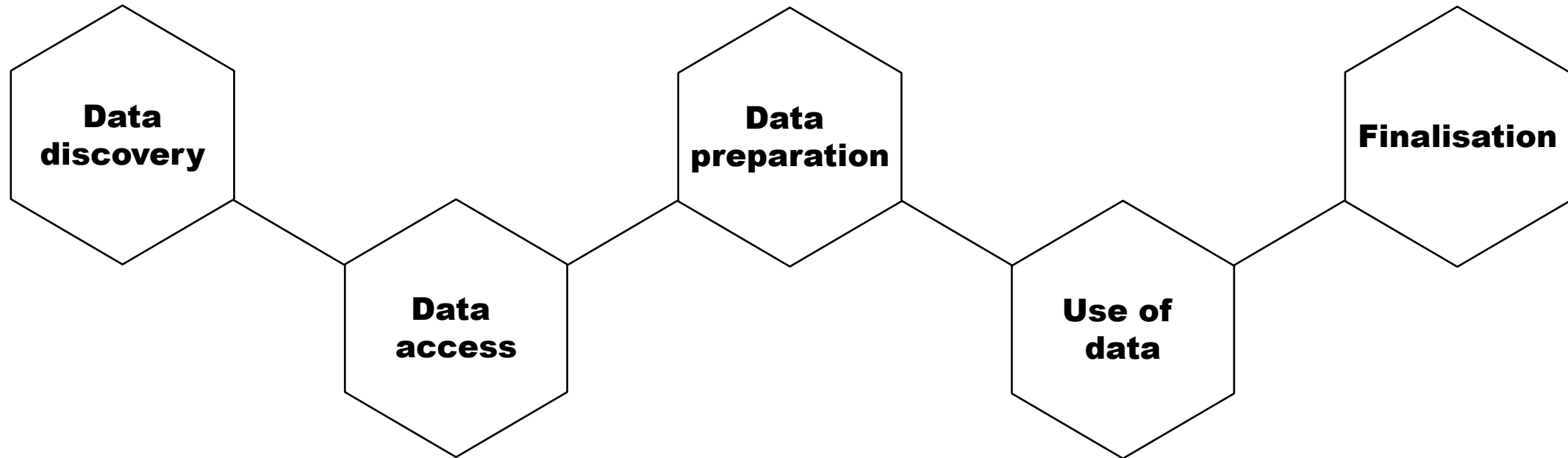
May–June 2026

7 documents in public
consultation

EHDS user journey and related WP deliverables 1/2



EHDS user journey and related WP deliverables 2/2



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

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

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

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

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

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

Public consultation results

- Summaries integrated as part of the final documents
- Common feature: more specific or operational guidance expected

- KPI: 30 replies for each guideline from at least 14 European countries
- **1st public consultation:**
 - **4 documents: 78–106** responses/guideline, **15–16** countries
 - Altogether around 350 responses

- **2nd public consultation:**
 - **11 guidelines: 40–99** responses/guideline, **12–16** countries
 - Altogether around 760 replies (consolidated responses)



Your voice matters!

- 3 TEHDAS2 public consultations: tehdas.eu/public-consultations
- Third public consultation: **5 May – 28 June**

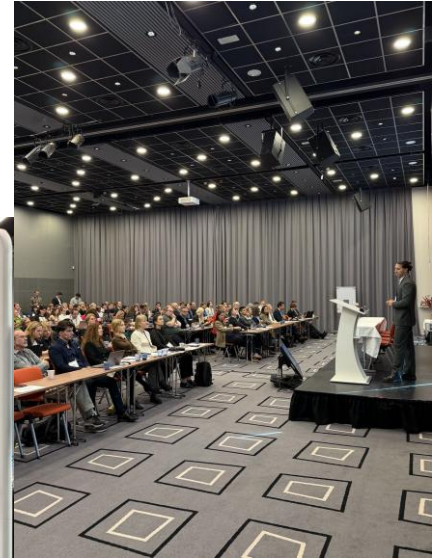
- 3 stakeholder forums
(Warsaw, Copenhagen, and Limassol)

- 3 topic-specific workshops, and
ad hoc consultations based on WP needs

- National Expert Groups

- External Advisory Board

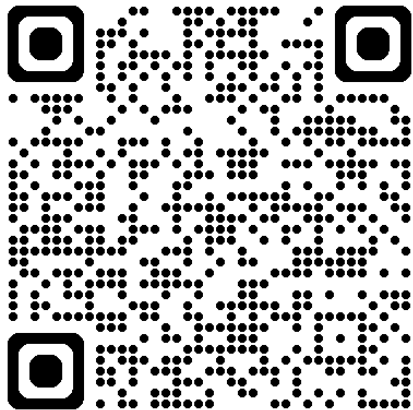
- **TEHDAS2 Final conference in November 2026 in Brussels**



Follow our TEHDAS2 work:

- TEHDAS2 website: tehdas.eu
- TEHDAS2 LinkedIn: [TEHDAS2 joint action](#)
- Contact the TEHDAS2 coordination team: tehdascoordination@sitra.fi
- Contact: elina.drakvik@sitra.fi

Evaluation survey on TEHDAS2 work:



Thank you!



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Draft guideline on a framework for collaboration

Beatriz Jacinto Barros, Health Policy Expert and Researcher, Sciensano

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Framework for collaboration

Beatriz Jacinto Barros

***European Health Union for a Connected
Health Data Space Ecosystem***



Introduction

CHALLENGE

Where in the secondary use framework is collaboration between different actors needed, and *how* can it be established and implemented?

VALUE

This document offers a draft non-binding framework to support those implementation efforts. It draws on structured stakeholder engagement (workshops, surveys, and interviews) to provide grounded, actionable recommendations.

What it offers:

- Guidance on conditions for collaboration across ethical governance, coordination models, and intellectual property (IP) protection
- A mapping of how research infrastructures can contribute to and integrate within the EHDS ecosystem
- Input for EU and national implementation planning on collaboration models

Directed at:

- HDABs, data holders, data users, research infrastructures, and policy-makers at national and EU level

Main elements of the draft guideline

PART I – Topic-wise dimension: conditions for collaboration

Three thematic areas addressed through stakeholder workshops:

- Ethical governance in the EHDS
- Collaboration models and coordination mechanisms
- Protection of IP rights and trade secrets

For each topic: key perspectives, challenges identified, and recommendations

PART II – Stakeholder-wise dimension: research infrastructures and networks

- Landscape analysis of services and functions offered by research infrastructures, networks and initiatives in the health data domain
- Mapping of where these can contribute added value across the EHDS secondary use journey
- Roles and pathways for engagement within the EHDS framework
- Actionable recommendations to build on synergies and collaboration opportunities

Further development of the guideline

Collect public consultation feedback

Is the framework complete and actionable?

For each topic, have we captured the full picture of challenges and opportunities? Are the recommendations actionable? For Part II, does the document reflect the realities of research infrastructures and networks on the ground?

Your feedback will shape the final guideline!

Feedback on the recommendations

Collaboration in the EHDS is complex and there is no one-size-fits-all solution. The recommendations provided aim to provide **guidance that helps move discussions forward and supports implementation decisions regarding collaboration**. We need your feedback: is this guidance useful? Is it sufficiently granular? Are there areas where more detail or different approaches would be needed?

Beyond the guideline: from ideas to practice

Bringing health domain expertise into EHDS implementation

The stakeholder engagement process revealed the wealth of expertise, best practices, and experience that already exists across the health data domain. As implementation progresses, it will be important to continue creating opportunities for joint discussion and to leverage this collective knowledge to strengthen the collaboration frameworks we are building together within the EHDS.



Have your say!

Participate in the public consultation between 5 May and 28 June

PUBLIC CONSULTATION

Your feedback is essential for developing collaboration frameworks that are practical, actionable, and fit for implementation across the EHDS ecosystem

- Please use this possibility to review, respond and share your expertise!
 - Do the recommendations on ethical governance, collaboration models and IP rights protection adequately address the challenges identified? Are there recommendations you would add or prioritise differently?
 - Does this document adequately address the topic of collaboration in the EHDS secondary use framework? Are there perspectives, actors, or dimensions of collaboration that you feel are missing or should be given greater attention?

Thank you!



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A circular portrait of Prof. Fidelia Cascini, a woman with dark hair, wearing a dark blue top and a gold necklace, smiling. The background of the portrait is a blurred indoor setting.

Draft guideline for health data access bodies on international and third country access and transfer of electronic health data

Prof. Fidelia Cascini, Department of Hygiene and Public Health, Università Cattolica Del Sacro Cuore

TEHDAS2

International and third country access and transfer of electronic health data

Fidelia Cascini

European Health Union for a Connected Health Data Space Ecosystem



Introduction

CHALLENGES

Balancing access and protection: health data access bodies (HDABs) need a mechanism allowing international organisations (IOs) and third countries (TCs) access to data while **ensuring strong safeguards for EU citizens' rights/sensitive information.**

Fragmented national approaches: EU Member States currently apply **different rules, safeguards, and reciprocity requirements** creating a lack of harmonisation.

VALUE

Practical recommendations to HDABs and stakeholders to implement EHDS rules for electronic health data access by IO/TC and international data transfer. Focus on:

- Two main access pathways: **1. authorised participation; 2. reciprocity;**
- **Interaction with GDPR** (additional EHDS safeguards for data access/transfer)

Main elements of the draft guideline

- **Scope and legal context:** electronic health data access and transfers under articles 75, 87, 88, 90 and 91 EHDS.
- **Real world evidence:** multicountry survey on current data access practice by IO/TC and data transfer.
- **Possible scenarios :**
 - Scenario 1 – access by applicants from authorised IO/TC integrated in HealthData@EU
 - Scenario 2 – access based on reciprocity mechanism
- **Transfer and storage rules:** personal and non-personal electronic health data; conditions for using secure processing environments (SPEs) when outside the EU.
- **Guidelines' interdependencies:** cross-references with other TEHDAS2 deliverables (fees and penalties, data user duties,...) to support a harmonised governance model.

Further development of the guideline

Element 1 – Pathways

Authorised participation in HealthData@EU offers **deeper integration and interoperability**.

Available for IO/TC **from 2035**.

Electronic health data access by IO/TC will be available also based on **reciprocity under Article 91(1)(b)**.

Implementing acts will be provided.

Element 2 – Safeguards

EHDS (Ch. IV) introduces additional safeguards on data **transfer and storage** compared to GDPR (Ch V).

Need for **structured technical and organisational measures** (e.g. encryption, logging, localisation, SPE use,...) for e-health data and trade secret protection is highlighted.

Consistent assessment criteria for reciprocity, transfer conditions and SPE localisation, are emphasised supporting harmonised decisions by HDABs

Element 3 – Considerations

The document is an **expert guidance** under TEHDAS² and it's **not legally binding**; it will need to be read alongside future **implementing acts and national measures**.

As EHDS is rolled out, the guidance can be **refined with practical experiences**, feedback from HDABs and evolving EU-level criteria on reciprocity and authorised participation.



Have your say!

Participate in the public consultation between 5 May and 28 June

PUBLIC CONSULTATION

Your feedback is essential to clarify conditions for e-health data access by IO/TC, and to ensure that safeguards for transfer and storage are both robust and workable for HDABs

Please use this opportunity to review the guideline and share your expertise, especially on:

- gaps or ambiguities in the interpretation of EHDS provisions on international access and transfer;
- additional safeguards or governance tools you consider necessary in practice;
- concrete examples of reciprocity and “de facto governance” that could inform future EHDS implementation

Thank you!



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**Front row comments
from stakeholders**





Front row comment:

Draft guideline on a framework for collaboration

Stamatiki Kritas, Manager of Hellenic BioCluster and
Communication Leader of the InnoMedCatalyst-project



Front row comment:

Draft guideline for health data access bodies on international and third country access and transfer of electronic health data

Gianluca Violante, Senior Manager for Digital Health Policy,
DIGITALEUROPE

Draft guideline for data enrichment

Anna Niemeyer, Scientific Employee – Clinical Research,
Technology and Methods Platform for Networked Medical
Research (TMF)



TEHDAS2

Data enrichment for secondary use: conceptual framework and practical guidance

Anna Niemeyer

European Health Union for a Connected Health Data Space Ecosystem



Introduction

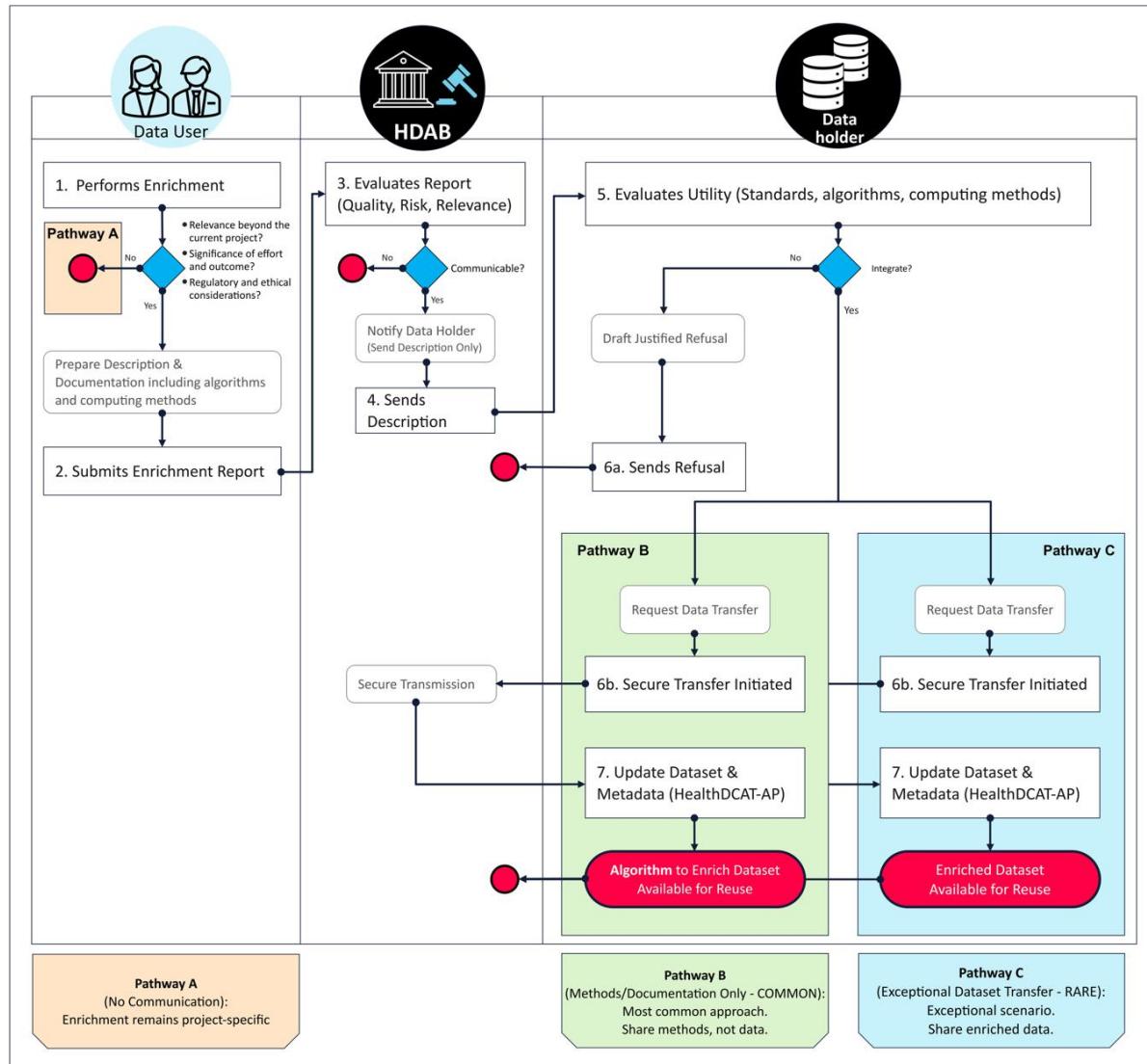
CHALLENGE

- **Supporting reuse:** Enriched datasets, derived variables, and intermediate outputs contribute to reproducibility, transparency, and cumulative knowledge generation.
- **Regulatory ambiguity:** The EHDS Regulation does not define specific legal obligations or mandatory workflows for data enrichment, leaving it to Member State competence.
- **Risk of fragmentation:** Without a common framework, there is a risk of inconsistent national procedures, which could hinder cross-border interoperability and the reuse of enriched datasets.

VALUE

- **Shared understanding:** Explains when and why data enrichment is valuable and illustrating how it could be integrated into the EHDS secondary use framework.
- **Harmonisation:** It provides a **non-binding, exploratory framework** to encourage consistent procedures across Member States, supporting a coherent and interoperable EHDS ecosystem.
- **Practical guidance:** Clarifies what data enrichment is, where and by whom it can occur in the EHDS secondary use journey, and provides illustrative examples, governance and technical considerations, as well as key challenges for implementation.

Main elements of the draft guideline



- **Conceptual understanding of data enrichment**

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

- **Data enrichment in the EHDS user journey**

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

- **The feedback loop:** Envisioning a process where users return descriptions of improvements, following the data user journey and roles of key actors (data users, HDABs, data holders)
- **Pathways:** Emphasizing sharing methodologies, code, and algorithms, supporting reuse and reproducibility

- **Governance, legal and operational considerations**

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

Further development of the guideline

The document is an **expert guidance** under TEHDAS2 and **not legally binding**; it will need to be read alongside **national measures**.

Standardisation of communication

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

Clarification of roles and incentives

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

Examples and governance approaches

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



Have your say!

Participate in the public consultation between 5 May and 28 June

PUBLIC CONSULTATION

- **Your expertise is essential** for refining the proposed approaches to data enrichment, including the relevance and scientific value of enrichment and how it is communicated within the EHDS framework.
- We specifically seek feedback on the **proposed pathways**, as well as the **legal, organisational, and operational considerations**, including the role of **HDABs as intermediaries** and how to ensure feasible and efficient processes.



Draft guideline for data user navigating the catalogue

Anna Niemeyer, Scientific Employee – Clinical Research,
Technology and Methods Platform for Networked Medical
Research (TMF)

TEHDAS2

**Navigating the EU dataset catalogue:
a comprehensive guide for health data
users**
Anna Niemeyer

***European Health Union for a Connected
Health Data Space Ecosystem***



Introduction

CHALLENGE

- The EHDS Regulation introduces new infrastructures for data discovery, such as the HealthData@EU catalogue, based on harmonised metadata (HealthDCAT-AP) and common rules for secondary use. Potential data users may require guidance to understand these new systems, navigate catalogues, and interpret metadata effectively.

VALUE

- This guideline provides a non-technical, high-level orientation to support users in navigating the EHDS catalogue ecosystem.
- It explains how catalogues are organised, what type of information is available, and how to identify and assess relevant datasets for research, innovation, and policymaking.
- It bridges the gap between initial discovery and the formal application process.

Main elements of the draft guideline

- **The pre-authentication workflow:** Detailed mapping of the discovery phase, covering keyword retrieval, dynamic filtering (e.g., by coding systems like ICD-10 or SNOMED CT), and advanced SPARQL queries.
- **Dataset record interpretation:** Instruction on evaluating provenance, governance, and technical interoperability through structured metadata.
- **Basket functionality:** A preparatory tool for shortlisting and comparative analysis of datasets prior to formal login.
- **Orientation aids:** Alongside this comprehensive manual, a **quick guide** has been developed to provide users with an immediate visual overview and rapid orientation of the platform's core functionalities

QuickGuide EU Dataset Catalogue
This Quick Guide highlights the key elements of the EU Dataset Catalogue website. Further explanations can be found in the user guide.

Start page of the EU Dataset Catalogue

HealthData@EU Central Platform

Dataset Records

How to get there:
<https://accessance.data.health.europa.eu/healthdata-central-platform/datasets>

Clicking on one of the dataset records found leads you to the details page

Nr.	Name	What is it for?
1	Filter	A structured filter panel to refine the search result by selecting different filter options.
2	Search Field	A search field for keywords such as dataset titles, disease areas, etc., that can be used before applying filters
3	Dataset Record	The list of dataset records available after filtering. Click one for more information about its contents and contact the data holder.
4	SPARQL Search	Advanced search option for directly querying machine-readable metadata.
5	Implementation Support	A set of supporting tools and documentation embedded in the platform to help users interpret and work with the catalogue's metadata model.

Dataset record detail page

Nr.	Name	What is it for?
6	Access Level	A high-level indicator in the dataset record describing how the dataset can be accessed (commonly presented as Public, Restricted, or Non-public), helping you anticipate whether formal authorisation will be required.
7	Dataset Record Details on content	The main descriptive elements explaining what the dataset is about and what it covers, typically including title, description, provenance, purpose, keywords/thematic annotations, and high-level coverage information (geographic and temporal scope)
8	Information on the status of the dataset record/other functions	Metadata and controls indicating dataset record currency and maintenance and providing navigational actions linked to the record view.

Further development of the guideline

Feedback from public consultation

Data users are encouraged to test the HealthData@EU platform, use this guideline as support, and provide feedback through the public consultation on the usefulness of the materials

Guideline updates and alignment with the platform

The HealthData@EU platform will continue to evolve up to 2029. This guideline will be updated following the public consultation and aligned with future platform releases

Future user guidance and support

Expanding the scope of the guidance to other EHDS functionalities (e.g. secure processing environments) and developing user-centred support tools such as interactive materials and how-to videos across the user journey



Have your say!

Participate in the public consultation between 5 May and 28 June

PUBLIC CONSULTATION

- Your feedback is essential
 - to ensure the guideline’s operational utility within the EHDS framework.
 - to validate conceptual and linguistic clarity and if the academic language remains accessible to non-technical users.
- Please use this possibility to review, respond and share your expertise!
 - We specifically request evaluations of the **quick guide** to determine its efficacy as a standalone resource for rapid user onboarding and intuitive navigation of the HealthData@EU Central Platform

Thank you!



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**Front row comments
from stakeholders**



Front row comment:

Draft guideline for health data access bodies on enrichment of health datasets

Panayiotis Kolios, Assist. Prof., Department of Computer Science, and KIOS Research and Innovation Center of Excellence, University of Cyprus

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Front row comment:

Draft guideline for data user navigating the catalogue

Apostolos Dimitriadis, Business Development & Innovation,
Manager at the Centre for eHealth Applications and Services of
ICS-FORTH



Draft guideline for health data access bodies on linkage of health datasets

Justin Ansotte, Data Analyst, Belgian Health Data Agency

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Linkage of health data

Justin Ansotte

*European Health Union for a Connected
Health Data Space Ecosystem*



Introduction

CHALLENGE

- Balancing the amount of detail, while providing precise recommendations on how to implement data linkage in the EHDS.

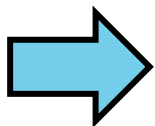
VALUE

- The guideline focuses on two or more datasets at the individual level. It offers insights into possible linkage scenarios, activities performed by the linking organisations, use cases and templates that can be used by the involved actors.
- This guideline aims at supporting HDABs supervising or performing data linkage within the EHDS.
- HDABs, data holders and trusted data holders form the target audience. Moreover, it can also assist data users in understanding the linkage processes and in formulating improved data requests or data access applications.

Main elements of the draft guideline

We are addressing the following questions:

- Why, when and by whom can data be linked within the EHDS?
- What data are being linked?
- How is data linked?
- How is quality and accuracy of linked datasets considered?
- How can role-based accesses to linkage processes enhance privacy?
- How are repeated or frequent applications to (linked) data possible within the EHDS?



The guideline provides detailed scenarios, methods, considerations regarding data types, recommendations for role-based access to linkage processes and elaborates on frequent and repeated data requests/applications.

Further development of the guideline

Public consultation



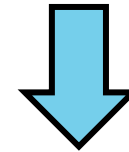
Implementing the feedback we will receive during the public consultation and improve our guideline further.

Quasi-identifiers – data minimisation

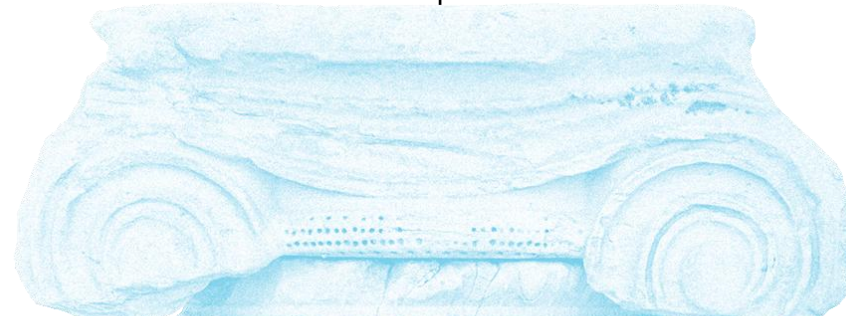


Successful data linkage might need additional quasi-identifiers, which could result in a larger amount of data than strictly necessary for the application at hand.

Efficient communication between linking actors



To facilitate data linkage, efficient and easy communication between the linking actors is key, but it remains



Have your say!

Participate in the public consultation between 5 May and 28 June

PUBLIC CONSULTATION

- Your feedback is essential to help us address gaps in our guideline or inconsistencies! The public consultation questions are straightforward and offer to provide feedback per section.
- Please use this possibility to review, respond and share your expertise!



Thank you!



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Draft guideline for health data access bodies on informing natural persons about the use of health data – “Citizen Information Point”

Lorenz Dolanski-Aghamanoukjan, Data Scientist and Health Expert, Austrian National Public Health Institute, Austria

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Citizen Information Points

Information > Transparency > Trust > Value

Lorenz Dolanski-Aghamanoukjan

***European Health Union for a Connected
Health Data Space Ecosystem***



Introduction

CHALLENGE

- Guide health data access bodies (HDABs) in informing natural persons about the use of health data.

VALUE

- For HDABs:
 - Be EHDS compliant.
 - Learn about good practices, consider optional features. → Increase impact.
 - Involve citizens.
- For natural persons (“citizens”):
 - Know your rights.
 - Understand what is being done. → Build trust.
 - Explore results. → Get curious, involve yourself.

Main elements of the draft guideline

- What is an information point?
- What information shall be provided?
 - Legal basis, safeguards, individual rights, who does what, results
- What additional information can be provided?
 - Awareness, trust and engagement, interplay with other relevant EU legislation, ...
- How should the information be provided?
 - Accessibility, structure, visuals, communication methods, ...
- When should the information be provided?

Further development of the guideline

Citizens' / Patients' input

Listen to the target audience directly, assert their needs.

Clarity & granularity

Keep it brief, but elaborate where comments suggest lack of explanations.

Landscape analysis

Expand the analysis of existing portals to learn from the best.



Have your say!

Participate in the public consultation between 5 May and 28 June

PUBLIC CONSULTATION

- Your feedback helps improve:
 - Transparency of the secondary use of health data for citizens
 - Requirements and feasibility of the Citizen Information Point
- Questions we welcome:
 - What is missing?
 - What is unclear from a citizen point of view?
 - And any other feedback

Thank you!



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Draft guideline for data users on handling research outcomes

Chryso Pieridou, Senior Laboratory Scientist,
Karaiskakio Foundation

TEHDAS2

Handling research outcomes under the EHDS

Chryso Pieridou

*European Health Union for a Connected
Health Data Space Ecosystem*



Introduction

CHALLENGE

- Lack of clarity on how to handle outcomes generated from EHDS secondary use
- Uncertainty regarding:
 - Reporting obligations
 - Dissemination and transparency
 - Interaction with GDPR and IP rights
- Risk of inconsistent practices across Member States

VALUE

- Clear, structured guidance on outcome-related obligations under EHDS
- Supports secondary data users in:
 - Reporting and dissemination
 - Managing IP and commercial outcomes
- Promotes transparency, accountability and legal certainty

Main elements of the draft guideline

- Defines the roles and responsibilities of secondary data users, HDABs and data holders in relation to outcomes.
- Outlines obligations to report results to HDABs and ensure transparency, covering scientific, policy, and commercially relevant outcomes.
- Explains requirements for secure processing environments, anonymisation, and prevention of re-identification when exporting results.
- Distinguishes between use of data and use of outcomes, supporting innovation and commercialisation while respecting EHDS transparency obligations.

Further development of the guideline

Legal and governance framework

- Further clarification of roles and responsibilities under EHDS
- Refinement of the distinction between data processing and handling of outcomes

Reporting and dissemination of outcomes

- Clarification of requirements for submission of results to HDABs
- Further guidance on transparency and conditions for public availability
- Feasibility of reporting timelines and level of detail

Safeguards and compliance

- Practical implementation of secure processing environments
- Ensuring effective anonymisation and prevention of re-identification

Intellectual property and collaboration

- Balancing transparency obligations and IP
- Clarifying use of outcomes in collaborative and multi-partner projects
- Supporting innovation while maintaining EHDS safeguards



Have your say!

Participate in the public consultation between 5 May and 28 June

PUBLIC CONSULTATION

Your feedback is essential to:

- Ensure legal clarity and consistency
- Validate feasibility in practice
- Improve guidance on:
 - Secure processing constraints
 - Reporting obligations
 - Balance between transparency and IP

Please use this possibility to review, respond and share your expertise!

- What content is missing?
- Are the requirements realistic and implementable?

Thank you!



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**Front row comments
from stakeholders**



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Front row comment:

Draft guideline for health data access bodies on linkage of health datasets

Igor Ruiz de los Mozos Aliaga, Specialist in Personalised Medicine and Bioinformatics, NASERTIC, Personalised Medicine Department, Government of Navarra

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Front row comment:

Draft guideline for data users on handling research outcomes

Enrique Bernal Delgado, Senior Scientist, Institute for Health Sciences in Aragon (IACS)

Public consultation

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



TEHDAS²

