

The background of the entire page is a dark blue color. It features a network diagram consisting of numerous small, light blue squares connected by thin, light blue lines. These lines form a complex web of connections across the entire page. The logo 'POLHIS' is positioned in the upper left quadrant. The letters 'POL' are white, 'H' is orange, and 'IS' is white. A vertical orange line is placed to the right of the 'H'.

POLHIS

ETHICS AND POLITICS OF
HEALTH DATA ECOSYSTEMS

**Governing the European Health Data
Space (EHDS):
Ethical and Political Perspectives
on the TEHDAS2 Second
Public Consultation**

Governing the European Health Data Space (EHDS): Ethical and Political Perspectives on the TEHDAS2 Second Public Consultation

POLHIS WHITE PAPER 2026/01

With the endorsement of



Foreword by BION - Cluster Lombardo Scienze della Vita

The European Health Data Space (EHDS) represents a pivotal opportunity to unlock the full value of healthcare data for the benefit of patient access to care across Europe, as well as for research and innovation. We strongly believe that designing policies and systems through cooperative approaches is essential to deliver impactful projects for a Europe that calls on Innovation Clusters to strengthen collaboration across Member States.

EHDS has the potential to enhance European excellence in healthcare by enabling full interoperability, accelerating scientific discovery, and improving the quality and sustainability of healthcare systems, key challenges faced by all Member States (MS) over recent decades. In this context, fostering a coherent ecosystem where data can be responsibly accessed and used for the public good is a strategic priority.

The Lombardy Life Sciences Cluster BION endorses this important work by POHLIS and is committed to supporting further initiatives on EHDS and other strategic EU health and life sciences priorities, bringing together public and private stakeholders, as well as citizens, to build shared positions and a common vision for a better Europe.

***POLHIS** is a research center at the University of Milan dedicated to examining the ethical and political dimensions of health data ecosystems. Its work focuses on data governance, public value, digital infrastructures, and the societal implications of data-driven health systems. POLHIS brings together an interdisciplinary ensemble of scholars in the social sciences, ethics, law, medicine, and computational biology to support responsible data policies in Europe and beyond.*

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Executive Summary

This white paper consolidates POLHIS comments submitted to the TEHDAS2 second public consultation on the TEHDAS2 guidelines (September 2025). TEHDAS2 guidelines provide practical guidance and operational interpretation of key provisions of the EHDS Regulation, aimed at supporting consistent implementation across Member States while allowing for national flexibility.

The guidance addresses core aspects of the secondary use framework, including fee structures, permitted and prohibited uses of health data, metadata cataloguing, data access application and request procedures, enforcement and sanctions, and individual opt-out mechanisms. Across the guidelines, foundational principles such as transparency, proportionality, non-discrimination, due process, competition neutrality, data minimization, and alignment with FAIR principles are emphasized. The guidelines also clarify procedural requirements, including compliance monitoring, verification and assessment workflows, coordination mechanisms, and transparency obligations at both national and EU levels.

While the guidelines offer valuable operational clarity, our analysis identifies several areas where further specification, harmonization, or clarification would strengthen implementation. These include, among others: the rationale and consistency of fee models and accounting standards; cross-border coordination and enforcement; alignment with GDPR requirements and AI governance; interpretation of allowed purposes and public interest; handling of intellectual property and trade secrets; metadata scalability and resource constraints; differentiation between data and dataset quality; and the practical implementation of opt-out mechanisms, particularly in relation to genetic data, vulnerable populations, and communication strategies.

The following sections contain detailed recommendations for each guideline.

KEYWORDS: European Health Data Space, EHDS, THE DAS2, public consultation, data governance

Table of Contents

1. Comment on the DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON FEES RELATED TO THE EHDS REGULATION (Work Package M4.1.1) 11

A) Clarify the underlying rationale of the fee model	12
B) Prevent self-reinforcing inequities and access stratification	12
C) Strengthen preferential access for public research	13
D) Address inconsistencies regarding excluded and eligible cost categories	13
E) Include guidance on harmonized accounting standards and cost definitions.....	14
F) Sustain access to infrequently accessed data	14

2. Comment on the DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON PENALTIES FOR NON-COMPLIANCE RELATED TO THE EHDS REGULATION (Work Package M4.1.2) 15

A) Sourcing HDAB Expertise Within Member States	15
B) Address how risks are defined for triggering oversight.....	15
C) Specify desiderata for procedural elements of enforcement	15
D) Identify how criteria for administrative fines will be defined and operationalized	15
E) Outline thresholds for notifying DPAs	16
F) Clarify link between algorithmic misuse and 'serious infringement'	16
G) Clarify what is meant by intended obstruction of data access	16
H) Link penalty matrices and risk assessments to public benefit discussions	16
I) Consider how penalties implicate other draft documents	17

3. Comment on the DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON MINIMUM CATEGORIES AND LIMITATIONS ON THE REUSE OF HEALTH DATA (Work Package M5.2) 18

A) Link data entitlement to legitimacy of activity where overlaps in purpose exist.....	18
B) Stretching the notion of public interest should be accompanied by clarifications	18
C) Consider enhanced monitoring and testing for data uses considered "high risk"	19
D) Harmonized standards are needed in assessing trade-secret status	19

4. Comment on the DRAFT GUIDELINE FOR DATA HOLDERS ON MAKING PERSONAL AND NON-PERSONAL ELECTRONIC HEALTH DATA AVAILABLE FOR REUSE (Work Package M6.1) 20

A) Develop specifications for experimental human model systems	20
B) Clarify governance of research-native datasets	20
C) Introduce tiered metadata frameworks for dataset complexity.....	21
D) Support resource-constrained data holders	21
E) Clarify obligations in joint data controller scenarios.....	21
F) Address gaps in AI model sharing provisions	21

5. Comment on the DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON THE PROCEDURES AND FORMATS FOR DATA ACCESS (Work Package 6.3) 22

A) Clarify criteria for data permit duration	22
B) Introduce flexible publication timeline requirements	22
C) Clarify cross-border assessment protocols	23
D) Distinguish data quality from dataset quality	23
E) Recognise context-dependent quality criteria	23

6. Comment on the DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON IMPLEMENTING OPT-OUT FROM THE SECONDARY USE OF HEALTH DATA (Work Package M8.1) 24

A) Clarify the scope of the opt-out	24
B) Clarify implementation of stricter safeguards for genetic data	25
C) Improve coordination between EHDS opt out and GDPR right to object	25
D) Clarify how promoting health literacy relates to acceptance of the EHDS	25
E) Describe how health literacy efforts will be financed	26
F) Provide guidance on the practical management of granular opt-out	26
G) Clarify practical management of the opt-out registry	26
H) Allow citizens to share reasons for their opt-out	27
I) Advance directives for vulnerable populations (reference to Section 5.2.1.3)	27
L) Ensure effective opt-out through timely citizen communication	28

Conclusion 29

Introduction

TEHDAS Second Public Consultations on Draft Documents Related to the European Health Data Space Regulation (EHDS)

TEHDAS2 (*Towards the European Health Data Space 2*) is a Joint Action funded by the European Commission that supports the implementation of the European Health Data Space (EHDS) Regulation. TEHDAS2 develops practical guidelines and technical specifications to enable cross-border health data exchange for secondary use across Member States. The Joint Action brings together health authorities, data protection experts, and technical specialists to translate the EHDS Regulation's legal provisions into implementable standards (<https://tehdas.eu>).

In September 2025, TEHDAS2 released a series of draft guidelines for public consultation, addressing key aspects of the EHDS implementation. These guidelines covered diverse topics including metadata standardization for data catalogues, procedures for Health Data Access Bodies (HDABs), fee structures for data access, opt-out mechanisms, data quality labeling, and secure processing environments. The consultation period invited stakeholders across Europe to provide input on these foundational documents that will shape the data space.

We participated in these consultations as members of POLHIS, the Research Centre on the Ethics and Politics of Health Data Ecosystems at the University of Milan. This white paper collects our comments submitted during the consultation period, offering them to a broader audience interested in the ethical and political dimensions of European health data governance, including potential lessons for other jurisdictions pursuing similar efforts.

We focused our commentary exclusively on guidelines where normative choices are most consequential (e.g. fee structures that shape research access patterns, opt-out mechanisms that balance individual rights with collective benefits). Worth noting, is that we approach technical specifications as inherently normative, as they affect who can access health data, under what conditions, and to which ends. The guidelines we did not comment on addressed issues beyond the Centre's immediate research focus.

1. Comment on the DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON FEES RELATED TO THE EHDS REGULATION (Work Package M4.1.1)

The guideline establishes principles for fee structuring under Articles 62 of the EHDS Regulation, outlining transparency, non-discrimination, proportionality, and competition neutrality as foundational criteria. It distinguishes between recoverable costs and non-recoverable regulatory obligations (i.e. compiling metadata catalogues), allows MS flexibility in determining fee methodologies, and permits preferential pricing for public research at national discretion. We identify gaps related to the underlying fee model rationale, insufficient harmonization of accounting standards, inconsistencies between excluded and eligible cost categories, and differential access patterns for rare versus common diseases. We summarize our recommendations below.

A) Clarify the underlying rationale of the fee model

The guideline and its underlying principles (transparency, non-discrimination, proportionality, competition neutrality) do not clearly articulate whether the fee mechanism is conceived as: (i) a pure cost-recovery model; (ii) a hybrid public value-oriented approach, aimed at balancing access conditions between actors with differing levels of resources (for instance, by subsidizing access for public research institutions); or (iii) a strict competition-neutral pricing framework, granting access on a non-discriminatory basis to any categories of eligible Data Users regardless of their size (i.e. including large corporations).

The lack of an explicit normative framework risks producing inconsistent practices across actors and Member States, while also reinforcing structural asymmetries across institutions (see point B below).

B) Prevent self-reinforcing inequities and access stratification

A pure cost-recovery model or a competition-neutral pricing framework may insufficiently account for differences in purchasing power across Member States and between different categories of data users (for instance, privileging well-resourced and repeat commercial applicants who are better positioned to internalize administrative and technical transaction costs).

Likewise, excluding any consideration of the underlying scientific (and thereby commercial) value of publicly generated datasets (such as hospital EHRs), while simultaneously guaranteeing non-discriminatory access to all actor types including large technology or pharmaceutical companies, may unintentionally depreciate the strategic commercial value of those datasets. If public data holders are unable to

recover the value that commercial actors would otherwise pay in a market setting, this may undermine the financial sustainability of health systems - particularly in a context where many EU Member States operate under enduring fiscal constraint, and where (public) healthcare institutions increasingly explore data monetization as a mechanism to sustain service provision.

C) Strengthen preferential access for public research

While preferential pricing for public research is mentioned (consultation document section 3.3), its implementation is discretionary. A minimum EU baseline would prevent national divergence and ensure consistency for users (important e.g. for public research that must budget for costs at the grant application phase)

D) Address inconsistencies regarding excluded and eligible cost categories

The guideline states that costs related to data catalogues and metadata preparation cannot be charged to users since they are regulatory obligations (consultation document section 3.4). Yet later sections allow recovery of fixed infrastructure development costs, including database development and modelling, which in practice overlap with catalogue-building activities (consultation document section 3.4.7). This conceptual inconsistency requires clarification, as it affects whether institutions are afforded (or not) the recovery of large investments already made in preparing data for secondary use.

Explicitly allowing Data Holders to recover costs associated with database development, data standardization and metadata structuring may generate divergent effects that warrant careful assessment:

- **Positive incentive effects.** Granting Data Holders the partial recovery of long-term infrastructure investments may operate as a meaningful incentive for their proactive participation in the EHDS, thereby supporting the scalability (and ultimately the success) of such initiative. Moreover, the framework might address how data reuse creates value loops returning information to Data Holders, ensuring they experience concrete benefits for their – crucial - efforts towards data quality (in that regard, it should be noted that investments in how data is collected and structured during primary processing can clearly have a positive effect in the quality, cost and ease of access for secondary uses).
- **Risk of structural inequity and market consolidation.** At the same time, the possibility to recover these costs may disproportionately benefit institutions with existing data infrastructure, a

high level of digital maturity, and the administrative capacity to operationalize fee calculation. Well-resourced centres may leverage sunk investments, while smaller or less digitally mature institutions may be unable to do so, effectively absorbing similar costs without compensation. This dynamic risks creating uneven market positioning, where highly digitised centres accumulate competitive advantage over time, reinforcing systemic asymmetries. To avoid this issue, it may be advisable to apply an economies-of-scale criterion, allowing small and medium-sized centres to federate with larger national (data) infrastructures.

E) Include guidance on harmonized accounting standards and cost definitions

The current approach allows Member States to determine methods autonomously, with only publication of methodologies required (section 3.4.7). Without common accounting standards, such flexibility may lead to fragmentation and creates incentives for strategic fee positioning.

F) Sustain access to infrequently accessed data

The fixed-cost recovery model (Section 3.4) may inadvertently create differential access patterns based on disease prevalence. If infrastructure costs are distributed across data requests, common diseases with frequent data access would bear lower per-request costs than rare diseases with infrequent access, potentially reinforcing existing research disparities.

2. Comment on the DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON PENALTIES FOR NON-COMPLIANCE RELATED TO THE EHDS REGULATION (Work Package M4.1.2)

The guideline provides HDABs with a practical interpretation of Articles 63 and 64 of the EHDS Regulation, detailing how to monitor compliance, issue enforcement measures, and impose administrative fines. It clarifies notification and due-process obligations, describes proportionality criteria for sanctions, and outlines transparency requirements and future Commission responsibilities. We identify some gaps related to cross-border enforcement, alignment with GDPR requirements, misuse of AI, coordination across MS, and evidence-collection standards. We summarize our recommendations below.

A) Sourcing HDAB Expertise Within Member States

The document outlines a wide investigative mandate for HDABs (audits, inspections, data requests), but doesn't address how expertise will be sourced in MS with different available resources and trained professionals. In addition to offering funds and resources for training, the Commission could establish a central technical assistance unit, or explicitly allow delegation to accredited external experts through clearly defined approaches.

B) Address how risks are defined for triggering oversight

The document could further address how risks are defined for triggering oversight, providing some meta-criteria that could inform the HDABs coordination.

C) Specify desiderata for procedural elements of enforcement

While the Regulation standardizes enforcement tools, which are described in the draft document, MS retain flexibility over procedural elements (appeals, timelines, competent bodies, administrative steps). This may reproduce fragmentation across MS. There could be minimum desiderata specified for these procedural elements as well as guidelines for cross-border workflows where enforcement affects multiple MS national authorities or HDABs. These could take into consideration the different policy, regulatory, and legal statuses of different competent authorities across MS, which may also involve regional authorities. It may also benefit from the specification of dispute resolution and joint decision-making processes.

D) Identify how criteria for administrative fines will be defined and operationalized

Similarly, the draft document specifies that in assessing whether to impose an administrative fine, the assessment must be comprehensive, balanced, and well-

reasoned, ensuring that each sanction reflects the specific characteristics and impact of the infringement in question. The draft document specifies some key criteria for those assessment, but could benefit from further explication of how those criteria will be defined and operationalized. The use of penalty matrices or risk assessment frameworks is a good move in that direction but may require cross-HDAB standardization (see point H below).

E) Outline thresholds for notifying DPAs

The draft document acknowledges that there may be cases where breaches also fall under the scope of the GDPR, meaning HDABs would have an additional duty to inform the competent supervisory authority. Future work including implementing acts should specify thresholds for notifying DPAs, the division of labour in joint investigations, and the handling overlapping sanctions.

F) Clarify link between algorithmic misuse and ‘serious infringement’

While the draft document specifies that more serious infringements (unauthorized processing, re-identification attempts, or refusal to comply with HDAB enforcement) may attract fines of €20 million or 4% of turnover, whichever is higher, it is unclear exactly how re-identification attempts will be made known to HDABs. This issue is exacerbated by machine learning and other advanced analytic techniques which make this possible. The final text of the EHDS specifies that AI is permitted when it falls within the scope of scientific research. More attention should be paid to whether algorithmic misuse constitutes “serious infringement” (including for example the subsequent generation of synthetic data) or any obligations for explainability during investigations. These obligations may invoke issues related to intellectual property and trade secrets.

G) Clarify what is meant by intended obstruction of data access

The document specifies that intended obstruction of data access by data holders can result in fines, but there are no criteria or evidentiary tests for establishing intent, which risks rendering this provision ineffective while also leading to uneven application.

H) Link penalty matrices and risk assessments to public benefit discussions

The draft document specifies that to support consistency, HDABs may adopt tools such as penalty matrices or risk assessment frameworks. These should be informed by a broader framework otherwise there will be fragmentation and forum shopping. It may be worth linking this issue to the discussion of public benefit found in the “Minimum Categories & Limitations on Reuse” document. TEHDAS2 may also consider generating draft worksheets or templates.

l) Consider how penalties implicate other draft documents

Similarly, it may be worth explicitly outlining which draft documents this one implicates/links to, as was done for the “Minimum Categories & Limitations on Reuse” document for example.

3. Comment on the DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON MINIMUM CATEGORIES AND LIMITATIONS ON THE REUSE OF HEALTH DATA (Work Package M5.2)

The guideline offers practical interpretation of Article 53 allowed purposes and Article 54 prohibited uses and operational advice for HDABs. We identify some important topics which may benefit from further specification, including especially allowed purposes based on entitlement, use and application of public interest, potential for discrimination, and IPR/trade-secret handling.

A) Link data entitlement to legitimacy of activity where overlaps in purpose exist

In applications, HDABs will be responsible for verifying that the stated purpose is one of the six permitted ones and is clearly specified: if the purpose is (a–c), the HDAB also checks the applicant’s legal status/affiliation or mandate authorizing that reserved purpose, whereas for (d–f) no special institutional mandate is required and eligibility is assessed on a case-by-case basis. The former distinction is about entitlement, not the legitimacy of the purposes. The emphasis on entitlement through institutional identity rather than assessment of capability or risk, or public interest, doesn’t address common overlaps in activities between private and public actors. Examples might include a ‘big tech’ company carrying out analyses of mobile phone motion data for public health authorities, or a non-profit analyzing epidemiological data to inform local public health planning. This could be mitigated by defining EU-level minimum criteria for contracts, post-approval audits for compliance with declared purposes, and clarified rules for joint or overlapping purposes.

B) Stretching the notion of public interest should be accompanied by clarifications

In the EHDS regulation, public interest is mentioned frequently. The draft document acknowledges the vagueness and controversiality of the concept, and suggests the adoption of public interest as 1) an enabling principle, 2) governance standard, 3) risk trigger, and 4) procedural guarantee. While this ambition is understandable, stretching the notion of public interest without clearer criteria may generate further ambiguity. Each of these applications of public interest could be accompanied by a framework that specifies how the criteria that should be applied to specific provisions of the EHDS, including but not limited to minimum categories and limitations. It should be also clarified how a broad notion of ‘public interest’ overlaps with the technical legal notion of public interest under e.g. the GDPR.

C) Consider enhanced monitoring and testing for data uses considered “high risk”

The guideline acknowledges that discrimination or misuse will rarely be transparent at the application stage, and may surface only after harm has occurred. It suggests that HDABs should require applicants to provide a binding declaration that the data will not be used for prohibited purposes under Article 54(a–b), including profiling, scoring or automated decision-making, that leads to exclusion or discrimination. However, binding declarations offer limited protection against AI-mediated discrimination, especially when the applicants’ aims appear legitimate but downstream model behaviour is not. HDABs should complement binding declarations with enforceable, risk-based technical and procedural safeguards. For example, applicants developing models or conducting analyses with discrimination potential (based on a set of criteria defined in advance, including for example models that affect structurally marginalized groups) should be required to provide additional documentation of measures taken to reduce the potential for discrimination. HDABs may consider enhanced monitoring such as periodic checks for prohibited outputs. Applicants could also be required to participate in technical reviews or red-team testing (“ethical hacking”). Similar processes could be implemented for data uses considered at high risk of producing “harmful products or services”.

D) Harmonized standards are needed in assessing trade-secret status

Because data holders can assert trade-secret status and HDABs bear the burden of assessing the adequacy of those claims, without specific and contextual EU-level harmonized guidelines, application of the relevant EHDS provisions may considerably diverge among Member States. These guidelines could be articulated in future implementing acts or guidelines for HDABs, including incorporating evidentiary thresholds, and should be aligned with Directive 2016/943 on the protection of trade secrets, as well as the implementing national provisions.

4. Comment on the DRAFT GUIDELINE FOR DATA HOLDERS ON MAKING PERSONAL AND NON-PERSONAL ELECTRONIC HEALTH DATA AVAILABLE FOR REUSE (Work Package M6.1)

This guideline supports health data holders in meeting their obligations under EHDS Regulation Articles 60 and 77 by providing practical guidance on using the HealthDCAT-AP metadata model to describe datasets for secondary use. It outlines the framework for creating standardized, machine-readable metadata records meant to enhance data discoverability across national and EU-level catalogues while ensuring compliance with FAIR principles. The guideline specifies mandatory, recommended, and optional metadata elements tailored to different data access types (public, restricted, and sensitive personal health data). We identify gaps related to specific data types (e.g. experimental human model systems), metadata scalability, resource constraints for smaller data holders, and joint controllership scenarios. We summarize our recommendations below.

A) Develop specifications for experimental human model systems

Article 51 appropriately includes "other human molecular data such as proteomic, transcriptomic, metabolomic" (category g). However, technical specifications appear calibrated primarily for clinical care-derived data (EHRs, registries, administrative records), creating challenges for experimental human models included in category "g", such as iPSC lines, organoids and engineered biological systems in general. These require distinct metadata: cell line derivation, culture conditions, passage numbers, differentiation protocols, none of which clearly map onto HealthDCAT-AP's current framework. TEHDAS2 might develop supplementary guidance or vocabularies specifically addressing experimental human model systems.

B) Clarify governance of research-native datasets

The EHDS distinguishes between "primary use" of electronic health data, linked to the provision of healthcare, and "secondary use", defined by reference to the purposes listed in Chapter IV rather than by the origin of the data. This distinction reflects traditional clinical data flows but may fit poorly with contemporary biomedical research creating confusion with GDPR framework for further processing (Article 6(4)) and purpose limitation principles. For example, when researchers collect multi-omics data from patient-derived samples, or when research cohorts are profiled explicitly for research purposes, the initial processing does not correspond to "primary use" in the EHDS sense, as healthcare delivery is not the purpose. At the same time, subsequent access to or reuse of such research-native datasets via the EHDS mechanisms for Chapter IV purposes would typically fall under the EHDS regime for secondary use. The guideline might clarify how research-native datasets are situated within the

EHDS and, in particular, how the EHDS concept of secondary use should be interpreted in relation to the GDPR notions of primary and further processing.

C) Introduce tiered metadata frameworks for dataset complexity

HealthDCAT-AP applies uniform metadata requirements across widely different dataset types. This creates opposing challenges: extensive documentation may overcomplicate straightforward datasets (aggregate statistics, simple registries), while complex multi-modal datasets (linked genomic-transcriptomic-proteomic data with longitudinal follow-up) may require additional properties to capture technical interdependencies and processing pipelines. TEHDAS2 might explore tiered metadata frameworks or optional extension modules allowing appropriately scaled documentation.

D) Support resource-constrained data holders

HealthDCAT-AP's requirements reflect infrastructural capacity typical of healthcare institutions but may overwhelm smaller type of data holders lacking dedicated data stewardship resources.

E) Clarify obligations in joint data controller scenarios

When multiple entities serve as joint controllers for the same dataset, the guideline provides limited clarity on EHDS access obligations. Which entity bears responsibility for catalogue provision, data preparation, and access facilitation? Can obligations be allocated between joint controllers, or must each independently fulfil all requirements? TEHDAS2 might develop operational guidance addressing joint controllership scenarios, particularly common in academic-clinical research collaborations.

F) Address gaps in AI model sharing provisions

The EHDS regulation explicitly facilitates data sharing for AI model training, yet it does not consider AI models themselves - neither implicitly nor explicitly - among the data types to be shared under the framework. This creates a significant gap: while researchers can access training data, the trained models remain outside the regulation's scope, preventing independent validation of AI-generated or AI-processed data increasingly present in health research. TEHDAS2 might develop guidance on AI model sharing mechanisms, including appropriate metadata standards (model provenance, validation datasets, performance metrics, uncertainty quantification) that would enable transparent assessment of AI-mediated data transformations while respecting legitimate intellectual property concerns.

5. Comment on the DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON THE PROCEDURES AND FORMATS FOR DATA ACCESS (Work Package 6.3)

This guideline provides HDABs with operational guidance for implementing Articles 67-73 of the EHDS Regulation. It establishes verification procedures for application completeness before evaluating legal and regulatory compliance, outlines assessment criteria (purpose alignment, data minimization, ethical considerations, safeguards), and describes coordination with health data holders, SPE management, and monitoring obligations. The guideline distinguishes between data access applications (for personal-level data in SPEs) and data requests (for anonymized statistics), and provides standardized request templates. We identify gaps related to data permit conditions, cross-border coordination protocols, distinguishing data quality from dataset quality, and context-dependent quality assessment frameworks. We summarize our recommendations below.

A) Clarify criteria for data permit duration

Article 68 (12) establishes a maximum validity period of ten years for data permits, but the guideline provides limited operational guidance on how HDABs should determine appropriate durations for specific projects. Clarification in this area is particularly relevant because requesting an extension of a data permit duration would require the submission of an amendment, which may entail administrative charges both for the processing of the amendment and for the additional period of data use. In the absence of harmonised criteria for determining permit duration, divergent national practices could therefore result in differing data access costs for applicants solely due to variations in permit duration rules. Developing criteria supporting duration decisions, or providing illustrative examples, would support more consistent HDAB practice across Member States and help applicants better understand what durations to request for different research designs.

B) Introduce flexible publication timeline requirements

The guideline specifies that "results or outputs should be published within 18 months after the completion of data processing in the SPE" as a monitoring condition. While standardized timelines support accountability, this single requirement applies uniformly across widely different research types. Eighteen months may exceed necessary timeframes for straightforward analyses while proving insufficient for complex multi-institutional collaborations, longitudinal studies, or projects requiring extensive validation. The framework might benefit from differentiated publication expectations calibrated to project characteristics, or explicit provisions for justified extensions addressing unavoidable delays.

C) Clarify cross-border assessment protocols

Multi-country applications require HDABs to coordinate assessments, timeline synchronization, and fee consolidation across jurisdictions with potentially different procedures, assessment criteria, and administrative capacities. The guideline describes coordination mechanisms but might develop protocols addressing: how HDABs resolve divergent assessments of the same application, which HDAB takes lead coordination responsibility in multi-country requests, and how timeline extensions in one jurisdiction affect others.

D) Distinguish data quality from dataset quality

The guideline's quality framework primarily addresses dataset-level characteristics, structure, interoperability, documentation standards. However, one might have perfectly interoperable, well-structured datasets containing unreliable data values. Data quality (accuracy, scientific validity, coherence of individual values) differs fundamentally from dataset quality (metadata richness, technical standards compliance). TEHDAS2 might explicitly distinguish these dimensions and provide guidance on how data holders should document value-level quality characteristics.

E) Recognise context-dependent quality criteria

Quality assessment frameworks risk treating criteria like "completeness" as universal indicators applicable across all data types. Completeness - for instance - functions differently for prospective versus retrospective data collection. Prospectively designed clinical cohorts with systematic protocols should achieve high completeness, making missingness a quality concern. In retrospective clinical datasets, missing values are frequently informative; the absence of laboratory measurements may indicate that clinicians identified no clinical indication for testing, thereby conferring meaning to data incompleteness. TEHDAS2 might develop context-sensitive quality guidance distinguishing evaluation criteria appropriate for different data collection modalities.

6. Comment on the DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON IMPLEMENTING OPT-OUT FROM THE SECONDARY USE OF HEALTH DATA (Work Package M8.1)

This guideline supports HDABs in implementing Article 71 of the EHDS Regulation, detailing mechanisms for individuals to opt out from secondary use of their personal electronic health data. It distinguishes the EHDS opt-out from the GDPR right to object, outlines centralized versus decentralized national implementation models, addresses opt-out registries, vulnerable populations, granular opt-out options (by purpose or data category), and public health exceptions under Article 71(4). We identify gaps related to clarifying opt-out's limited scope, unclear provisions for genetic data consent requirements under national discretion, coordination complexity between EHDS and GDPR rights, conflation of health literacy with EHDS acceptance, operational challenges of granular opt-out implementation, and insufficient communication strategies. We summarize our recommendations below.

A) Clarify the scope of the opt-out

The opt-out right granted by the EHDS Regulation in respect to secondary use (art 71) concerns only withdrawing data from the EHDS infrastructure. This is a crucial element regarding the scope of the opt-out: even when individuals exercise such right, this will not entail a withdrawal from any secondary use of health data, but only from the secondary use of health data as part of the EHDS. This means that secondary use of data based on other legal basis, permissions or regulatory frameworks (e.g. as part of other secondary uses provided for by individual datasets or other national legislation) will still be possible. For example, if a cohort is built up in a country (or across countries) as part of a research project, and this involves the collection of health data for the research project the cohort is based on, it is still likely that that data is made available for third parties for secondary research purposes for the research collaborations the cohort organises as part of their activities and alongside internal data access provisions. It is thus crucial that citizens are informed that the opt-out right (even when exercised) concerns only opting out from the EHDS infrastructural architecture, and it does not equate a 'general opt out' preventing all secondary uses of health data for that citizen. The draft guideline briefly mentions this point (e.g. in chapter 5.4.1.1 National discretion), but with insufficient emphasis. Countries would benefit from advice on how to explain this very complicated – almost legalistic – distinction to citizens, i.e. that the opt-out applies only to EHDS and not to all secondary uses outside of the EHDS infrastructure. This is crucial, otherwise citizens may believe having provided a general opt out for all secondary uses, and may thus lose trust if – only in the aftermath, maybe after discovering their data were

nevertheless reused for secondary purposes outside of the EHDS infrastructure – they realise the opt-out has a limited outreach.

B) Clarify implementation of stricter safeguards for genetic data

The guideline mentions briefly in the chapter titled “Relationship between the legal basis and the opt-out” that “under the EHDS Member States (MS) cannot introduce further consent rules [for genetic data], except for stricter safeguards.” This probably refers to article 51(4) of the EHDS regulation, which states “Member States may introduce stricter measures and additional safeguards at national level aimed at safeguarding the sensitivity and value of the data that fall under paragraph 1, points (f) [i.e. “human genetic, epigenomic and genomic data”], (g), (i) and (q).” Here, the guideline still does not help to clarify whether MS – as part of these legal provisions – could still be legally authorised to set stricter rules for the secondary use of genetic data, which possibly even requires consent as a necessary requirement, instead of the general EHDS rules (no consent required, only right to opt out). This is a key point that the guideline does not address: would MS still be authorised to create separate rules for genetic data that are possibly based on a consent-requirement? This unclear formulation risks, among other things, to leave open the risk of a fragmented regulatory landscape across MS.

C) Improve coordination between EHDS opt out and GDPR right to object

The guideline goes at great length to distinguish these two rights. They also underscore that “Controllers must respect both decisions [to opt out via EHDS art 71 and to object to data processing via GDPR art. 21] separately and ensure that both objections and opt-outs are recorded and implemented appropriately, according to their respective legal bases and effects.” However, two things would deserve more detailed guidance. First, how can we ensure that these two separate options (as well as their distinct legal effects) are well understood and used by citizens? Second, this also requires – on the part of data controllers – a detailed and specific knowledge of legal provisions and their distinct effects. This is also difficult to ensure, since it cannot be expected of all stakeholders involved in the EHDS to have the same level of legal knowledge (indeed most stakeholders in the EHDS will likely not have a legal background).

D) Clarify how promoting health literacy relates to acceptance of the EHDS

In the guidelines, recommendations about opt-out implementation and the need to improve health literacy often seem to imply that this equates to promoting acceptance of the EHDS infrastructure and its functioning. For example, in chapter 5.1.4.3 (Promoting awareness of societal benefits) it is written that citizens must be informed of “how their achievement [of societal benefits through a secondary

use of all data] could be affected when exercising opt out”. The reduced value of incomplete dataset is indeed an important issue and should be addressed. At the same time, the objective of fostering health literacy should remain value-neutral, rather than aimed at promoting acceptance. Better health literacy is about people understanding what health data are, what they are used for and why, regardless of whether they then choose to support such activities or not. The guidelines should thus not pass the message that “better health literacy = more approval of EHDS = less opt outs”. Promoting better health literacy should remain value-neutral and just aim at making citizens more aware.

E) Describe how health literacy efforts will be financed

The guideline rightly explains in great length the need for digital health literacy promotion and the actors that can be involved in it. They describe this as a key activity to ensure both knowledge about the opt out option amongst citizens and also about the EHDS as a whole. However, campaigns and activities to promote health literacy and citizens involvement are extremely demanding (in terms of know-how) and also expensive – if they aim to be effective. It is thus surprising that the issue of how these could be financed is not tackled, since recommendations in this respect would be very useful.

F) Provide guidance on the practical management of granular opt-out

The guideline discusses in detail that opt out can be granular, i.e. that it can be organised by different states as having different levels (e.g. in terms of opting out from specific uses of the data or specific types of data). However, little is said on how then data holders could administer and manage this level of granularity. For example, if a MS decides to allow the possibility to opt-out only for specific types of data (e.g. genetic data), how would a data controller deal with this, if it holds both genetic and non-genetic data? Imagine a research cohort that contains both the results of genetic analysis and also other health data. If a person has opted out from genetic data reuse, and then the cohort receives a request for access for secondary use through the EHDS, would they have to provide access to all data, but exclude the genetic data of the person who has opted out? This may be difficult since it would require a lot of work in terms of data preparation. Or would they have to provide access only to the data of people who have not exercised any opt out (thus excluding all data from those who exercised it, since it would be incomplete data about those persons – i.e. only the non-genetic data)?

G) Clarify practical management of the opt-out registry

One way the guideline recommends to record opt-out is by setting up an opt-out registry. This, however, raises several questions since it would require doing a lot of

data-linkage activities. E.g. consider the case of an entity requiring access to a dataset through the centralised health data access body. The body would then have to contact both the data source (to which access is requested) and to the opt out registry (to check whether amongst the people who recorded their opt-out, there is anyone whose data is included in the data source). There would thus need to be an activity of data linkage, i.e. verifying whether PersonA (who recorded the opt out) has any data in the requested data source. This would require linkage between data of PersonA in the opt out registry, with data of PersonA in the data source (if present). This may be extremely difficult, since the data source may have recorded data from PersonA through encryption. It would thus be difficult to actually check if any of PersonA's data is contained in the data source. To do that, data in source A may need to be de-encrypted (or de-pseudonimised) which creates additional ethico-legal (but also practical) issues.

H) Allow citizens to share reasons for their opt-out

The guideline stresses in several parts (e.g. the beginning of chapter 5.1) that the legal right to opt-out includes also a provision specifying that citizens do not need to declare a reason for the opt-out. This issue is quite uncontroversial. This means states cannot OBLIGE citizens to provide a reason for opting out. However, what the guideline does not address, is whether states can still provide citizens the POSSIBILITY for citizens to provide a reason (optional choice, without obligation). This is a crucial point for two reasons. First, and most importantly, the possibility to provide citizens with the (optional) chance to declare why they are opting out could allow to collect important information to determine why people exercise this right. This information can be crucial, as it can reveal – for example – reasons why citizens do not trust the EHDS infrastructure, thus also allowing to improve certain provisions that – in the future – would enhance citizens participation, or even to correct certain issues that maybe generate justified concerns – and thus motivate people to opt out. Second, it could allow to get a better idea of who are citizens who are opting out. In health research, it is common to investigate both why people want to participate in a project, but also what motivates them against participation and how the analysed sample may thus generate results with limited generalisability.

I) Advance directives for vulnerable populations (reference to Section 5.2.1.3)

In Section 5.2.1.3, the guideline notes that Member State legislation will determine how vulnerable populations, such as minors, people with limited legal capacity, or persons under guardianship, can exercise the opt-out, and that legal guardians may act on their behalf. To strengthen this part, we recommend explicitly allowing natural persons to create advance directives regarding the EHDS opt-out for the moment when they may become legally incapable in the future (e.g., due to

neurodegenerative diseases). Such a provision would ensure that individuals in vulnerable situations have their previously expressed wishes respected, including granular preferences if allowed (e.g., opting out only of certain secondary-use purposes or specific data categories). This would enhance autonomy, clarity, and protection for vulnerable populations while preserving the underlying objectives of the opt-out right.

L) Ensure effective opt-out through timely citizen communication

While the guideline rightly emphasises the importance of digital and health literacy (e.g., Article 84 EHDS), it does not address a critical operational implication of Article 71(3): since the opt-out has no retroactive effect, citizens must be able to exercise this right **before** secondary use activities start at the moment the Regulation becomes applicable. Without a structured and timely communication mechanism, individuals may have their data included in newly authorised secondary-use activities from day one, without having had a meaningful opportunity to opt out. To ensure the right is effective in practice, the guideline should recommend that MS establish an early, coordinated, and proactive communication **strategy** prior to the EHDS application date. This strategy should go beyond general public awareness campaigns and include trusted, high-reach channels, such as primary care **providers** and general practitioners, who are well positioned to explain to citizens, in clear and accessible terms, what secondary use entails and how they can exercise their opt-out. Such an approach would strengthen legal certainty, safeguard individual autonomy from the outset, and support a more legitimate and socially robust implementation of the EHDS.

Conclusion

As one of the European Union's most consequential regulations concerning health-related data, the EHDS is poised to affect citizens and residents, care providers, researchers, innovators, policymakers, and the very health systems we rely on. The TEHDAS2 draft guidelines therefore represent an important opportunity to address key aspects of the regulation's responsible implementation.

We identify a number of opportunities for further clarification in this regard: metadata standardization, procedures for Health Data Access Bodies (HDABs), fee structures for data access, opt-out mechanisms, data quality labeling, and secure processing environments. Underpinning these themes lies an important and largely unacknowledged issue related to expectations of value that inform key decisions throughout development and implementation. Without explicit attention to (i) how different conceptions of value (e.g. scientific, public, commercial) may create tensions or require tradeoffs, and (ii) what the EHDS is ultimately intended to achieve, we risk obscuring fundamental choices that demand public scrutiny.

The EHDS should hinge on publicly agreed-upon thresholds of citizen protection and benefit, and must therefore be explicitly recognized not merely as a technical endeavor, but as a normative and political one. As researchers keenly committed to informing the responsible implementation of the EHDS, we call for more explicit recognition of this dimension through collaborative engagement that includes not only subject-matter experts, but also communities of patients, citizens, and residents in all EU member states.

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