M5.3 Draft technical specification on the national metadata catalogue – public consultation questions

TEHDAS2 – Second Joint Action Towards the European Health Data Space

19 December 2024

This project has been co-funded by the 4th EU Health Programme (2021–2027) under Grant Agreement no 101176773.

Disclaimer
Views and opinions expressed in this deliverable represent those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

Contents

1 Part A questions for generic feedback 3
1.1 Demography 3
1.2 Quality 3
1.3 Generic feedback 4
2 Part B questions for specific feedback 4

1 Part A questions for generic feedback

These questions will be asked in each public consultation to provide an understanding of the recipients' demographics, the quality of the document and to gather generic feedback. Questions marked with an asterisk are mandatory.

1.1 Demography

Country* [-List of countries-, EEA (Iceland, Liechtenstein and Norway, Europe non-EEA,European Organisation (European Commission, EMA, etc.), International Organisation (UN, WHO, etc.), Other]

Belgium

Type of the responder* [Public organisation, Private organisation, Non-governmental organisation (NGO), Academic or research institution, Interest group, Individual expert or professional, Patient representative, Individual citizen, Other]

Non-governmental organisation (NGO),

Sector* [Health care provider, Health care administration, Government/public administration, Research and development, Manufacturer of medical devices, Pharmaceutical industry, Education and academia, Information technology, Data management/processing, Patient advocacy, Legal and compliance, Information & media, Other]

Other, Organisation representing healthcare professionals

Organisation size* [Micro (1–9 employees), Small to medium enterprise (10–249 employees), Large enterprise (250+ employees), Not applicable/Individual citizen

Micro

Professional role/function [open text field]

Senior policy Advisor

1.2 Quality

From your perspective, how ready is the document to meet the expected needs?* [Early draft, Major additions/changes needed, Minor additions/changes needed, Only final editorial changes needed]

What is the level of quality of the document?* [Rate 1 (Low) – 4 (Very High)] **High**

Is the document easy to understand?* [Rate 1 (not clear nor easy to understand) – 4 (very clear and easy to understand)] **Not applicable**

How well does the document address the key issues and challenges related to its subject matter?* [Rate 1 (not well) – 4 (very well)] **Not applicable**

How feasible and implementable do you find the guidelines or technical specifications presented in the document?* [Rate 1 (not feasible and implementable at all) – 4 (very feasible and implementable)] **Not applicable**

1.3 Generic feedback

Do you have any suggestions for improving the document? Are there any additional topics or areas that should be covered? [Please provide feedback and ideas for enhancing the document] [max. 750 characters]

- Healthcare software manufacturers need to support healthcare professionals and healthcare providers by automating the creation and provision of metadata descriptions for health data access bodies. They must be addressed first.
- The duties for healthcare professionals and healthcare providers related to data descriptions and data transfers under the secondary use regime of the EHDS Regulation are seen as an administrative burden to their primary task of diagnosing and treating a patient.
- Considering the current health workforce crisis, healthcare professionals' precious time cannot be exhausted in preparing data for third parties including those which pursue private and commercial interest. CPME supports the 'once-only principle'.

2 Part B questions for specific feedback

Do you expect the technical specification for national dataset catalogue to affect you or your work?* [**Yes**, No, I don't know]

Do you find it clear which actors will be affected by the technical specification? If not, please explain your answer. [Open text answer]

Are the responsibilities of HDAB and Data Holders appropriately and clearly described? If not, please explain your answer. [Open text answer]

- The maturity and capability of health data holders is different, and this difference is not addressed in the deliverable.
- Requesting health data holders, which includes healthcare professionals, to provide dataset descriptions in the HealthDCAT-AP standard, and update the information regularly, is disproportionate.

What are your thoughts on the terminology used in the document? Is it clear and appropriate for the context? Please explain your answer. [Open text answer]

Are the purposes and goals provided in section 3 clearly described? If not, please explain your answer. [Open text answer]

- The deliverable mentions that the catalogue should also include the conditions for making electronic health data available (section 3.3). It is not clear how this process will be carried out. If a transfer of health data from health data holders to the HDAB, it should be clear how data is anonymised or pseudonymised. Healthcare professionals cannot be burdened with any additional tasks for secondary use purposes. Doctors should not be data harvesters for other users and interests.
- Moreover, health data holders require specific training on data management which currently they (healthcare providers) do not have or receive.

From your perspective, how do you perceive the scope of the specification outlined in section 4?* [Too narrow, Appropriate, Too wide, Unclear, Other (please specify)]

Do you think the methods described in Annex 5 are appropriate for achieving the intended objectives? If not, please explain your answer. [Open text answer]

Are the user stories listed in section 5 appropriate and clearly described? Are there any user stories you believe are missing? Please explain your answer. [Open text answer]

Although the document is of high quality, the user stories (chapter 5.1.1) regarding data owners (especially GPs and small practices) do not reflect reality. Doctors primarily want to treat patients. Data descriptions and transfers are seen as an administrative burden to their primary task. The user stories and any regulations derived from them should take this into account. Software vendors should be addressed first, as they need to automate all these processes. The ideal situation would be that a physician does not have to do anything to fulfil his/her duties regarding data provision and description.

Do you think the requirements listed in section 6 are appropriate and adequately categorised (e.g., mandatory, recommended, optional)? Are there any requirements you believe are missing? Please explain your answer. [Open text answer]

- The HealthDCAT-AP standard does not include any reference to ethical requirements or risk to medical ethics.
- Mandatory metadata descriptions should be minimal.
- As a health data holders, I should not use extra resources to describe metadata that will not be used. Not all metadata descriptions are useful.
- As a data holder, I should be able to describe metadata in free text format, and it should be up to the health data access body to translate into the appropriate standard. The tools and methods to do so should be sorted between Member States and the healthcare software industry, which needs to be addressed first.

The document does not include specifications on non-functional requirements in section 6. Do you think non-functional requirement would be needed? If yes, please explain your answer. [Open text answer]

Are the capabilities outlined in section 7 adequate for the intended purpose? Are there any capabilities you believe are missing? Please explain your answer. [Open text answer]

- The maturity and capability of health data holders is different, and this difference is not addressed in the deliverable.
- Requesting health data holders, which includes healthcare professionals, to provide dataset descriptions in the HealthDCAT-AP standard, and update the information regularly, is disproportionate.
- The deliverable needs to be coordinated with deliverable M5.1. It should be clearer in deliverable M5.3 who should transcribe the meta data description into the HealthDCAT-AP standard (section 7.1. in deliverable M5.3). HCP should not be burdened with this standardisation task.

What is missing from the specification for Member States to develop a national metadata catalogue? Please explain. [Open text answer]

- The role of health data intermediaries is not addressed. To what extend would be their role and how can they support HCPs which fit into the description of health data holders? Doctors should not be data harvesters for other users and interests.
- Secondary use data should be generated from structured primary data. The EHR system should provide for multiple uses across uses, including billing and statistical reporting.
- Doctors should be required to code only once for the continuity of care in the EHR. CPME welcomes current international initiatives which aim to explore seamless data conversion and linkages of different coding terminologies for users. European doctors call for further engagement from coding organisations to enable a common language worldwide.