Summary page:

TEHDAS2 public consultation on 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

This consultation has 4 pages and 26 questions. The first and the second pages are common to all TEHDAS2 public consultations and cover demography of the responder and overall quality of the document. Pages 3 and 4 consist of questions specific to this document.

Demography

1. Country *

Other

2. Type of responder *

Academic or research organisation

3. Are you responding on behalf of several organisations? *

If yes: On behalf of how many organisations?

No

4. Sector *

Other

International academic research and policy center

5. Organisation size *

Small to medium enterprise (10–249 employees)

6. Professional role / function

Professor

Quality

7. Is the document easy to understand? *

3

8. How well does the document address the key issues related to its subject matter? *

2

9. How feasible do you find the guidelines or technical specifications to implement, as outlined in the document? *

3

10. Generic feedback

Do you have any suggestions for improving the document? Are there any additional topics or areas that should be covered? Max. 5000 characters.

The guideline is a positive step, but it requires conceptual and ethical clarifications. The guideline here addresses only the role of the HDAB in receiving, from the data user, and forwarding, to the data holder, reports of significant findings (SF). In this sense, the current guideline is limited in what it covers and what it doesn't—but it raises significant issues that require further clarification to promote a consistent (if bespoke) Member State approach.

First, a more precise definition of what constitutes a "significant finding" is needed. The draft guidance describes many findings, but not the criteria for significance. Research using secondary data often results in a correlation that has yet to be validated. What level of evidence, or regulatory review, is required to share a "finding?" Secondly, does the finding need to be "clinically actionable" or is "personally actionable" (e.g., the wish to notify family members of a potential genetic mutation, even if no medical intervention can be offered) sufficient? It would be helpful to define clinically actionable findings, personally significant findings, suspected but unvalidated signals, and non-actionable results. What are the standards for "actionability," including predictive value, strength of the evidence, and immediacy of potential action? Are there differences depending on the type of data (e.g., genomic, imaging, safety signal, etc.)? Providing concrete examples and thresholds would prevent both under- and over-notification.

In the research setting, the expectation that validation will occur before notification is problematic. Secondary-use datasets are heterogeneous, often incomplete, or not necessarily clinical grade (in the US, "CLIA certified"). What are the minimum standards for analytical validity, clinical validity, and actionability? Clarity on who is responsible for validation and what level of certainty is required would be helpful.

The guideline is appropriately clear that it is not the role or responsibility of the HDAB to interpret the actionability of findings or communicate findings directly to individuals. If the HDAB has, however, created the pseudonymized dataset, how should the HDAB interpret their responsibility for communication? Additional guidance on documentation, auditability, and governance would be welcome, including templates or minimal expectations for records of findings assessed, decisions made, validation procedures, and communications.

Cross-border issues of the EHDS remain an issue. The data holder may reside in a different Member State than the HDAB and different again from the researchers. Which Member State directive should be followed? The guideline should propose mechanisms for coordinating cross-border notifications, mutual agreement on responsibilities, and secure identity authentication. Translation requirements, data protection considerations, and interoperability issues should be detailed.

Finally, the guideline should address special populations and circumstances (e.g., pediatric populations, individuals lacking capacity, families of deceased persons, etc.).

The guideline should be clear about the data user's responsibility for timely communication, and whether there is any expectation to continue to query data to which it has access (we think not). For example, the significance of genetic variants changes over time; is the data user expected to "re-run" the query periodically, and if so,

how often?
Overall, while the draft guideline offers a solid foundation, it would benefit from clearer definitions, stronger procedural guidance, explicit legal grounding, and practical implementation tools. These improvements would enhance consistency, protect individuals, and ensure that the notification process is proportionate, ethically sound, and feasible for HDABs across the European Union.

The following questions are specific for 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

11. Do you expect the proposed guideline on the obligation of notifying natural persons on significant findings from the secondary use of their health data to impact your organisation or activities?

I don't know

12. Do you find the scope and objective of the guideline (as outlined in the introductory part) clearly described?

Unclear — please specify
As discussed above, the scope would benefit from further clarification, specifically which findings require notification, who is required to notify, and under which circumstances. Which secondary-use contexts are included or, alternatively, excluded (e.g., clinical research, AI model development, registries), if any? The scope of responsibilities remains unclear. What are the minimum criteria for determining significance, ensuring interoperability between Member States, clarifying which Member State directive to follow in cross-border notifications, and the responsibilities across different entities?

13. Do you find the explanation of significant findings (Chapter 1) sufficiently clear and appropriate?

If no: Please explain

No
The current definition lacks specified thresholds for clinical validity, seriousness of finding, or relevance. It lacks clarity on whether the definition of “significant” is from the patient’s perspective or the clinical risk assessment, and it lacks details for managing the retrospective discovery of SFs. Primary research, incidental findings, and secondary-use studies are not differentiated, and each has different ethical and regulatory implications. The scope, as previously noted, does not clearly differentiate between SFs requiring urgent medical intervention vs. population-level insights or the responsibilities for different populations.

14. Do you find it clear which actors (HDABs, data holders, data users) are involved and what their roles are (Chapters 2 and 3)?

If no: Please explain

No
This guideline clearly states that it is addressing only the role of the HDAB in receiving SF from the data user and referring the SF to the data holder, and thus it is difficult to assess in the absence of guidance addressing the roles and responsibilities of other components in the system. Cross-border settings present a particular challenge that should be further clarified.

15. Do you consider the responsibilities of HDABs presented in the document (Chapter 4) appropriate to support the implementation of the provisions of the EHDS Regulation on significant findings?

I don't know – please explain
As previously noted, insofar as this guideline addresses only the role of the HDAB in receiving SF from the data user and referring the SF to the data holder, the responsibilities are clear. As stated, if the HDAB has also been responsible for pseudonymization, further clarity would be helpful, as would settings of cross-border transfer of SF information.

16. Do you find the level of detail provided in the recommendations for process and the communication between actors (Chapter 3) appropriate?

Unclear – please explain
The conceptual flow is clearly laid out. As with other aspects of this document, however, the procedural details are insufficient to be functionally operational. Details such as timelines, standards of data validation, procedures for data re-identification, and communication pathways require further specificity. The technical infrastructure for secure communications, auditability requirements (if any), interoperability, and minimal standards for reidentification are needed. Further missing details include criteria for situations when re-identification is justified; thresholds for minimum dataset quality; instructions for managing AI-derived findings; clinical validation standards and adjudication committees; and population-specific communication workflows (e.g., pediatric, persons with intellectual disabilities). Issues related to the lack of interoperability of EHRs across sites and Member State systems are particularly problematic

17. Do you see any technical or organisational challenges in implementing the notification of significant findings under the EHDS Regulation as described in the document?

Max. 5000 characters.

There are multiple and significant challenges that may impede implementation. First, a secure and interoperable system for matching identities across Member States is necessary, as well as standards and clarity for pseudonymization methods. Multinational (cross-border) interoperability is essential for establishing a robust data infrastructure with secure data transfer capabilities, standards for metadata, and protocols for quality, versioning, and validation.
Challenges include the fact that critical data is often missing from secondary datasets (e.g., family history, developmental stage, medications), which undermines the determination of SFs; lack of clinical expertise and validation complexity; resource needs for clinical validation of data (e.g., domain expertise, specialist committees, and structured procedures; systems for re-identification, case tracking, and communication with requisite infrastructure investments. These issues may be further compounded by the varying national rules that govern each Member State, which impede accurate and timely notifications.
Which entity is responsible for honoring the right “not-to-know” and for maintaining the currency of that choice?
Throughout this guidance, inadequate attention is paid to emerging AI signal-detection algorithms that generate large volumes of “potential findings” of uncertain validity.
Significant challenges exist in reidentification infrastructure, clinical validation pipelines, interoperability, workforce capacity, and cross-border coordination. Without detailed operational models, technical specifications, and investment in Member State capacity, implementation will be fragmented and inconsistent.

18. Do you see any legal or data protection challenges in implementing the notification of significant findings under the EHDS Regulation as described in the document?

Max. 5000 characters.

The notification obligation introduces significant legal and data-protection challenges that the draft guideline does not yet resolve. Key risks relate to lawful basis, role allocation, reidentification safeguards, the right not to know, proportionality, accuracy, and divergence across national legal systems. To ensure compliance and protect individuals' rights, the guideline will need more explicit operational guidance, clearer legal mapping, and stronger safeguards for reidentification, communication, and controller accountability. Some but not all involve the HDAB role as it is described in this guideline.
The EHDS creates a new legal obligation for HDABs to notify data holders of SF derived from secondary use. GDPR, however, requires a legal basis for processing, including reidentification and communication. How does one reconcile these two legal frameworks? Importantly, even if one establishes a legal basis for processing, secondary-use research is often conducted for research, not clinical care. Recontacting individuals for potentially health-relevant information may fall outside the original purpose. The guideline acknowledges shared responsibility but should define which entity is the controller for identifying a finding, validating it, reidentifying a person, performing the notification, or providing post-notification support with case examples (e.g., HDAB performs pseudonymization and holds the key, other, etc.), including the complexities introduced by cross-border notification. The responsibility for maintaining and respecting the 'right not to know,' under various scenarios, should be clarified. Notifying an individual requires reidentification, which reintroduces the risks of identifiability. Much pseudonymized data remain personal data; HDABs must balance safe reidentification with data minimization principles. Liability for misidentification or failed reidentification is not addressed.

19. Is the level of flexibility foreseen for national implementation sufficient while ensuring compliance with the EHDS Regulation?

If no: Please explain

No
The level of flexibility negatively impacts national implementation, with Member State differences undermining the goal of harmonization. Equity and consistency can only be ensured with minimum common standards for validation, communication, and timelines, coupled with a responsibility grid. Excessive flexibility can lead to divergent interpretations, including variations in standards for clinical validity and actionability, data re-identification procedures, and data validation standards. The lack of harmonization will ultimately have a negative impact on harmonization efforts and trust. Supporting equity across the Member States can be enhanced with the issuance of grievance processes and standards.

20. Is the level of legal and technical interoperability foreseen for national implementation sufficient to ensure harmonised implementation of the EHDS Regulation?

If no: Please explain

No
Major gaps remain, including interoperability across EHR systems, consent-tracking tools, and cross-border identity management. Without a harmonized technical layer, inconsistent implementation will continue to be problematic. Significant gaps remain in technical interoperability, re-identification procedures, and governance frameworks. The lack of a harmonized vocabulary will magnify interoperability issues, as will gaps in definitions and identifiers for cross-border patient movement. Without harmonization in these and likely other regards, cross-border secondary-use research will be impeded.

21. Do you consider the data protection aspects of notifying significant findings clearly explained and appropriate in the document?

I don't know – please explain
As previously noted, various key elements, including lawful basis for re-identification, responsibilities under GDPR, handling of preference changes, and minimization principles, remain problematic and require enhanced clarity. Furthermore, pediatric data protection issues, the lawful basis for re-identification, communication pathways (e.g., to guardians versus adolescents) and cross-border discrepancies are not addressed in sufficient detail. Once SF notifications occur, it is not clear what the audit processes or access to data sources will be.

22. Do you consider the recommendations on the issues to be addressed at national level are appropriate to support the implementation of the obligations concerning significant findings under the EHDS Regulation (Chapter 4)?

I don't know – please explain
The recommendations provide a general direction but not sufficient actionable detail. National guidelines should require patient and public involvement in the implementation processes and should include specifics on clinical validation, population-specific processes, data quality standards, and cross-border coordination, in addition to the areas discussed above.

23. Do you think the guideline should include recommendations on the communication format (e.g., plain language, layered information, patient portals) for notifying individuals?

If no: Please explain

No
Clear guidance and recommendations on plain-language communication, accessibility standards for people with disabilities, layered disclosures, digital patient portals, and accessibility are necessary to ensure that individuals understand SFs sufficiently and can then seek follow-up consultation and care, as indicated. Processes for notification of SFs in urgent situations should be made explicit. The needs of specific populations (e.g., people without digital access or low digital literacy, people with disabilities, pediatric populations) require tailored communication that includes population-specific and age-appropriate materials, layered plain-language explanations, patient portals, and consideration of mental health needs. Miscommunication risks are high without such guidance.

24. What kind of capacity-building, funding, or infrastructure would HDABs need to operationalise this notification obligation in a sustainable way?

Max. 5000 characters.

Implementing notification of significant findings under the EHDS will require HDABs to build technical, organizational, clinical, and governance capacities. Dedicated funding, specialized personnel, interoperable digital infrastructure, and long-term institutional development are needed.
First, as mentioned above, HDABs and all other stakeholders) require a consistent understanding of “significant findings,” triage protocols, and decision thresholds that will be critical to prevent fragmentation across institutions and Member States.
Second, HDABs will require robust technical infrastructure for secure reidentification, including privacy-preserving identity management systems, secure encryption, key management environments, and audited channels. Member States will need to develop and operationalize interoperable pseudonymization or record-linkage systems capable of handling large-scale, cross-border secondary-use data. HDABs will require investment in high-assurance authentication, national patient identifier integration, logging tools that meet GDPR Article 32 requirements, and cross-border capabilities. The success of the notification obligation depends on interoperable health information systems, national electronic ID schemes, and secure data exchange networks.
Third, sustainable implementation will require dedicated clinical and scientific validation capacity. Before a finding can be communicated, its scientific validity, clinical actionability, and potential impact must be assessed by qualified experts. HDABs will therefore need to develop or access panels of clinicians, geneticists, biostatisticians, AI specialists, and domain experts who can review findings and document rationales. For many HDABs, this represents a new function that will require resources to maintain expert panels, digital systems, training, and staff. Appropriate funding models must be developed.
Fourth, a structured communication infrastructure is needed to deliver notifications effectively to data holders (or, if the HDAB is a data holder, to the individual). Effective systems must support secure messaging, multilingual communication, and integration with national patient portals or digital health records. Because Member States' digital maturity varies widely, HDABs may require new platforms for sending sensitive health-related information and for routing communications through appropriate intermediaries (e.g., investigators, clinicians, or primary care providers). Audit trails, preference management for individuals who exercise the right not to know, and escalation pathways for urgent findings are necessary.
Fifth, HDABs may require additional capacity-building and long-term funding. They will need specialized staff trained in data protection, the ethics of returning results, risk communication, and the management of vulnerable populations.
Sixth, implementation demands formal governance structures and legal support. HDABs must maintain clear accountability frameworks, model contractual clauses, and joint-controller arrangements that define roles for data users, data holders, and clinical intermediaries. Sustained legal expertise will be required to manage cross-border cases, national legal divergence, and compliance with GDPR transparency and fairness

principles. These governance systems must also facilitate oversight, auditability, and reporting to supervisory authorities.

25. Should the guideline provide more guidance on cross-border scenarios (e.g., how findings are notified when data users and data subjects are in different Member States)?

If no: Please explain

No
Cross-border research is standard in clinical trials and in other research and innovation modalities. Notification pathways, jurisdictional responsibilities, timelines, and liability need harmonized EU-level guidance to avoid fragmentation with implementation in the Member States. An EU-wide registry or “help desk” to assist with cross-jurisdiction SF notifications or other complicated cases would provide additional support.

26. Do you believe that this obligation, if not uniformly applied across Member States, could affect citizen trust in the EHDS framework?

If no: Please explain

No
Inconsistent notification practices would erode public trust. If citizens in certain Member States receive clinically important information while others do not, the EHDS will be perceived as inequitable and unreliable. Inconsistencies in whether and how individuals receive significant findings—particularly across borders (and potentially magnified by divergent socioeconomic contexts) could undermine trust in the EHDS, clinical research, and the fairness of health data reuse. Transparency via published implementation audits across the Member States could enhance perceptions of fairness and equity in data access and re-use.