Summary page:
TEHDAS2 public consultation on draft guideline for data holders on making personal and non-personal electronic health data available for reuse

This consultation has 7 pages and 41 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, 6 and 7 consist of questions specific to this document.
Demography

1. Country *

Netherlands

2. Type of responder *

Other
Non-profit

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? *

1

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. 750 characters.

At Q7 Not easy to understand: not because it's not well-written, but because it's a lot of information and complex subjects.
Concrete examples would help understand the document, it's a lot of theory and the interwovenness of the whole TEHDAS2 documentation collection makes it hard to keep the overview. This is partly what makes it hard to implement, besides the obvious challenges of connecting a landscape filled with legacy products and varying standards.

The following questions are specific for the TEHDAS2 draft guideline for data holders on making personal and non-personal electronic health data available for reuse

11. What role do you have according to the EHDS regulation?

An HDAB
Data User
Other
HDAB-NL program

12. (if Data Holder was selected) As a data holder, do you hold open data, restricted non-personal data or personal data, or a mix? Please answer this question according to the majority of the datasets held.

No answers

Chapter 3 “Legal obligations of health data holders under the EHDS regulation”

13. As a data holder, does chapter 3 fit your data type and organisation?

Not applicable

14. Does chapter 3 help you understand the role of a trusted data holder and Intermediation Entity and assess relevancy to your situation?

If no: Please explain

Yes

15. On a scale from 1 to 4,

	1=very little	2=little	3=much	4=very much	not applicable
how much does this chapter help you understand your legal duties?	○	○	◉	○	○
how much do the good practice examples and recommendations in this chapter help you prepare for the EHDS as a data holder?	○	○	○	○	◉
how clear did you find this chapter?	○	○	◉	○	○

16. Where and how could we improve clarity in chapter 3?

Max. 5000 characters.

I worry about this statement:
HDIEs cannot be trusted data holders, page 20. I think certain organisations have the expertise for both roles that may not be found elsewhere and think it could be blocking important work to enforce it like this. I do agree to keep the roles separate or at least to keep responsibilities clear.

17. Are any of your questions relating to your legal obligations and recommended tasks not addressed in chapter 3?

If no: Please explain

No
Paragraph 3.6.2 “Under Article 60(3) of the EHDS Regulation, data holders are required to ensure appropriate data quality when making data available for secondary use” • Feedback: It is not clear from the document 1) what this mean, 2) how the checks/monitoring/etc. will be carried, as well as 3) who will do the checks.

18. Do you have any suggestions for improving chapter 3?

Max. 5000 characters.

Can it be possible that a trusted data holder can also be an intermediation entity? If not, why not? If yes, example?

P20 To support this, the HealthDCAT-AP common metadata model is being fine-tuned and validated in TEHDAS2 for application in the EHDS framework for secondary use, ensuring dataset discoverability and semantic interoperability.”: the expectations raised here of HealthDCAT-AP for data discovery as needed by data users are unrealistic. There will definitely be a need for further information about the data – either through data explorer functions or by communication channels with the data holder. It would be good to replace “ensuring” by “striving for”.
Page 22 I found really informative and important. Helped me understand why there is 3 types and not 2.
Though maybe there should be an addition that still if you want to combine data, you might do a permit for open data? Or at least you would want it in an SPE..
The visualisations are much appreciated.
The emphasis on the need for communication reflects the worry of our stakeholders if the process was to be done without the proper communication. It has often been emphasized that actually without a preparation phase before the request or permit application is needed to ensure correct applications and requests. This would save the HDAB a lot of time.

Chapter 4 “Making Data available”

19. As a data holder, does section 4.1 fit your data type and organisation?

If no: Please explain

Not applicable

20. Does section 4.1 help you assess which data to make available when a data permit or request is approved (section 4.1)?

If no: Please explain

Not applicable

21. On a scale from 1 to 4,

	1=very little	2=little	3=much	4=very much	not applicable
how much does section 4.1 help you understand your legal duties as a data holder regarding which data should be provided (section 4.1)?	○	○	○	○	◉
how much do the good practice examples and recommendations in section 4.1 help you prepare for the EHDS as a data holder?	○	○	○	○	◉
how clear are the processes in section 4.1 described?	○	○	○	◉	○

22. As a data holder, does section 4.2 fit your data type and organisation?

If no: Please explain

Not applicable

23. Does section 4.2 help you prepare the data in case of an approved data request or permit application?

If no: Please explain

Not applicable

24. On a scale from 1 to 4,

	1=very little	2=little	3=much	4=very much	not applicable
how much does section 4.2 help you understand your legal duties as a data holder regarding Data Preparation (section 4.2)?	○	○	○	○	◉
how much do the good practice examples and recommendations in section 4.2 help you prepare for the EHDS as a data holder?	○	○	○	○	◉
how clear are the processes in section 4.2 described?	○	○	○	◉	○

25. Where and how could we improve clarity in chapter 4?

Max. 5000 characters.

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26. Are any of your questions relating to which data to provide or data preparation not addressed in Chapter 4?

If no: Please explain

No answers

27. Do you have any other suggestions for improving chapter 4?

Max. 5000 characters.

Nice that FAIR is linked to places in the documentation and EHDS.
I think the timeframe in which this must be done is unrealistically narrow, thought I'm not a data holder myself. I wonder how often the extension of 3 months would be needed.

Chapter 5 "Providing data"

28. As a data holder, does chapter 5 “Providing data” fit your data type and organisation?

If no: Please explain

Not applicable

29. On a scale from 1 to 4 how much

	1=very little	2=little	3=much	4=very much	not applicable
does chapter 5 help you understand your legal duties as a data holder regarding data provision?	○	○	○	◉	○
do the good practice examples and recommendations in chapter 5 help you prepare for the EHDS as a data holder?	○	○	○	○	◉
help you prepare for the EHDS as a data holder?	○	○	○	○	◉
help you understand how to provide the data to the HDAB or SPE?	○	○	○	○	◉
help you understand the processes after the data has been prepared and provided?	○	○	○	○	◉
how clear are the processes in Chapter 5 “Providing Data” described?	○	○	○	○	◉

30. Where and how could we improve clarity in this chapter 5?

Max. 5000 characters.

No answers

31. Are any of your questions relating to data provision not addressed?

If no: Please explain

No answers

32. Do you have any other suggestions for improving the chapter?

Max. 5000 characters.

Page 54 “However, data holders of open databases do not have an obligation according to the EHDS to provide the data to the HDAB.”
What if the data needs to be linked with personal datasets? HDAB is responsible for fetching it?

Chapters 6 and 7

33. On a scale from 1 to 4, how clear did you find chapters 6 to 9?

3

34. Do you have any suggestions for improving the chapters?

Max. 5000 characters.

Did you mean 6 to 7 instead of 6 to 9? I see 7 as the last chapter.
Maybe also make clear the role that the capability building team will play in more detailed help? Because people may be looking to get all that from these guidelines?

35. On a scale of 1 to 4, how helpful did you find

	1=very little	2=little	3=much	4=very much	not applicable
Annex 3 Maturity levels	○	○	○	◉	○
Annex 4 Considerations for implementations	○	○	○	◉	○
Annex 5 Steps and illustrative checklists for data holders	○	○	○	◉	○
Annex 6 Data holder resources	○	○	○	◉	○

36. Do you have any suggestions for improving Annex 3 Maturity levels?

Max. 5000 characters.

An indication of staff needed to coordinate these actions. How many persons would you need to approach this properly, in relation to organisation size (rough indication of course).

37. Do you have any suggestions for improving Annex 4 Considerations for data holders?

Max. 5000 characters.

The quality registry in the example could very well be well equipped to help others in a HDIE role. Why should that not be allowed? Or should organizational measures be taken to not confuse and mix the roles within the organization of they would combine it?
Important distinction on pag 83: Don't the HDIE's get listed as publisher, and the data holder as data holder? (data holder is introduced in Release 6 of the Central Platform). Meaning the HDIE would be an autonomous entity, a publisher.
A4.2 maybe I missed it, but which is an example of non-personal but still restricted data? I get asked that a lot.

38. Do you have any suggestions for improving Annex 5 Steps and illustrative checklists for data holders

Max. 5000 characters.

No answers

39. Do you have any suggestions for improving Annex 6 Data holders resources

Max. 5000 characters.

No answers

General

40. Did we miss any essential topics in preparing to make data available?

Max. 5000 characters.

Page 9 states:
“It focuses on the health data holders’ responsibilities in the data preparation and provision phases that follow the issuance of a data permit or approval of a data request by a HDAB, as defined in Chapter IV of the EHDS regulation”
But it also focuses on making metadata available and making public data accessible, both are not only after the request, so this statement. is confusing.

Paragraph 3.6.2 “Under Article 60(3) of the EHDS Regulation, data holders are required to ensure

appropriate data quality when making data available for secondary use”

- Feedback: It is not clear from the document 1) what this mean, 2) how the checks/monitoring/etc. will be carried, as well as 3) who will do the checks.

41. Do you have any other questions or comments?

Max. 5000 characters.

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.