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 *

Belgium

2. Type of responder *

Other
European Doctors

3. Are you responding on behalf of several organisations? *

If yes: On behalf of how many organisations?

No

4. Sector *

Health care provider

5. Organisation size *

Not applicable / Individual citizen

6. Professional role / function

Senior Policy Advisor

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. 750 characters.

Page 5 – it summarises that health data holders have to provide data in a “timely, secure and structured manner” which can lead to misinterpretation. Article 60(2) refers to “(…) put the requested electronic health data (…) at the disposal of (…) within a reasonable time and no later than three months”. There is no reference made to “secure and structured data”. Please indicate the precise legal provisions which indicate that the latter two characteristics – secure and structured data - are legally required. Please note that healthcare professionals need to work with structured and unstructured data and this Regulation should not increase administrative digital burdens for healthcare professionals. Recital 56 of the EHDS Regulation is not a binding provision.
Page 10 - CPME agrees with the recommendation for Member States to establish supporting governance structures and infrastructure to facilitate compliance of health data holders of their core duties under the EHDS Regulation, in particular preparing metadata using the HealthDCAT-AP standard or the one adopted at national level.

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?

Other
Representing European Doctors

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

No
Provide more details on the future role and responsibilities of Health Data Intermediation Entities.

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.

Chapter 3.3, “What data needs to be provided and how.” It is not clear how health data holders are expected to collect and deliver this data. The description of healthcare providers (page 12, section 3.1) is inaccurate, as it includes the term “hospital.” A hospital is a building, whereas the other terms refer to persons. This creates ambiguity.

Chapter 3.3, should include a clear statement that electronic data should be submitted in a user-friendly way for healthcare providers, consistent with CPME policy on implementing a user-friendly EHR – please see https://www.cpme.eu/api/documents/adopted/2025/03/cpme_ad_22032025_015.final.friendly.ehds.pdf .

Existing digital data (structured or unstructured) should not have to be manually re-entered into another system (the HDAB).

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

If no: Please explain

Yes

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

Max. 5000 characters.

Section 3.3.2 Dataset descriptions for national dataset catalogues, page 21 – as a general rule all health information is sensitive by default, however access to certain personal data can be more stigmatising than other. The patient should have a role in qualifying what can be highly sensitive, since it is context dependant. Consider whether a highly sensitive data category could be added as another type of health data, allowing such category to be surrounded by stronger safeguards. In relation to non-personal health data that has been rendered anonymous, it is necessary that the identity of the patient is not tracked back (reengineering patient identity).
Section 3.4.1, page 25 - Explain the advantages of using the trusted health data holder under the EHDS mechanism if a parallel system at national level can be faster and cheaper when an applicant requires only electronic health data held from such trusted health data holder. Why an applicant would introduce an application via the HDAB?
Section 3.4.1, page 25 – reference is made to Article 63(7) of the EHDS Regulation where the HDAB may impose proportionate enforcement measures, including penalties and access restrictions, in case of unjustified delays or non-compliance. This paragraph should be complemented with an explanation in relation to the possibility of the health data holder to appeal from the HDAB decision and corresponding deadlines for appeal. National administrative rules should apply in the absence of EU law in this case. This is necessary to avoid discriminatory and unjustified decisions by HDAB.
Section 3.6 interaction and communication in the national EHDS infrastructure, page 29 – time spent with communication and interaction between the health data holder and the HDAB needs to be accounted for compensation. It would also be useful to understand what other interactions can be expected with other parties within the EHDS ecosystem, as they can be disruptive for health data holders, such as clinics, hospitals or healthcare providers, which do not carry out secondary use obligations as their core activity (their primary sole purpose is the provision of healthcare). A section similar to Section 3.6.3. for interactions of HDH with HDAB should be foreseen for other entities.
Section 3.6.2 – cooperation with assessment on data quality and usability, page 30 – the expectation on data quality should be limited in relation to electronic health data from EHRs. Doctors and healthcare professionals record information for the provision of healthcare, not for research purposes. There should be an explicit recognition that the use of electronic health data from EHRs is dependant from the primary source, and that HDAB cannot condition the provision of care, the clinical workflows and how data is recorded with risks for patient safety, errors or misdiagnosis due to the need to use the said data for research. It should be clear that for this data category, HDAB will receive what is possible to share, in full respect of medical confidentiality and professional secrecy. In addition, “free text fields,” are necessary for primary use, as well as images, videos and audios, and they may contain very sensitive information with the possibility of identifying an individual patient. Several scholars have shown that with little information (e.g. weight-size ratio, age and sex), the re-identification of natural persons is possible and remains a risk to protect patient’s privacy – in this sense see Sweeney L, Abu A, and Winn J. Identifying Participants in the Personal Genome Project by Name. Harvard University. Data Privacy Lab. White Paper 1021-1. April 24, 2013. (PDF), ;

Gutmann, A. (2013). Data re-identification: prioritize privacy. Science, 339(6123), 1032-1032, ; El Emam, K., Jonker, E., Arbuckle, L., & Malin, B. (2011). A systematic review of re-identification attacks on health data. PloS one, 6(12), e28071, < https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0028071>; Y. Sei, H. Okumura and A. Ohsuga, "Re-Identification in Differentially Private Incomplete Datasets," in IEEE Open Journal of the Computer Society, vol. 3, pp. 62-72, 2022, doi: 10.1109/OJCS.2022.3175999,

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.

Section 4.1.3 verification, pages 35-36 – there should be assurances that no penalties or sanctions should arise to HDH when it is not possible to provide data in accordance with the request from the HDAB. The examples provided in the guidelines are helpful and many more can still be expected.

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.

Very useful the table 1 summary of key steps for data preparation, page 36. Reproduce similar tables where possible on responsibilities and obligations for each phase of the user journey.

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.

Page 46 it states: “Data validation before delivery: Before delivery, the EHDS Regulation (Art. 60(1)) prescribes a data holder to provide the data for which a data permit or data request approval is issued. This implies that a data holder should perform a data check to ensure the accuracy of the data with respect to the issued data access permit or data request.” If this becomes the responsibility of healthcare professionals, it will inevitably come at the expense of clinical work. A clarification is required as to who should perform this task. CPME believes that it should not be the healthcare professional (who is currently defined as the data holder). The key point is that healthcare professionals must not be burdened with additional administrative tasks. The HDAB should be an automated system that can generate and validate existing data automatically.

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.

No answers

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.

Invite national competent authorities to engage at national level with relevant HDHs and stakeholders representatives of healthcare professionals, in particular national medical associations and chambers.

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.

No answers

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

Max. 5000 characters.

This Annex is useful to understand doubts competent authorities have with the legal provisions. Section A4.1 Legal obligations of health data holders under the EHDS regulation, page 81 – pursuant to recital 56 of the EHDS Regulation, “free text” is considered to be structured data. However, in non-legal language it can be understood that free-text notes are non-structured data. This recital should be evidenced more. Caution with the use of free-text, videos, audios, images notes is also required due to the risk of patient re-identification. It will need to be checked if used.

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

Max. 5000 characters.

Response to question 10 communication & interaction with HDAB, Page 86 - It is not clear why a normal health data holder needs to establish communications with the data user, since the relationship is between the HDH and the HDAB.

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.

Explain the advantages of using the EHDS mechanism altogether if a parallel system at national level can be faster when an applicant requires only electronic health data held from one trusted health data holder.

41. Do you have any other questions or comments?

Max. 5000 characters.

For Q17, as the online form did not allow explaining, CPME replied yes, for the following reasons:
Section 3.6.1 means of communication, page 29 – the guideline mentions that the HDH must confirm the feasibility of the data request through the standardised form. What criteria can be accepted for the HDH to consider that the data request is not feasible, for example, lack of expert knowledge to process the data request in full respect of medical confidentiality and professional secrecy, lack of financial or human resources, etc. CPME would recommend moderation and limit the “appetite” for electronic health data from EHRs to specific trusted HDH that are mature and have the resources to carry out secondary use obligations. A national strategy should be put in place to identify those frontliners HDHs. CPME has advocated for the exclusion of small practices (employing fewer than 50 persons and whose annual turnover does not exceed EUR10 million) from these secondary use obligations, or at least adherence should be made voluntary (at national level) - See CPME position on the European Health Data Space, section 14, page 13, https://www.cpme.eu/api/documents/adopted/2022/11/cpme.2022-065.FINAL.CPME.position.EHDS.pdf

For Q18, due to the limited space, CPME would still like to add in relaiton to Chapter 3 the following suggestions for improvement:
Section 3, first paragraph, Page 11 – add as examples for exemption the case of natural persons such as general practitioners and individual researchers.
Section 3.2.1, Designation process, page 17 – since the EHDS does not mandate the frequency of reviews from Member States on whether trusted health data holders continue to fulfil the “trusted” conditions, the guidelines should provide a recommendation for the frequency.
Section 3.3.2 Dataset descriptions for national dataset catalogues, page 20 – the guidelines recognise that the level of effort required for this task may vary depending on the volume and complexity of data. The creation, updating and maintaining datasets descriptions should be an eligible cost for compensation for health data holders. It is not clear why this cannot count as eligible. Health data holders need to be compensated for incurred costs irrespective of whether datasets descriptions are used or not. This comment is also valid for Section 3.4.2 Invoicing, fees and eligible costs, page 26. It is also important to have clarity on whether “data consolidation” costs are eligible costs (term mentioned in Section 4.1.4 data subset creation, page 35) as well as good practice tasks (e.g. additional validation steps, identified in Section 4.2 Data preparation - data validation before delivery, page 46).