
# Summary page: TEHDAS2 public consultation on draft technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure

This consultation has 4 pages and 23 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 and 4 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

Coordinator, Dutch Health Data Infrastructure for Secondary Use; Member, HDAB-NL Project

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.

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 technical specification for Health Data Access Bodies on the implementation of the common IT infrastructure

11. Do you expect the proposed technical specification for the HealthData@EU cross-border infrastructure to impact your organisation or activities? *

Yes

12. Do you find the scope and objective of the common IT infrastructure (as outlined in Section 4) clearly described? *

Appropriate

13. Do you find it clear which actors (e.g. NCPs, central platform operators, Member States) are involved and what their roles are? *

Max. 5000 characters.

Yes

14. Do you consider the separation between the business layer and the messaging (transport) layer in the architecture to be appropriate and sufficiently clear to support implementation and governance? *

Yes

15. Do you find the description of the dispatcher component sufficiently clear and appropriate? *

If no: Please explain

Yes

16. Do you find the description of the access point component sufficiently clear and appropriate? *

If no: Please explain

Yes

17. Do you think the level of detail provided in the data model overview (Section 6.1.3) is appropriate? *

Appropriate

18. Do you anticipate any technical or organisational challenges in implementing the interoperability components (e.g. eDelivery configuration, certificate exchange, AS4 support, Dispatcher integration)? *

Please specify if additional support or documentation would be needed.
Max. 5000 characters.

eDelivery expanded over time. We should rebuild all code from scratch and have SIMPL handle professional maintenance. Consider using this mechanism to transfer data sets between nodes or SPEs.

19. Is the foreseen level of national flexibility (e.g. regarding internal workflows, national modules, or implementation choices) sufficient while maintaining EU-wide interoperability? *

If no: Please explain and specify which areas need more flexibility or more harmonisation.

Yes

20. Are the terms used in the document (e.g., Dispatcher, Access Point, Dataset Record) clearly defined? *

If no: Please explain your answer and suggest improvements or completions if needed.

Yes

21. Is the intended interaction between national infrastructures and the central HealthData@EU platform clearly explained? *

If no: Please explain.

Yes

22. Based on the current state of the technical specification, do you believe your organisation would be ready to implement and test these components in 2025-2026? *

Yes

23. Do you consider eDelivery to be the most appropriate and optimal technological solution for ensuring the connection between national infrastructures and the central HealthData@EU platform or would you also consider other solutions? *

Please explain your answer for any of the solutions.

EDelivery expanded over time. We should rebuild all code from scratch and have SIMPL handle professional maintenance.