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Annex 1: National progress report (survey template)

National Progress Report EHDS2 (VALO Project)

This is part of VALO Workstream 2. Compilation of answers will be presented at the next Nordic EHDS2 Competence Forum. This is an updated version where colour-marked question indicates that it is a new question. If you need clarifications, please contact michel.silvestri@ehalsomyndigheten.se

Answering organisation(s)? (Preferably one single answer per country)

Contact information to respondent(s)

Date of submitting answers

Topic	Question
1. Policy and regulatory readiness	
1.1 Existing Strategies, Laws, and Guidelines on Secondary Use of Health Data	
	1.1.1 Are there existing national strategies, guidelines or recommendations specifically addressing the secondary use of health data? If yes, please provide details, including the main objectives and scope of these.
	1.1.2 Are there any existing laws or regulations in your country that govern the secondary use of health data? If yes, please provide details, including any relevant legal texts or guidelines. Is there an English or Scandinavian version of the text?
1.2 Need for Regulatory Updates and Revisions	
	1.2.1 Will legislation updates or new laws be necessary to fully implement and support the secondary use of health data under the EHDS framework? If yes, what are the key areas that need to be updated? (e.g., data protection, interoperability requirements). Is there a planned timeline?
	1.2.2 Are there risks of different interpretations of EHDS regarding the secondary use of health data? Please describe briefly any proposed solutions.
1.3 Supervisory and Penalty Framework	

1.3.1 Is there already an appointed authority for overseeing the secondary use of health data within the EHDS framework?

Please specify the name of the authority and its responsibilities.

1.3.2 Have penalty and/or fee levels been decided for non-compliance with regulations governing the secondary use of health data?

If yes, please provide details.

1.3.3 Do you currently have national-level legislation or instructions on fees for the secondary use of health data?

If yes, please provide details.

1.3.4 Do regions or organizations publish their fee structures related to permit fees or health data use fees?

If yes, please describe how and where this information is made available.

1.3.5 Do you have national-level supervision for the secondary use of health data?

If yes, please specify the responsible entities and their roles.

1.3.6 Do you currently have national-level legislation or instructions on penalties for the secondary use of health data? If yes, please provide the details.

1.4 Legislation Adjustments and Flexibility for Member States

1.4.1 Opt-Out Derogation: **Will your country adopt national laws that allow for derogation from the opt-out provision for the secondary use of health data (as per Article 71(4) of the EHDS regulation)?**

If yes, please provide details on the conditions under which this derogation will apply.

1.4.2 Additional Conditions for Data Access: **Will your country impose additional conditions for accessing certain types of health data, as allowed under the EHDS regulation?**

If yes, please specify the types of data and the additional conditions that will apply.

1.4.3 National Legislation for Processing Purposes: **Will your country introduce or maintain national legislation that specifies additional data categories, in line with the flexibility provided by the EHDS regulation?**

If yes, please provide details on the additional purposes and the rationale behind them.

1.4.4 Establishment of Additional Safeguards: **Will your country establish additional safeguards beyond those required by the EHDS regulation for the secondary use of health data?**

If yes, please describe these safeguards and their intended impact on data protection.

2. Organisational readiness

2.1 Designation of Health Data Access Bodies (HDAB)

2.1.1 Has a Health Data Access Body (HDAB) been formally appointed in your country?
If yes, please provide details on whether it is a single national HDAB or if there are several HDABs with one coordinating entity.
2.1.2 Are the HDAB functions and responsibilities distributed between existing authorities? If yes, please explain how these responsibilities are shared.
2.1.3 Has a new HDAB authority or authorities been established specifically for the EHDS? If yes, please provide details on their roles and functions.
2.1.4 Has the health data access application process been decided and assigned to the HDAB? Please provide more information on how this process is managed.

2.2 Appointment of National Contact Points for Secondary Use (NCP2)

2.2.1 Has a National Contact Point (NCP2) for the secondary use of health data been formally appointed?

If so, please provide detailed information on their role and contact details.

2.3 Training and Capacity Building

2.3.1 What training programs are in place or planned to prepare staff for EHDS implementation or to build capacity within existing entities?

2.4 Impact Assessment and Cost Estimates

2.4.1 Has an impact assessment been conducted to evaluate the readiness of your country for EHDS implementation?

If yes, please summarize the key findings and any identified challenges.

2.4.2 Has a national cost estimate been produced regarding the preparations, establishing and administration of EHDS when it comes to secondary use? If yes, please provide more information.

3. Technical readiness

3.1 Secure Processing Environment (SPE)

(may also be known as Trusted Research Environment)

3.1.1 Is there a clear national organization and responsibility assigned for the EHDS SPE? If yes, please describe the organization responsible.

3.1.2 Is there currently any SPE in your country used for analysing health data? If yes, please provide more information.
3.1.3 Do national legislation or technical specifications exist for SPE (or similar)? If yes, please provide details on these specifications.

3.1.4 Is the responsibility for making SPE requirements currently distributed to organizational levels (=not centralized at national level)? If yes, please specify how this is managed.

3.2 Metadata Management

3.2.1 Do national specifications exist for how to use and publish metadata related to health data? If yes, please provide more information.

3.2.2 Do national catalogues exist for providing metadata on datasets or registers?

If yes, please describe these catalogues.

3.2.3 How far are you in the process of taking the EHDS requirements into account in the national health data catalogue? Please provide a short description.

3.2.4 Do regional or organizational catalogues exist for providing metadata on datasets or registers?

If yes, please provide details on how they are used and maintained.

3.3 Infrastructure and Systems

3.3.1 Are there ongoing or planned upgrades to your IT infrastructure to accommodate EHDS requirements for secondary use?

If yes, please provide details on these upgrades. If no, explain why.

3.4 Data Protection and Security

3.4.1 Are there any specific data protection challenges anticipated with the implementation of EHDS?

Please describe these challenges and any planned solutions.

4. Strategic and budgetary considerations

4.1 Monitoring and Evaluation

4.1.1 How will the progress of EHDS2 implementation be monitored and evaluated?

Please describe any frameworks or indicators that will be used to assess progress.

4.2 Data Localization

4.2.1 Does your country have specific data localization requirements for secondary use of health data under the EHDS framework? (i.e localization following data discovery)

If yes, please describe these requirements and how they will impact the implementation of EHDS.

5. Communication and collaboration

5.1 National Communication Strategy

5.1.1 Do you have a national communication strategy in place to inform stakeholders and the public about EHDS? Please describe the strategy and provide URL if available.

5.2 Stakeholder Engagement

5.2.1 Have you organized events, panels, or discussions about the EHDS with national stakeholders? If yes, please provide details on these activities.

5.2.2 Have you planned communication campaigns on the EHDS?

If yes, please provide details on the content and scope of these campaigns.

5.3 Permanent Groups and Forums

5.3.1 Do you have permanent national groups or forums where the secondary use of health data is discussed?

If yes, please provide details on these groups and their activities.

5.4 Public Information

5.4.1 Do you currently provide information about how health data is used for secondary purposes?

For example, do you publish a list of permits granted for secondary data use? Please describe how this information is communicated to the public.

5.5 International Collaboration

5.5.1 Do you as a country participate in any key initiatives or programmes when it comes to international collaboration in the secondary use of health data? If yes, please provide more information.

5.5.2 Do you have a national collaboration strategy or plan on how to participate in externally funded (e.g., EU) projects on the secondary use of health data?

If yes, please provide details on your collaboration strategy or plan.

6. Additional comments or feedback

6.1.1 Any additional comments or information? Feedback on the questions above - missing anything? Specific issue to raise at Competence Forum?

Addendum in 2026:

7. Additional mappings

7.1 Support functions

7.1.1 Do you have national support functions provided by government authority on pre- and/or post-application level? (i.e. before or after the secondary user submits formal application) If yes, please provide details.

7.1.2 Do you have support functions provided by regional/local authority or institution on pre- and/or post-application level? (i.e. before or after the secondary user has submitted formal application). If yes, please provide details.

7.2 Guideline awareness

7.2.1 The body/bodies you have for support according to 7.1 above, are they aware of the TEHDAS2 milestone M6.2 - "Draft guideline for data users on good application and access practice"? https://tehdas.eu/wp-content/uploads/2025/01/2025-01-20-tehdas2-milestone-6.2.pdf
Please elaborate on potential usefulness of this support document.

7.3 Ethical review

7.3.1 Do you have requirements for ethical review prior to providing (potential) access to health data for research?
If yes, please provide details on a) **what the requirement is based on** (national law, guideline or something else.), b) **which authority or other institution** is responsible for this, and c) briefly about the **ethical review process**.

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