Summary page:
TEHDAS2 public consultation on draft guideline for Health Data Access Bodies on fees related to EHDS regulation

This consultation has 5 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, 4 and 5 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? *

2

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 over all the guidelines:
- The implementability of the guidelines constitutes a significant concern. It is essential that, at the outset, the workflow of the “data journey” can at least be executed end-to-end in a minimal form. This should then gradually evolve from a basic process into an increasingly comprehensive one. Accordingly, it is not advisable to attempt to regulate and operationalise all details from the very beginning through implementing acts. Instead, a learning-by-doing approach should be adopted. At the same time, a critical challenge lies in preventing the creation of excessive discretionary space for Member States to establish divergent national legislative arrangements (as illustrated by the shortcomings experienced under the GDPR). Therefore, particularly in the initial phase, a learning and growth perspective should be applied, combined with clearly defined, directly implementable requirements per phase regarding the HOW, which do not allow for differing interpretations or implementations across Member States.

- Each guideline should be designed to incorporate an iterative learning and development trajectory. In this context, implementation should commence with a limited scope, including a reduced set of mandatory fields and/or requirements, while, at the same time, establishing predefined timelines at which additional obligations will be introduced, without predetermining in advance the specific nature of those future obligations. Each implementation phase should serve as a basis for evaluation, on the grounds of which decisions shall be taken as to the introduction of further mandatory elements in subsequent phases.

- The guidelines set out in Chapter 4 are largely drafted from a cohort- and research-oriented perspective. Since the data in question predominantly originate from the healthcare sector, the guidelines should also be formulated from a clinical care perspective. Accordingly, in addition to research expertise, the appropriate (clinical) expertise should be duly involved in the development of the substantive guidelines, including expertise relating to Chapters 2 and 3 of the EHDS.

- Each guideline should include cross-references to other relevant guidelines and should also contain explicit references to Chapters 2 and 3 of the EHDS. At present, the overall coherence between the guidelines is insufficiently ensured, and the timelines and processes for input and consultation meetings are, in some cases, (too) short. Moreover, there are significant differences in the level of detail, with some guidelines being highly high-level, while others are detailed and technical. In certain instances, the substantive content is also not fully aligned across the documents. The inclusion of an overall reader’s guide for the full set of documents would improve accessibility and usability; in addition, attention should be given to ensuring consistent terminology and a uniform roles and responsibilities model.

- In the development of the TEHDAS2 documentation, which describes the full process

of data application, data discovery and related procedures, it has been observed that the documentation is largely drafted from the perspective of a centralised analysis environment. Insufficient clarity is provided regarding the concept of federated analytics, its implications (for example, the requirement that permits must also be capable of being 'controlled' by data stations), as well as the respective advantages and disadvantages of centralised versus federated approaches.

Generic feedback on this particular guideline:

- The HDAB should be a national public utility. Costs of HDAB related activities should not be borne by the data user.
- Investments (financial or otherwise) by a data holder to make health data available for secondary use should be stimulated under the EHDS. The proposed financing in the guidelines will not stimulate but rather stagnate the willingness to invest in technical or other solutions to make health data (more efficiently) available. There is a high risk that data holders will wait for requests to invest in solutions making health data available.
- The proposed invoicing guidelines are too complex, bureaucratic and create a high administrative burden.

The following questions are specific for TEHDAS2 draft guideline for Health Data Access Bodies on fees related to the EHDS regulation

What fees are to be paid

11. In what role/perspective are you replying to this questionnaire according to the definition of the EHDS? *

as a possible Health Data Access Body (HDAB)
as a Health Data Holder (DH)
as a Private Data User (DU)
as a Public Data User (DU)

12. As a Health Data Holder, have you already shared data with data users?

No answers

13. As a possible future Health Data Access Body or a Health Data Holder, are the eligible costs identified representative of the tasks required to respond to a data user's request? What is well captured? What is missing? What should be excluded?

Max. 5000 characters.

The eligible costs are well identified and captured, however, deducting costs for each specific item and data request is very complex and risks high bureaucracy, high administrative burden and difficulties to implement. Moreover, in a thriving health data ecosystem where secondary use is stimulated the HDAB should be a national public utility with governmental funding to adhere to its tasks.

14. Have you developed, or do you plan to develop a data warehouse or equivalent infrastructure to support the secondary use of the health data you hold?

No answers

15. As a Data User, have you already previously submitted requests for secondary use of health data from data holders?

No answers

16. What type of data access projects have you pursued or are planning to pursue?

No answers

17. As a Data User, do you consider current or proposed fee structures predictable enough to support budgeting in grant applications?

Max. 5000 characters.

Fixed fees as far as possible for eligible items

18. Are you planning to compare fees between Heath Data Access Bodies from different Member states to inform your future application strategy?

Yes

19. In your opinion, what level of detail should be displayed in the invoice provided to data users? *

Max. 5000 characters.

Medium

20. In your opinion, are the proposed fees related to the eligible costs fair? *

3

If you selected 1, 2 or 3 above, please explain why it is not fair. *
Max. 5000 characters.

There are no specific fees mentioned in the guidelines, only the eligible costs! However, the guidelines reades throughout the document that only costs related to making the health data available for secondary use can be claimed. This seems fair, however, a huge risk is that it will not stimulate the DH to invest in solutions making health data available for secondary use. From the perspective of the DU it is less fair that the DU is paying in part for the investments a DH is responsible for under the EHDS regulation (keeping in mind that the EHDS should support making investments by the DH to make data available).

21. Do you consider that, in some cases, specific project-related data discovery efforts should be recoverable through fees, even though general discovery costs are not covered by the EHDS Regulation? Please provide examples if applicable. *

Max. 5000 characters.

Yes. In some (many?) cases, the information a DU needs to decide if data is applicable for the intended use, will not be publicly available and a DH would have to make efforts to make clear the details/context of the data. For instance, the DU needs to know the number of eligible patient records to answer the (research)question to perform the correct statistics. The DH then needs to provide the number of records including patients with disease x, scan/imaging y, age z, within a specific time frame. This can be a large effort for a DH to found out. Especially in the beginnings of the EHDS regulation when DH's infrastructures are not mature enough to answer these questions quickly. When time goes by, DH should have an infrastructure in which these detailed questions are answered in an automatic way. Hence, the need to have a financing model that stimulates investments by the DH to facilitate data availability for secondary use.

To whom the fees are paid

22. In your opinion, is the recommended scenario clear enough? *

2

If you selected 1, 2 or 3 above, please explain which part(s) are unclear and what aspect should be clarified?
Max. 5000 characters.

It is overcomplicated and difficult for a DH to specifically deduct all the costs for the specific items.

23. What challenge do you foresee in applying the recommended model in your national or organisational context (e.g. legal, financial, operational)? *

Max. 5000 characters.

1. High risk of implementation difficulties (operational, administrative).
2. The total costs for a request are not predictable. From a funding perspective, in which you need to know upfront wat the costs for the use of the data are, this is a difficulty.

When the fees are paid

24. In your opinion, is the recommended scenario clear enough? *

3

If you selected 1, 2 or 3 above, please explain which part(s) are unclear and what aspect should be clarified?
Max. 5000 characters.

No answers

25. What challenges do you foresee in applying the recommended model in your national or organisational context (e.g. legal, financial, operational)? *

Max. 5000 characters.

For the section ‘When the fees are paid’ no specific challenges are foreseen. However the costs related to the HDAB activities should not be paid by the DU but the HDAB should be a public utility.

Areas for further exploration

26. In your opinion, are there aspects that have not been addressed in the document and should be added to the pending questions section?

Max. 5000 characters.

- The way the financing model is proposed, what should be regulated on a national level? What freedom do the member states have and how do we make sure that there are no undesirable competition between countries? We opt for a growthmodel in which the focus is on possible competition between member states and how to deduce, by every step in the growthmodel.
- In the guideline there is a section about optional reduced fees for specific types of DH's, it is up to the member state to define DH's eligible for a reduction. Also in this case, possible competition between countries as a result of member states decisions should not result in undesirable situations. A growtmodel also taking into account undesirable differences should be one of the focus points.
- Implementing the guidelines as proposed gives a huge risk that DH will not invest in solution to stimulate secondary use of health data within their organization. But instead might wait for DU's to request specific data. Under the EHDS regulation, investments made by the DH should be stimulated and not be discouraged. This is a huge red flag, it has the potency to stagnate a thriving ecosystem of secondary use of health data and is opposite of the objectives and intentions of the EHDS. To counter this, one of the possibilities that needs further exploring in this context is to have reductions or discounts in play for DH that invest in making data available for secondary use, and therefore promoting organisations and institutions to make investments.
- This guideline does not address governmental responsibility towards an HDAB as a national public utility.

- Please clarify further in the Finalisation paragraph or elsewhere in the guidelines what is meant when referring to "Data user must publish the results of secondary use of health data within 18 months of the completion of the data processing in a secure environment or of receiving the requested health data". Does the latter part of this sentence refers to receiving the requested health data IN a Secure Processing Environment, or otherwise?