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 *

Netherlands

2. Type of responder *

Other
Non-profit foundation

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

If yes: On behalf of how many organisations?

No

4. Sector *

Other
Health data research infrastructure

5. Organisation size *

Small to medium enterprise (10–249 employees)

6. Professional role / function

No answers

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.

Generic feedback applying to this guideline:
The guideline clearly describes the HDAB's procedural role, although its narrow scope limits its contribution to harmonised EHDS implementation. While the content is mostly clear, challenges remain regarding differing national interpretations of what is considered a significant finding, the potential overburdening of data holders with having to follow up the notifications, and balancing data protection with enabling findings by using individual level data. Furthermore, some content is repeated (e.g., examples of significant findings in both 5.2 and 5.3) and could be streamlined.

Although this may be addressed in Milestone M8.4 or in future guidance provided by the EHDS Board, there is currently uncertainty about how data users should classify findings as "significant" when using data from multiple Member States with different national criteria.

The guidelines states that Member States are encouraged to establish clear national processes and to build the necessary capacity within HDABs. We are concerned that not all Member States will have clear national processes or capacity. This might affect citizens' trust in the EHDS framework.

Generic feedback applying to all guidelines:
The implementability of the guidelines is a key concern. The "data journey" workflow should function end-to-end in a minimal form from the start and then mature gradually. It is neither feasible nor advisable to regulate all details upfront through implementing acts; a learning-by-doing approach is needed. However, this must not create wide national discretion leading to divergent Member State practices, as seen under the GDPR. Early phases should therefore combine gradual growth with clear, directly implementable requirements that prevent differing interpretations.

Each guideline should follow an iterative learning and development path. Implementation should begin with a limited scope—fewer mandatory fields and requirements—while establishing predefined timelines for expanding obligations without fixing their exact content in advance. Each phase should be evaluated and should determine which additional mandatory elements will be introduced in subsequent stages.

The Chapter 4 guidelines are largely written from a cohort- and research-driven angle. Because the data mainly originate from healthcare delivery, the guidelines must also reflect a clinical care perspective. Clinical expertise should therefore be involved in shaping the substantive guidelines, including those linked to Chapters 2 and 3 of the EHDS.

Each guideline should contain cross-references to other relevant guidelines and explicit links to Chapters 2 and 3 of the EHDS. Current coherence is insufficient: timelines for input and consultation are sometimes too short, and the level of detail varies widely across documents. In some cases, content is not fully aligned. A single reader's guide for all documents would improve usability, and terminology as well as roles and responsibilities should be made consistent.

The TEHDAS2 documentation, describing processes for data application and data discovery, is drafted mainly from the perspective of a centralised analysis environment. It provides too little clarity on federated analytics, its implications (e.g., the need for permits controllable by data stations), and the advantages and disadvantages of centralised versus federated approaches.

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?

Yes

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

Unclear — please specify
The introduction states that the guideline focuses solely on describing the procedural role of the HDAB. It does not address the responsibilities of data users regarding when and how to report significant findings to HDABs (this is foreseen in Milestone M8.4), nor does it clarify how Member States should operationalise the individual's right not to be informed. However, the guideline does touch upon those topics. On the other hand, according to the introduction, the guideline 'contributes to a harmonised and rights-respecting implementation of the EHDS across Member States'. However, given that its scope is limited to the procedural role of the HDAB — which is relatively narrow — we expect that this guideline alone will not substantially contribute to harmonised implementation of the EHDS across Member States.

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

If no: Please explain

Yes

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
The roles are generally described clearly, and some of the current gaps will likely be addressed in Milestone M8.4 or are described in the chapter about what issues have to be addresses at Member State level. However, the interpretation of what constitutes a significant finding may differ between countries. It is not clear which actor should bridge this gap when a data user (who may work with data from multiple countries) is uncertain about what qualifies as a significant finding in each Member State, what might lead to notifications of findings that are not considered significant in the end.

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

The HDAB's described responsibility is to receive and forward significant findings, acting solely as an intermediary in the reporting chain (according to the guideline). In our view, the most critical phases are the discovery of the significant finding and the communication with the data subject — both of which are outside the HDAB's remit and, therefore, beyond the scope of this guideline. Without a clear understanding of those phases, it is difficult to assess whether HDABs should have additional responsibilities beyond those currently described.

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

Appropriate. However, in cases of international data use, it would be helpful to include additional guidance on how to handle findings that might be considered significant in one Member State but not in another. We assume that this will be covered in Milestone M8.4.

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.

We foresee challenges particularly in international data use, as Member States have different national rules defining what constitutes a significant finding. While full harmonisation may not be feasible, it is important to provide sufficient support for all parties to ensure clarity and consistency when dealing with diverging national procedures.

Additionally, we anticipate practical challenges for data holders that may receive large numbers of notifications of significant findings (for example, the Hartwig Medical Foundation). This could include multiple notifications of the same finding or findings already known to the data holder. It is essential to prevent data holders from having to devote excessive time and resources to the administration, validation, and follow-up of findings that ultimately are not transmitted to the data subject (e.g., because they are already known or clinically insignificant).

The guideline appropriately emphasises that only findings with substantial consequences for an individual's health or well-being should be classified as significant, which sets a high threshold and helps to avoid overburdening individuals with uncertain or non-actionable information. This approach also benefits data users and holders by preventing the process of identifying, documenting, communicating, and following up on findings from becoming unmanageable.

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 guideline includes the following statement: “Criteria on completeness, consistency, and representativeness should be applied in a way that facilitates the identification of significant findings to researchers, to prove their result's validity, and subsequent communication by HDABs. For example, genomic datasets should retain sufficient detail (e.g., variant-level information rather than aggregated summaries) to enable the validation of pathogenic mutations, and laboratory datasets should maintain precision in measurement units and reference ranges so that abnormal values indicating conditions such as leukaemia can be reliably interpreted.”
This appears to suggest a preference for the use of individual-level data over aggregated summaries, thereby potentially prioritising the facilitation of identifying significant findings over data minimisation and privacy protection. If this interpretation is correct, we are concerned that the balance between enabling significant findings and ensuring data minimisation may be misaligned — particularly since significant findings are currently relatively rare.

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

If no: Please explain

Yes

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
Although this may be addressed in Milestone M8.4 or in future guidance from the EHDS Board (in accordance with Article 94(2)(c) of the Regulation), there remains uncertainty about how data users should classify findings as “significant” when using data from multiple Member States with differing national rules.

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

Yes

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)?

Yes

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
If the guideline's scope remains limited to the procedural role of the HDAB, then recommendations on communication format would fall outside its remit. However, it is important that such recommendations are included in other, more relevant guidance documents.

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

Max. 5000 characters.

HDABs would require an easy-to-use but secure system to receive, transmit, and track all notifications of potentially significant findings efficiently.

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

Yes

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

Yes

Finish