Summary page:
TEHDAS2 public consultation on draft guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data

This consultation has 10 pages and 73 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, 7, 8, 9 and 10 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.

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.

These questions are specific for TEHDAS2 draft guidelines for HDABs on minimum categories and limitations on the reuse of health data

11. Are you currently part of a Health Data Access Body (HDAB) and/or do you expect to have a role in fulfilling HDAB responsibilities under the EHDS Regulation in the future? *

Yes, I am currently part of an HDAB
No, but I expect to take part in HDAB roles/responsibilities in the future

12. To what extent does the guideline provide helpful and feasible interpretation of Article 53 of the EHDS Regulation? *

3

13. To what extent does the guideline provide helpful and feasible interpretation of Article 54 of the EHDS Regulation? *

3

14. Is the overall structure of the guideline (e.g., sections on assessment, definitions, implementation, recommendations) helpful for HDABs' daily work? *

If no: Please explain what structural elements hinder your daily work

Somewhat

15. Are the implementation considerations throughout the document feasible for your national or institutional context? *

If no: What changes or additions would help?

Yes

Any legal, ethical or procedural issues regarding the draft guideline

16. Are there any legal issues that remain unclear or unresolved in the current draft of the guideline? *

If yes: Please explain

Yes
the definition of ‘scientific research’ and the scope of scientific research, especially for access to data by companies (e.g. to validate algorithms) are unclear.

17. Are there any ethical issues that remain unclear or unresolved in the current draft of the guideline? *

If yes: Please explain

No

18. Are there any procedural issues that remain unclear or unresolved in the current draft of the guideline? *

If yes: Please explain

No

19. Do you have any remarks on the section with “Open questions – Matters still to be refined" in the guideline? *

Max. 5000 characters.

Definition of scientific research.

20. Do you have any recommendations for topics to be covered in future updates of the guideline or complementary documents? *

Max. 5000 characters.

-

21. What kind of support would be most helpful for your HDAB to implement this guideline effectively? *

Clarified assessment templates (e.g. standardised forms or annexes)
Legal guidance on borderline cases (e.g. between innovation and marketing)
More examples in the guideline

Article 53(1)(a) – Use in the public interest

22. How well does the guideline support your understanding and evaluation of secondary use requests based on the purpose of "use in the public interest"?

2

23. Clarity of definition

2

24. Relevance of examples

2

25. Usefulness of implementation guidance

2

26. Optional comment or examples

Max. 5000 characters.

No answers

Article 53(1)(b) – Policy making and regulatory activities

27. How well does the guideline support your understanding and evaluation of secondary use requests based on the purpose of "policy making and regulatory activities"?

3

28. Clarity of definition

3

29. Relevance of examples

3

30. Usefulness of implementation guidance

2

31. Optional comment or examples

Max. 5000 characters.

No answers

Article 53(1)(c) – Statistics

32. How well does the guideline support your understanding and evaluation of secondary use requests based on the purpose of "Statistics"?

2

33. Clarity of definition

2

34. Relevance of examples

2

35. Usefulness of implementation guidance

2

36. Optional comment or examples

Max. 5000 characters.

No answers

Article 53(1)(e) – Scientific research

37. How well does the guideline support your understanding and evaluation of secondary use requests based on the purpose of "Scientific research"?

2

38. Clarity of definition

2

39. Relevance of examples

2

40. Usefulness of implementation guidance

2

41. Optional comment or examples

Max. 5000 characters.

The definition of scientific research is not clearly given in the guideline. The guideline mainly explains what scientific research ‘commonly’ or ‘often’ entails. Given that the EHDS wants to give a broad explanation of scientific research, including e.g. innovation and algorithm development, a clear definition of scientific research under the EHDS should be given. There seems to be a large grey zone where activities of especially companies may not be covered by the guidelines, e.g. validation of algorithms.

Article 53(1)(f) – Improvement of health care

42. How well does the guideline support your understanding and evaluation of secondary use requests based on the purpose of "Improvement of health care"?

2

43. Clarity of definition

3

44. Relevance of examples

2

45. Usefulness of implementation guidance

2

46. Optional comment or examples

Max. 5000 characters.

No answers

Article 54

47. Which concrete indicators or red flags should prompt HDABs to suspect a prohibited secondary use (e.g. vague objectives, sensitive populations, commercial ties)?

Max. 5000 characters.

These examples could indeed serve as indicators. It is important that the process and procedures of the application assessment is clear, as the context of every research application can differ. A research request for genomic data can be sensitive in a certain context and unsensitive in another context. Applying lists of research categories or types of data is not a solution.

48. Do you already have a system in place to monitor that data is not used in a way it should not be?

If yes, please describe the system and give examples, if possible.
Max. 5000 characters.

No, current data holders in the Netherlands mainly restrict use by third parties, especially companies, to avoid this issue. Monitoring systems are therefore not in place.

Article 54(a)–(b) – Decisions detrimental to individuals or groups and disadvantaging or discriminating decisions

49. How well does the document support your understanding and evaluation of secondary use requests based on, or showing indications of, uses that are or might be "decisions detrimental to individuals or groups and disadvantaging or discriminating decisions"?

2

50. Clarity of definition

2

51. Relevance of examples

2

52. Usefulness of implementation guidance

2

53. Optional comment or examples

Please provide structured examples of discriminatory uses that have been identified or anticipated, with references. Max. 5000 characters.

No answers

Article 54(c) – Marketing activities

54. How well does the document support your understanding and evaluation of secondary use requests based on, or showing indications of, uses that are or might be "marketing activities"?

3

55. Clarity of definition

3

56. Relevance of examples

3

57. Usefulness of implementation guidance

3

58. Optional comment

Please provide structured examples of (prohibited) marketing uses that have been identified or anticipated, with references. Max. 5000 characters.

No answers

Article 54(d) – Developing harmful product or service

59. How well does the document support your understanding and evaluation of secondary use requests based on, or showing indications of, uses that are or might be "developing harmful product or service"?

3

60. Clarity of definition

3

61. Relevance of examples

3

62. Usefulness of implementation guidance

3

63. Optional comment or examples

Max. 5000 characters.

No answers

Article 54(e) – Ethical provisions under national law

64. How well does the document support your understanding and evaluation of secondary use requests based on, or showing indications of, uses that are or might be "ethical provisions under national law"?

3

65. Clarity of definition

3

66. Relevance of examples

3

67. Usefulness of implementation guidance

3

68. Optional comment or examples

Do you find it necessary to implement a “single application” format also for the ethical assessment? Currently the ethical assessment would need to be done/applied for in each member state where the national law requires it. Thus, the “single application” principle does not materialise with the ethical assessment. Max. 5000 characters.

No answers

Article 52

Article 52(3) – Intellectual property rights (IPR) and trade secrets

69. How well does the document support your understanding of the importance to always consider (i) if the requested data is limited by IPR and trade secrets, and (ii) the necessity to take measures to protect such IPR and trade secrets?

2

70. Clarity of definition

2

71. Relevance of examples

3

72. Usefulness of implementation guidance

2

73. Optional comment

Please provide concrete examples (dataset type + legal/organisational/technical safeguards) used to protect IPR or trade secrets. Max. 5000 characters.

It is extremely important for the EHDS to function that data protected by IP rights and/or trade secrets are both well protected and accessible. Not being able to agree upon the conditions in a contract should not become an ‘easy way out’ for organisations not to provide access to data. HDABs should provide proper standard contracts with standard provisions to protect these datasets that enable and stimulate the re-use of data.