

Summary page:
TEHDAS2 public consultation on Draft guideline on a framework for collaboration

This consultation has 4 pages and 21 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
Professional representative organisation

3. Are you responding behalf of several organisations? *

If yes: On behalf of how many organisations?

No

4. Sector *

Other
Medical doctors

5. Organisation size *

Micro (1–9 employees)

6. Professional role / function

Secretary General

Quality

7. Is the document easy to understand? *

4

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

4

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 document brings important reflections, in particular the need for a structured feedback loops to ensure that health data holders receive information about the research outputs that their data generated. This should actually be applied in relation to clinically relevant outcomes, ensuring a robust procedure to update medical protocols, as appropriate, to reach the medical workforce, and thus ensure the public benefit of the outcome.
The recommendations will imply strong and continuous strategic alignment in the different areas and among all parties, which might be difficult to ensure.

The following questions are specific for TEHDAS2 Draft guideline on a framework for collaboration Part I - Conditions for Collaboration

Ethical governance

11. Are there any significant challenges related to ethical governance under the EHDS that are not reflected in this section?

Max. 5000 characters.

The challenges presented are very relevant and should be addressed. A point to explore further should be the use of AI in the decision-making process to ensure meaningful and effective human oversight throughout the procedure.

12. Do the recommendations on ethical governance adequately address the challenges identified? Are there recommendations you would add or prioritise differently?

Max. 5000 characters.

In relation to recommendation 3, on strengthening capacity and expertise for ethical assessment, there should be mandatory common training conducted by the EHDS Board for national public officials working in the Health Data Access Body (HDAB) to ensure alignment not only on public interest and societal benefit meanings, but also on the permitted and prohibited purposes, particularly in order to deal with multi-country applications.

Collaboration models and coordination mechanisms

13. Are there any significant challenges related to collaboration and coordination under the EHDS that are not reflected in this section?

Max. 5000 characters.

The challenges presented are very relevant and should be addressed. The workload pressures for health data holders (HDH) should be explored further, as support for data preparation pipelines and provision to the HDAB is still unknown, though being key for good collaboration with HDAB. The draft guidelines can also recommend Member States to consider the development of national roadmaps, coordinated by the European Commission, which identify the capacity and maturity of HDH to contribute to the EHDS, among other aspects. This preliminary exercise would avoid creating unnecessary workloads for HDH in providing datasets descriptions for HDAB, in particular if such data would not be used due to lack of data quality or data harmonisation. This preliminary exercise should involve national medical associations to support with medical ethics considerations.

14. Do the recommendations on collaboration models adequately address the challenges identified? Are there recommendations you would add or prioritise differently?

Max. 5000 characters.

Recommendation 2, on establish structured and inclusive support for health data holders, should include the additional possibility of offering structured dialogues between the health data holder and the HDAB, without repercussions (e.g. imposition of administrative fines), in case the requested data is not able to be provided for technical or ethical reasons. There can be cases where HDH cannot provide the data requested, either due to i) lack of time, ii) know-how, iii) the quality of the data, which could lead to incorrect interpretations due to lack of clinical context, iv) pending implementation updates of a patient opt-out, v) the transfer channel to HDAB does not offer sufficient safeguards to ensure minimisation, privacy, personal data protection and confidentiality of personal electronic health information, among other reasons. The power to fine from HDAB should be a last resort and after structured dialogues take place.

Protection of IP rights and trade secrets

15. Are there any significant challenges related to protection of IP rights and trade secrets under the EHDS that are not reflected in this section?

Max. 5000 characters.

No answers

16. Do the recommendations on protection of IP rights and trade secrets adequately address the challenges identified? Are there recommendations you would add or prioritise differently?

Max. 5000 characters.

No answers

Part II - Research Infrastructures and Networks in the EHDS

Mapping of services and functions

17. Does the mapping of services and functions provided by research infrastructures, networks, and cross-border initiatives in the health data reuse ecosystem feel complete? Are there services, functions, or types of organisations that should be added or better reflected?

Max. 5000 characters.

No answers

Roles and pathways for research infrastructures in the EHDS

18. Are the roles and pathways described for research infrastructures in the EHDS context clear and accurate? Do you have any suggestions for how they could be improved or refined?

Max. 5000 characters.

No answers

19. Do the observations from stakeholder engagement on role allocation reflect the perspectives of your organisation or community? Are there any additional remarks or perspectives that should be considered?

Max. 5000 characters.

The points addressed in relation to data preparation (p 42), community support, training and engagement (p 43), embedding domain expertise in the governance from the outset (p 44), and designing an integrated ecosystem with a sustainable value chain (p 45) are relevant for CPME.

Recommendations

20. Do the recommendations on collaboration models for research infrastructures in the EHDS secondary use framework adequately address the key challenges? Are there recommendations you would add, modify, or prioritise differently?

Max. 5000 characters.

In relation to HDH, the draft guidelines could develop recommendations which suggest healthcare software manufacturers to develop solutions which can support HDH in complying with secondary use obligations, such as automating the creation and provision of dataset descriptions for health data access bodies.

General remarks

21. Does this document adequately address the topic of collaboration in the EHDS secondary use framework? Are there perspectives, actors, or dimensions of collaboration that you feel are missing or should be given greater attention?

Max. 5000 characters.

No answers