Summary page:
TEHDAS2 public consultation on Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies

This consultation has 3 pages and 18 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. Page 3 consists 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? *

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? *

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. 5000 characters.

Governance & Decision-Making: Develop a European reference governance model for HDABs and appeals.
Data Permit Representation: Require machine-readable, structured data permits (JSON/XML).
API Specifications: Publish standardized OpenAPI schemas and data models.
Security & Privacy: Add guidelines for pseudonymization, federated analytics, and log retention.

- With respect to logging: Where does the logging take place, what is logged and how long is it stored?

Testing & Audit Framework: Develop an EU test and audit framework for DAAMS.
Operational Metrics: Define performance targets (uptime, response time).
User Guidance & UX: Develop standard user journey templates.

The following questions are specific for TEHDAS2 Data Access Application Management System (DAAMS) – Draft technical specification for health data access bodies

11. If you hold a role for the DAAMs development as part of your national EHDS implementation, please specify it.

Other
developer, operator and enterprise architecht (with focus op research)

12. How well does the specification cover the functional requirements for the DAAMs front office which enable applicants to submit Data Access Applications and Data Requests?

3

13. How well does the specification cover the functional requirements for the DAAMs back office which enable HDAB staff to process Data Access Applications and Data Requests?

2

14. How well does the specification cover the DAAMs requirements concerning the issuing and management of Data Permits?

3

15. How well does the specification cover the non-functional DAAMs requirements for the DAAMs such as usability, security, and auditing?

3

16. How well does the specification cover DAAMs integration into your national EHDS implementation?

3

17. Does the document help you to understand the technical requirements of a DAAMS?

Partially

18. Do you have any suggestions on what could improve the User Experience of such a system

Max. 5000 characters.

The cohesion between different documents could be better. For example, more reference to other documents other than M6.3. Moreover, we're missing (technical) requirements for SPE provisioning/order management. SPE seems to appear out of thin air.

Next to that in general:
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.