Summary page:
TEHDAS2 public consultation on draft guideline for Health Data Access Bodies on implementing opt-out from the secondary use of health data

This consultation has 4 pages and 24 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? *

4

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

3

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:
In general, the document is clear and describes how to implement the opt-out for reuse very well. It covers most relevant topics. We have three main suggestions for improvement:

In discussing the possibility of offering granularity in the opt-out procedure, we want to stress the fact that granularity also comes with serious downsides with respect to administrative burdens and the undermining of the overall coherence and interoperability of the EHDS framework. We agree with these downsides and propose that in order to overcome these issues, a small number of sets of essential, meaningful opt-out levels should be provided as either obligated or strongly suggested options. This will stimulate Member States to increase overall coherence and interoperability of the EHDS framework. Further, it may aid in restricting the overall granularity. We should

learn from the lessons provided by the Dutch Steering Committee Specific Consent, who informed the Dutch Minster of Health by letter1 that a high level of granularity is not feasible and causes patients to lose the overview over what is asked of them. We should learn from these experiences instead of trying to re-invent the wheel and ending up drawing the same conclusions. Importantly, with decreased granularity, the importance of providing proper information towards patients and citizens cannot be understated.

Reading between the lines, the guideline mentions the entity responsibly for implementing the opt-out mechanisms as a singular entity ('an opt-out database'). We feel that to avoid confusion, it is necessary to state explicitly that there should be one 'single point of truth' regarding citizens' opt-out statuses. Of course, several digital or non-digital channels should be available for patients and citizens to exercise their right to opt-out. However, the only feasible way to implement this opt-out right would be to have a single point of truth. A national opt-out registry with appropriate information and communication.

A topic that deserves more explanation is the relation between the opt-out for secondary use and reuse of data (and residual tissues and images as containers of data) that are collected earlier under informed consent. Given current discussions in the field, it would be helpful if it would be made explicit that the opt-out applies to these data as well, to avoid data holders' reluctance in data sharing. Also, it should me made explicit how HDABs and/or data holders should deal with the conditions under which these data are collected (e.g. if the data are collected under the presumption that only one organisation will use the data) and which information strategies HDABs or Member States can employ to provide clear information about this change in approach in data re-use.

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; a learning-by-doing approach is needed. However, this must not lead to divergent Member State practices, as seen with 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 angle. Because the data mainly originate from healthcare, 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 opt-out from the secondary use of health data

11. Will this guideline impact your organisation or activities?

If no: Please explain

Yes

12. Is scope and aim of the guideline clearly described in the Introduction?

If no: Please explain

Yes

13. Do you find the description of the opt-out with regard to electronic health data (Chapter 2 Opt-out from what?) sufficiently clear?

If no: Please explain

No
Actually yes, but with the exception that it should be made clearer that the opt-out also includes re-use of health data (and residual tissues and images as containers of data) that is collected under informed consent pre-EHDS.

14. Do you find it clear which roles with regard to the opt-out may be delivered by HDABs, data holders, trusted data holders and Member States?

If no: Please explain

Yes

15. Are the responsibilities of HDABs described in Chapters 3 & 4 appropriate to support the implementation of the opt-out?

If no: Please explain

No
Actually yes, but please add clearly the necessity of a ‘single point of truth’ regarding the opt-out. There should be national opt-out registry where all data holders are connected too or where citizens can control their opt-out.

16. Is sufficient detail provided in Chapter 4 “How to declare opt-out?”?

Unclear – please explain
Yes (appropriate), but please add 2 or 3 mandatory or strongly suggested best practices regarding the granularity to increase internal coherence and interoperability within the EU. The more granularity the less coherence between member states, which is undesirable. Additionally, we ask for clarity regarding the exception from the right to opt out in terms of public interest. Lastly, we think it is of great importance to pay attention to biases after the opt-out process has been implemented. We believe this is crucial for the validity, inclusivity, and scalability of research results.

17. Do you see any legal challenges in implementing the opt-out as described in the guideline?

Max. 5000 characters.

No.

18. Do you see any data protection challenges in implementing the opt-out as described in the guideline?

Max. 5000 characters.

No.

19. Does the guideline accurately describe the flexibility available for national implementation of the opt-out?

If no: Please explain

No
Actually yes, but less flexibility in implementing the granularity of opt-out, will increase interoperability within the EU. Procedures should be clear and harmonized for EU citizens.

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
granularity of opt-out should be restricted to harmonise implementation of the EHDS Regulation.

21. Is the relationship between GDPR and the EHDS Regulation regarding the opt-out clearly explained (Introduction and Chapters 1, 2, & 9)?

If no: Please explain

No
relation between data collected pre-EHDS under GDPR-consent should be explicated.

22. Are the recommendations for engagement and empowerment appropriate to support implementation of the right to opt?

If no: Please explain

Yes

23. Are the proposed steps for implementing the right to opt-out feasible for HDABs to adopt in practice?

If no: Please explain

Yes

24. Which sections or subject matter in the document require further elaboration?

Max. 5000 characters.

See above.

Finish