

Summary page:
TEHDAS2 public consultation on Draft guideline for data users on handling research outcomes

This consultation has 5 pages and 30 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, 4 and 5 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? *

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.

The document repeats the overarching obligations without going into detail on how to fulfil them. Presenting more concrete examples would help data users on what is the level of detail for output reporting (see for example, page 12, third paragraph, last sentence; page 13 section 5, third paragraph.
A specific mechanism should also be suggested on how clinically relevant outcomes are officially informed and reach the medical workforce, in order to revise and update medical protocols, as appropriate, and thus ensure the public benefit of the outcome. This return is the most important for the medical profession (section 7.3 is not sufficient).

The following questions are specific for TEHDAS2 Draft guideline for data users on handling research outcomes

11. Is the scope and aim of the guidance clearly described in the Introduction (i.e. handling of research and innovation outcomes under the EHDS)?

Yes

12. Are the key concepts (e.g. “outcomes”, “results”, “outputs”) clearly defined and used consistently throughout the document?

No – please explain
The key concepts are consistently used, but they are not defined in the paper. The guidelines would benefit from a definition or a distinction between “results” and “outputs” in the executive summary, page 4. The explanation of what is an “outcome” is clear, in page 4.

13. Is the intended target audience (secondary data users) clearly identified and consistently addressed throughout the document?

Yes

14. Is the relationship between the EHDS Regulation and the GDPR for secondary data users explained in a clear and legally accurate manner?

No – please explain
In table 1, page 11, in relation to the row on “export of processed data”, the term “transfer of personal data” under the GDPR is normally understood as transferring personal data to third countries or international organisations (Chapter V of the GDPR). Though the exact term of “download” does not exist in Article 4(2) of the GDPR to signal “export”, under the GDPR the latter term could fit into the term “retrieval”, “disclosure by transmission” or “otherwise making available”.

15. Does the document clearly distinguish between legally binding obligations and non-binding recommendations or good practices?

Yes

16. Are lawful bases for processing, accountability, and controller responsibilities of secondary data users sufficiently clear and accurate?

Yes

17. Are the roles and responsibilities of secondary data users, HDABs, and health data holders clearly distinguished particularly with regard to outcome handling, reporting, and dissemination?

No – please explain
In page 16, Section 5.5, the terms handling, reporting and dissemination are not used consistently. If “handling” covers reporting, dissemination, export and reuse, management of intellectual property and accountability, it would help to refer it in this section to the term “handling. Consequently, the term “handling” should be included in the scope under section 4, page 8, last paragraph, as covering all obligations in the guideline.

18. Does the document appropriately integrate ethical standards (e.g. research ethics, public interest, proportionality) into guidance on outcome handling?

No – please explain
Examples could be included on recognised international standards of ethical guidance, such as the Declaration of Helsinki and the European Code of Conduct for Research Integrity.

19. Is the guidance on clinically significant findings sufficiently clear, accurate and actionable for secondary data users?

No – please explain
No specific section was found for this point.

20. Are governance boundaries (prohibition of re-identification, notification via HDABs, role of data holders) clearly and consistently respected?

Yes

21. Are the constraints related to secure processing environments (e.g. output control, export limitations) realistically reflected and manageable in practice?

No – please explain
It is not clear how to comply with “the output control requirements of the secure processing environment” – what are these? Only downloading non-personal electronic health data and anonymised data? – please see page 14, section 5.2, second paragraph.

22. Does the document strike an appropriate balance between enabling innovation/IP generation and safeguarding transparency, public interest and EHDS objectives?

Yes

23. Are expectations regarding transparency and reporting of commercially relevant outcomes clear and proportionate and correctly limited to what is required under the EHDS framework?

No – please explain
Section 7.5 is very succinct and broad in what should be informed to the HDAB. Perhaps examples can be provided to understand the level of detail required.

24. Are dissemination and reporting obligations for research, policy, and outcomes related to product or service development (Article 47 EHDS) clearly described?

No – please explain
It is not clear in section 7.4 what the HDAB will publish to comply with their transparency and reporting obligations. There is a wide margin of discretion for HDAB which the guidelines do not help to reduce it.

25. Do you consider the proposed timelines and reporting practices realistic and feasible for secondary data users in practice?

Yes

26. Is the guidance on data sharing and collaboration aligned with EHDS governance and sufficiently clear for secondary data users?

Yes

27. Are cross-border and international collaboration aspects adequately addressed, in line with the responsibilities of secondary data users under the EHDS?

No – please explain
No specific section was found for this point.

28. Do you expect this guidance to have a practical impact on your organisation's or your own activities as a secondary data user under the EHDS?

No answers

29. Which sections of the document, if any, require the most improvement before finalisation?

Max. 5000 characters.

The different forms of outcomes examples should be included in the executive summary, as well as the definitions of “output” and “results. If the latter are to be understood as synonyms for the purposes for the guidelines, it should be mentioned.

30. Any additional comments or concerns regarding the handling of research outcomes under the EHDS that are not covered above?

Max. 5000 characters.

A specific mechanism should be suggested on how clinically relevant outcomes are officially informed and reach the medical workforce, in order to revise and update medical protocols, as appropriate, and thus ensure the public benefit of the outcome. This return is the most important for the medical profession - section 7.3 is not sufficient.
The guidelines should better frame the room for discretion of HDAB in their activities.