



M5.4 Draft guideline for data enrichment – public consultation questions

TEHDAS2 – Second Joint Action Towards the European Health Data Space

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0 Document info

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1 Introduction

By committing to a rigorous public consultation process, the TEHDAS2 project ensures that its deliverables are not only compliant with regulatory requirements but also practical, feasible, and supported by the community they are intended to serve.

1.1 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.

1.1.1 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]

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]

Are you responding on behalf of several organisations?* Yes/No

If yes: On behalf of how many organisations?

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]

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

Professional role/function [open text field]

1.1.2 Quality

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

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

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

1.1.3 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. 5000 characters]

1.2 Part B questions for specific feedback

SECTION A: BACKGROUND & EXPERIENCE

1. **What perspective describes best *your* affiliation?** Please choose one.
The perspective of a data user / The perspective of a data holder / The perspective of an HDAB / None of the above
2. **Does your organisation currently perform data enrichment on health datasets in secure environments?** Please choose.
No / Yes
 - a. **If yes, please describe the types of enrichment performed. Are there established internal procedures or national guidance for documenting and sharing enrichment activities?** [Please provide examples or references if available, max. 5000 characters].

SECTION B: KEY CONCEPTS & IMPLEMENTATION APPROACHES

3. **What approach do you consider most appropriate for handling data enrichment outputs? Please choose one or more.**
 - a. Sharing enrichment methods, documentation, and code only (without transferring enriched datasets)
 - b. Transferring enriched datasets to data holders for integration
 - c. Direct communication between data user and data holder (without HDAB intermediation)
 - d. No formal enrichment feedback mechanism
 - e. Other approach (please specify below)
4. **In your experience or context, what are the main barriers to sharing enrichment outputs?** [Please provide feedback, max. 5000 characters]

SECTION C: ROLES, RESPONSIBILITIES & GOVERNANCE

5. **Are the roles and responsibilities of data users, HDABs, and data holders in relation to data enrichment clear and appropriate? Please choose one.**
 - Strongly disagree
 - Disagree
 - Agree
 - Strongly agree

- Not applicable to my context

If you disagree or strongly disagree, please explain what clarifications or adjustments would be needed. [max. 5000 characters]

6. Is the proposed feedback loop (data user → HDAB → data holder) realistic and workable in your context? Please choose one.

- Not realistic/workable
- Somewhat realistic/workable
- Realistic/workable
- Very realistic/workable
- Not applicable to my context

If not realistic or only somewhat realistic, please describe the barriers. [max. 5000 characters]

SECTION D: LEGAL & TECHNICAL FEASIBILITY

7. Do you see legal constraints (e.g., GDPR, data permits, intellectual property, trade secrets) that would limit the sharing or reuse of enrichment outputs? Please choose one.

- No legal constraints anticipated
- Minor legal constraints
- Significant legal constraints
- Major barriers; sharing/reuse would be very difficult
- Uncertain

If you selected "Significant constraints" or "Major barriers," please elaborate on which legal issues are most problematic. [max. 5000 characters]

8. Do you consider the proposed implementation model (prioritising documentation/code sharing over dataset transfer) feasible in your context? Please choose one.

- Not feasible
- Somewhat feasible
- Feasible
- Very feasible
- Not applicable to my context

If not feasible or only somewhat feasible, please explain why and what would be needed to make it work. [max. 5000 characters]

9. How feasible is it for data users to document enrichment activities as suggested in Sections 5.1–5.3 (e.g., methodological descriptions, code sharing, reporting to HDABs)? [Please provide feedback, max. 5000 characters]

SECTION E: CLARITY & COMPLETENESS BY CHAPTER

- 10. Is chapter 4 clear and easy to understand?** Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand).
- 11. If there are specific topics missing in chapter 4, please elaborate on these below**
[Please provide feedback, max. 5000 characters].
- 12. Is chapter 5 clear and easy to understand?** Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand)
- 13. If there are specific topics missing in chapter 5, please elaborate on these below**
[Please provide feedback, max. 5000 characters].
- 14. Is chapter 6 clear and easy to understand?** Please rate from 1 (not clear nor easy to understand) to 4 (very clear and easy to understand).
- 15. If there are specific topics missing in chapter 6, please elaborate on these below**
[Please provide feedback, max. 5000 characters].