Summary page:

TEHDAS2 public consultation on draft guideline for Health Data Access Bodies on the procedures and formats for data access

This consultation has 6 pages and 36 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, 5 and 6 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? *

2

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? *

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.

There should be a growth model included in each guideline. Start with a minimal variant and set dates when each member state has to add more mandatory fields/processes/meta data etc. Learn from each stage. In 2029 each member state should be able to implement the HDAB workflow from a to z, in a minimal variant.
The guidelines don't always correspond with other guidelines or chapter 2 and 3 of the EHDS. Provide a comprehensive overview of how the guidelines interact and depend on each step in the workflow process.
This guideline leaves a lot open for the 'pre-application permit contact process' between data user and data holder. In practice there will be a great need to discuss what data is exactly needed. If this process is not taken into account in the timelines, the application process after being deemed complete/approved with a permit can be stagnated and might lead to many applications being unnecessarily complicated for the data holder. This may stall the whole HDAB request and application process.
General comments:
- 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.

The following questions are specific for TEHDAS2 draft guideline for Health Data Access Bodies on the procedures and formats for data access

11. What perspective best describes your role in the implementation of EHDS?

The perspective of a HDAB

Chapter 5 describes the application completeness check phase. This is recommended to ensure that an application is complete before entering the actual application assessment process.

12. Were the points to be checked presented clearly?

2

13. Do you consider the checklists for data access application and data request completeness check (annexes 7 ja 8) helpful in performing the completeness check?

2

14. Do you have suggestions for improving section 5? Was something missing or was something unnecessary?

Please provide feedback, max. 5000 characters.

No answers

Chapter 6 describes the application assessment process that begins after the application has been deemed complete in the completeness check phase. The application contents are reviewed, and it is evaluated whether a data permit can be granted, or a data request approved.

15. Were the different aspects to be reviewed presented clearly?

3

16. Were the What to check points helpful and concrete?

2

17. Do you have suggestions for improving section 6? Was something missing or was something unnecessary?

Please provide feedback, max. 5000 characters.

This guideline leaves a lot open for the contact process between data user and data holder. In practice there will be a great need to discuss what data is exactly needed. If this process is not taken into account in the timelines, the application process after being approved can be stagnated and might lead to many applications being unnecessarily complicated for the data holder.

18. Was the distinction between the completeness check phase and the application assessment phase clearly presented?

3

19. Would the distinction need to be clarified further? If yes, please provide suggestions.

Max. 5000 characters.

YES. The data user and the dataholder will need to discuss what data (fields) is exactly needed for the request. If this process is not adequately addressed this may lead to many requsts being stated as complete, but in practice not able to deliver the data by the holder.

20. Was the distinction between assessing data access applications and data requests clear?

2

21. Would the distinction need to be clarified further? If yes, please provide suggestions.

Max. 5000 characters.

YES
The guideline does not describe how HDAB and dataholders need to prepare, link pseudonomize and push data towards an SPE. It simply states that it's required and HDAB is responsible for it, but it does not state how. Should it link to other guidelines where this is further specified?
How do the guideline(s) link to chapter 2 and 3 EHDS?
How does the guideline foresee in contact between holder and user before and/or during the application request?
Our worry is that there is a lot of space for deviating ways between member states to implement the process of making data available, which may lead to interoperability problems

Chapter 7 describes the steps after the decision and the actions the HDABs need to take. Many of the topics are described in detail in other TEHDAS2 guidelines.

22. Were the responsibilities and actions to be taken after the decision presented clearly and on a sufficient level?

2

23. Do you have suggestions for improving section 7? Was something missing or was something unnecessary?

Please provide feedback, max. 5000 characters.

No answers

The following questions offer an opportunity to comment on the open questions and unresolved issues of Chapter 9.

24. Should the full applications, data permits and data request approvals be published in the transparency portal or only certain information from these?

If the full documents should be published, sensitive information related to e.g. the persons entitled to process the data, the detailed description of the granted data sets or other sensitive information might need to be transferred to a non-public annex or similar. The HDAB must justify all omissions.

YES and eventually maybe even on an individual level through a personal health suite. Merely publishing permits on a website does not give a patinet/client/ citizen more control or transparency what happens to data registered about them.

EHDS Article 68(2) states that the HDAB shall take into account (a) risks for national defence, security, public security and public order and (b) the risk of undermining the confidentiality of data in governmental databases of regulatory authorities.

25. What specific points should be considered when assessing the aforementioned risks? On what level these should be assessed?

No answers

EHDS states that if a data permit needs to be amended, the health data user shall submit an amendment request. Further, EHDS separately mentions two topics that an amendment can concern: extending the data permit validity period once or modifying the authorised persons with access rights to the electronic health data in a secure processing environment.

26. Do you foresee some other points in the data permit that should be allowed to be subject to amendment requests?What kind of implications this would have in your member state?
Potential options could include e.g. transferring the data to another secure operating environment, extracting additional variables from the datasets included in the original permit, and extending the period from which the data are extracted (i.e. extracting more data from the datasets included in the original permit). The original datasets and purpose of use should be maintained.

If the data holder, after the permit has been granted, states that the requested data should be slightly different in order to answer the research question.

Annexes 5-6 of this deliverable are templates for the common European data access application and data request, respectively, to be utilised when applying for data under the EHDS both through the HealthData@EU central platform and national HDABs.

27. Was annex 5 (the data access application template) clear and easy to understand?

2

28. Do you have any feedback related to annex 5 (the data access application template)? Please elaborate.

Max. 5000 characters.

No answers

29. Was annex 6 (the data request template) clear and easy to understand?

3

30. Do you have any feedback related to annex 6 (the data request template)? Please elaborate.

Max. 5000 characters.

No answers

Annexes 9-10 of this deliverable are templates for the data permit and data request approval, to be utilised by the HDABs or the European Commission when granting access to data.

31. Was annex 9 (the data permit template) clear and easy to understand?

2

32. Do you have any feedback related to annex 9 (the data permit template)? Please elaborate.

Max. 5000 characters.

No answers

33. Was annex 10 (the data request approval template) clear and easy to understand?

No answers

34. Do you have any feedback related to annex 10 (the data request approval template)? Please elaborate.

Max. 5000 characters.

No answers

Annex 11 describes the key recommendations for electronic contractual arrangements that may be used by health data holders and health data users for the sharing of data containing information or content protected by intellectual property rights or trade secrets.

35. Was annex 11 (the key recommendations for electronic contractual arrangements) clear and easy to understand?

No answers

36. Do you have any feedback related to annex 11 (the key recommendations for electronic contractual arrangements)? Please elaborate.

Max. 5000 characters.

this needs to be made more clear specifically for private companies requesting and/or holding data