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 *

Belgium

2. Type of responder *

Other
European Doctors

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

If yes: On behalf of how many organisations?

No

4. Sector *

Health care provider

5. Organisation size *

Not applicable / Individual citizen

6. Professional role / function

Senior Policy Advisor

Quality

7. Is the document easy to understand? *

3

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.

This submission highlights critical considerations for the implementation of opt-out mechanisms for secondary data-use covered in TEHDAS2.
The comments focus on minimizing operational burdens on healthcare providers, maintaining trust in national systems, ensuring robust privacy safeguards, and preventing unintended consequences such as data misuse or degradation of registry quality.

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 answers

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

No answers

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 answers

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

No answers

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

Max. 5000 characters.

Risk of burden on small healthcare providers
Relevant Sections: 4.2, 5.4
Small entities such as general practitioners often operate as micro-enterprises with limited capacity. It should not be possible for a country to delegate the responsibility for managing opt-out processes or implementing technical solutions to small enterprises. Opt-out mechanisms must be centralized and managed nationally, avoiding any requirement for individual electronic health records owners or clinics to handle patient requests or technical compliance. Additional patient inquiries regarding opt-out could significantly increase workload for clinicians. Clear national communication strategies are essential to prevent this and must be required.

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

Max. 5000 characters.

Pseudonymisation and national control
Relevant Sections: 4.2, 5.2.2
It must be explicitly stated that pseudonymisation or anonymisation occurs nationally before any data is shared across borders. This is essential to maintain public trust, particularly in countries with strong societal trust like the Nordic countries. Any secondary use involving identifiable data by foreign entities or commercial entities must require consent or another appropriate legal basis according to national law (for example, in Norway it would be explicit consent) and the principles of medical ethics. Clear communication of this framework is critical to avoid misconceptions and resistance.

National discretion - Section 5.7.2
Please indicate that Member States should explain what safeguards they foresee for Article 77(4) of the EHDS, in particular who controls whether the conditions of Article 77(4) are met and who has the power to act in case the conditions are not met.

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

If no: Please explain

No answers

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 answers

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 answers

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

If no: Please explain

No
Risk of misunderstanding among citizens Relevant Sections: 5.1, 5.4 Citizens may not fully understand what they consent to or opt out from, which could undermine trust. The guideline should emphasize clear, plain-language communication and user-friendly interfaces to mitigate this risk. A huge risk is that certain groups will use the EHDS initiative to spread disinformation and division among citizens. Granular opt-out options Relevant Sections: 5.1.4, 5.2.3 The guideline should explore granular opt-out mechanisms (e.g., by data type or purpose) to enhance citizen control without introducing excessive complexity. The level of granularity should be decided at the national level to respect national traditions and cultural differences. This approach can improve trust and engagement while maintaining usability.

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

If no: Please explain

No
Clinical documentation and workload Relevant Sections: 5.4 All clinical documentation should serve a clinical purpose. Clinical data may be reused for secondary purposes, but extraction must occur without adding workload or disrupting patient care. Clinicians must be protected from documenting information solely for secondary use.

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

Max. 5000 characters.

Preservation of registry quality
Relevant Sections: 5.1, 5.9
High opt-out rates risk degrading the quality of existing national health registries, which are critical for research, public health monitoring, and quality improvement. The guideline should to a higher extent acknowledge this risk and encourage strategies to maintain representative datasets while respecting individual rights and autonomous decision-making.
A discussion on what would be the acceptable target of opt out (e.g. 90%, ie 10% opt out or?) would be wise to align all stakeholders.

Transparency and Logging
Relevant Sections: 5.5
Public registers should provide aggregated information only, such as which institutions accessed which datasets and for what purpose. It must be clear that individual-level backtracking is not possible, reinforcing privacy guarantees.

Preventing misuse of “societal benefit”
Relevant Sections: 5.9
The guideline should address the potential loophole where commercial actors frame projects as societal benefit research to gain access to data despite widespread opt-outs. Specific recommendations to prevent such misuse are required.