



Funded by the
Nordic Council
of Ministers

Towards a Nordic guide to efficient and secure access to health data for secondary use under the EHDS

Report 1.0

Value from Nordic health data – VALO2 project

October 2026



Document info

0.1 Authors

Author	Partner
Michel Silvestri	Swedish eHealth Agency (SEHA)
Jenina Soimala	The Finnish Institute for Health and Welfare (THL)
Mari Mäkinen	The Finnish Institute for Health and Welfare (THL)
Sirpa Soini	The Finnish Institute for Health and Welfare (THL)
Persephone Doupi	The Finnish Institute for Health and Welfare (THL)
Vilma Piironen	The Finnish Institute for Health and Welfare (THL)
Florine Wettly	The Norwegian Institute for Public Health (NIPH)
Christina Møllebro	The Norwegian Institute for Public Health (NIPH)
Zuzana Nordeng	The Norwegian Institute for Public Health (NIPH)
Védís Helga Eiríksdóttir	Directorate of Health, Iceland
Rebekka Björg Guðmundsdóttir	Directorate of Health, Iceland
Anne Savolainen	National Board of Health and Welfare
Johanna Holm	National Board of Health and Welfare
Rasmus Elrud	National Board of Health and Welfare
Zoltan Thinsz	National Board of Health and Welfare
Marisa da Silva	Swedish eHealth Agency (SEHA)
Michael Peolsson	Swedish eHealth Agency (SEHA)
Margit Ramberg	The Arctic University, Norway (UIT)
Ingvild Haaland	University of Bergen, Norway (UIB)
Antti Piirainen	Findata – Finnish Social and Health Data Permit Authority
	and national experts listed in the source reports (annexes)

0.2 Keywords

Keywords	health data, Nordic, Baltic, EHDS, secondary use, HDAB, secure processing environment, metadata, HealthDCAT-AP, legal, ethical review, quality assurance, scientific research
-----------------	---

Disclaimer

The content of this report represents the views of the author(s) and do not necessarily reflect the views of the experts interviewed.

Copyright Notice

Copyright © 2026 The VALO2 Project – contributing parties and authors identified in this report.

This work is licensed under a Creative Commons Attribution-NonCommercial 4.0 International License (CC BY-NC), (<https://creativecommons.org/licenses/by-nc/4.0/>). Other uses require the written permission of THL and Sitra.

Contents

List of abbreviations	7
Executive summary	10
1 Introduction and background	14
1.1 Scope and method of consolidation	14
1.2 Previous outcomes and current deliverable	15
1.3 Purpose of this final report	15
2 Nordic cooperation for EHDS secondary use	16
2.1 Nordic EHDS2 Competence Forum	16
2.2 Value of Nordic cooperation	17
2.3 Sustainability beyond the VALO project	19
3 The User Journey as a common framework for EHDS2 services deployment	21
3.1 Overview of the User Journey	21
3.2 Objectives	23
3.3 Integrated view of bottlenecks and support functions	24
4 Metadata and metadata catalogues	26
4.1 Background and objectives	26
4.2 Key findings of the metadata work	26
4.2.1 HealthDCAT-AP implementation: progress and remaining challenges	26
4.2.2 Understanding the Nordic health data landscape	28
4.2.3 Preliminary understanding of the needs AI places on metadata	28
4.3 Summary of recommendations	29
5 Legal interpretation and implementation issues	32
5.1 Areas where the legal group reached a common interpretation	32
5.1.1 Statistical bodies – health data holders	32
5.1.2 Health data intermediation entities	32
5.1.3 Fees	32
5.1.4 Application assessment	33
5.2 Bottlenecks and implementation issues	33
5.2.1 Opt-out	33
5.2.2 Significant findings	33
5.2.3 IP rights and trade secrets	34



5.3	Questions that remain unresolved	34
5.3.1	Consent	34
5.3.2	Legal responsibilities of HDIEs	34
5.4	Legal implications for the User Journey and support functions.....	34
5.5	Recommendations for continued cooperation	35
6	Ethical governance of secondary use	37
6.1	National differences and opportunities for Nordic alignment.....	37
6.2	Quality assurance and scientific research	38
6.3	Practical impact demonstrated by the VALO2 pilot	39
6.4	Ethical implications for the User Journey and support functions	39
6.5	Conclusions and recommendations.....	40
7	The User Journey, bottlenecks and support functions.....	42
7.1	User Journey and recommended support functions.....	42
7.1.1	Pre-discovery and metadata publication.....	42
7.1.2	Data discovery.....	44
7.1.3	Data access.....	46
7.1.4	Data preparation.....	50
7.1.5	Use of data	51
7.1.6	Finalisation	53
7.2	Support functions – format and modalities	54
7.3	Prioritised recommendations and conclusions	55
7.3.1	Nordic cooperation	55
7.3.2	A smoother User Journey	56
7.3.3	Additional conclusions.....	57

Annexes

Annex 1. National progress report (survey template).....	59
Annex 2. Proposal for a User Journey support guiding matrix.....	65
Annex 3a. List of Nordic-Baltic national EHDS2-relevant authorities and bodies.....	70
Annex 3b. Secure Processing Environment candidates	74
Annex 4a. Metadata and metadata catalogues – full report.....	78
Annex 4b. HealthDCAT-AP pilot descriptions	94

Annex 4c. Nordic health data landscape analysis tables	127
Annex 5. Full report on Legal aspects	175
Annex 6. Full report on ethical aspects.....	198
Annex 7a. Data from the Nordics: Draft for a joint Nordic overview for data users	233
Annex 7b. Matrix of VALO outputs as a validation layer for EHDS implementation.....	237

List of abbreviations

The list includes abbreviations and short forms used in the main report and annexes. Organisational and technical abbreviations are expanded in English; where useful, the national name is included in parentheses.

Abbreviation	Meaning
AI	Artificial intelligence
AI Act	Artificial Intelligence Act (Regulation (EU) 2024/1689)
CoP	Community of Practice
CPU	Central Processing Unit
CSVW	CSV on the Web
DG SANTE	Directorate-General for Health and Food Safety, European Commission
DOI	Digital Object Identifier
DQUL	Data Quality and Utility Label
DRG	Diagnosis-Related Group
EDPB	European Data Protection Board
EHDS	European Health Data Space
EHDS2	Secondary-use dimension of the European Health Data Space
EHR	Electronic Health Record
ELI	European Legislation Identifier
EU	European Union
FAIR	Findable, Accessible, Interoperable, Reusable
FAQ	Frequently Asked Questions
FHI	Norwegian Institute of Public Health
FIMM	Institute for Molecular Medicine Finland
GDPR	General Data Protection Regulation (Regulation (EU) 2016/679)
GMS	Genomic Medicine Sweden
GPU	Graphics Processing Unit
HDAB	Health Data Access Body
HDIE	Health Data Intermediation Entity
HealthDCAT-AP	Health Data Catalogue Application Profile

HUS	Helsinki University Hospital
IA	Implementing Act
ICD-10	International Classification of Diseases, Tenth Revision
IP	Intellectual Property
IPR	Intellectual Property Rights
IT	Information Technology
JA	Joint Action
LLM	Large Language Model
MCP	Model Context Protocol
MONA	Microdata Online Access
MVP	Minimum Viable Product
NAISS	National Academic Infrastructure for Supercomputing in Sweden
NB8	Nordic-Baltic Eight
NCM	Nordic Council of Ministers
NCP2	National Contact Point for secondary use of health data
NGP	National Genomics Platform
NIPH	Norwegian Institute of Public Health
NSCLC	Non-Small Cell Lung Cancer
OKR	Objectives and Key Results
OMOP CDM	Observational Medical Outcomes Partnership Common Data Model
POC	Proof of Concept
PSG	Project Steering Group
QA	Quality Assurance
QUANTUM	Quality, Utility and Maturity Measured
RDF	Resource Description Framework
REC	Regional Committee for Medical and Health Research Ethics
SCB	Statistics Sweden
SEHA	Swedish eHealth Agency
SFM	Secure Research Environment (Säker forskningsmiljö)
SNOMED CT	Systematised Nomenclature of Medicine Clinical Terms
SPE	Secure Processing Environment

SPARQL	SPARQL Protocol and RDF Query Language
TEHDAS	Towards the European Health Data Space
TEHDAS2	Second Joint Action Towards the European Health Data Space
THL	Finnish Institute for Health and Welfare
TRE	Trusted Research Environment
UIB	University of Bergen
UIT	The Arctic University of Norway
UPPMAX	Uppsala Multidisciplinary Center for Advanced Computational Science
URI	Uniform Resource Identifier
URL	Uniform Resource Locator
VALO	Value from Nordic Health Data project
VALO1	Initial phase of the Value from Nordic Health Data project
VALO2	Extension phase of the Value from Nordic Health Data project
WS	Workstream
WS1	Workstream 1
WS2	Workstream 2
WS3	Workstream 3

Executive summary

The European Health Data Space Regulation, Regulation (EU) 2025/327, establishes a common European framework for the primary and secondary use of electronic health data. The secondary-use dimension (in this report the EHDS2) requires Member States to develop the legal, organisational, technical and governance capabilities needed to make health data available for permitted secondary-use purposes securely, transparently and efficiently.

The Value from Nordic health data project, VALO, was initiated and funded by the Nordic Council of Ministers to strengthen Nordic cooperation and support preparations for the implementation of the EHDS. Workstream 2 (WS2) contributed to this objective by establishing the Nordic EHDS2 Competence Forum, coordinating national progress reporting and enabling dedicated cooperation on organisational readiness, metadata, legal interpretation and ethical governance. This report consolidates the work and outcomes of WS2 and its expert groups.

From September 2024 to September 2026, eight Nordic EHDS2 Competence Forums were organised across the Nordic countries. Estonia and Lithuania participated as observers during the VALO2 extension, adding a wider Nordic-Baltic perspective. The Forums created a recurring, invitation-only setting in which ministries, authorities and experts could discuss implementation challenges, compare national approaches and develop practical responses.

Evaluations conducted after the Forums indicate that this format was highly valued by participants and support the conclusion that the Forum provided a trusting and useful environment for professional exchange and mutual learning.

Successful implementation of EHDS2 depends on coordinated readiness across multiple areas. Health Data Access Bodies, secure processing environments, metadata catalogues, health data holders, ethical review bodies and other relevant actors must form parts of a coherent end-to-end system. Legal, technical, organisational, ethical and metadata requirements should therefore not be addressed as isolated implementation tasks.

A central contribution of VALO2 is the use and further development of the secondary-use User Journey as a common organising framework. Building on the journeys developed through TEHDAS and TEHDAS2¹, VALO2 expands the framework upstream to include a pre-discovery and metadata publication phase and downstream to include data preparation, secure processing, analysis support, output release, archiving, reproducibility, publication and project closure – with associated recommendations for a smoother and more secure User Journey.

This expanded framework highlights the back-office capabilities that must exist before a data user can successfully discover and access data. These include identifying health data holders and datasets, producing and maintaining metadata, publishing records in national and European catalogues, assessing dataset suitability and study feasibility, processing applications, preparing

¹ [Second Joint Action Towards the European Health Data Space – TEHDAS2 - Tehdas](#)

and transferring data, onboarding users to secure processing environments, supporting analysis and controlling the release of results.

The metadata work demonstrates that HealthDCAT-AP remains difficult to interpret and implement consistently. Although the specification has matured and national understanding has improved, readiness remains uneven. Questions persist concerning the HealthDCAT-AP information model; the definition and granularity of datasets; the use of dataset series and distributions; the representation of different EHDS Article 51 data categories; and the interpretation of mandatory metadata properties.

Existing national health data catalogues generally require substantial adaptation to meet the EHDS requirements. The VALO2 work included mapping national catalogue properties to HealthDCAT-AP, piloting cancer registry descriptions, analysing the Nordic health data landscape under EHDS Article 51 and exploring metadata requirements for AI development and data-quality assessment.

The report recommends continued practical piloting, common Nordic examples and interpretations, more harmonised dataset definitions and further consideration of a Nordic HealthDCAT-AP extension. It also recommends developing a Nordic self-assessment tool to help organisations determine whether they qualify as health data holders and continuing the mapping of health data holders and datasets across all Article 51 categories.

Metadata quality is also identified as an important condition for AI-supported data discovery and responsible AI development. Structured, complete, standardised and regularly maintained metadata, including detailed variable-level information, can improve dataset discovery and help users assess provenance, availability, suitability and aspects of data quality. Current metadata and data-quality requirements, however, provide only a starting point for the more detailed assessments that may be needed for high-risk AI development.

The legal work examined selected EHDS provisions with practical significance for Nordic implementation. The participating experts reached common or broadly shared interpretations concerning statistical bodies as health data holders, certain organisational aspects of Health Data Intermediation Entities, the application of fee provisions and the scope of the Health Data Access Bodies assessments under Article 68(1)(b). These interpretations may support closer Nordic coordination but do not constitute formally adopted national positions.

Several important legal and operational questions remain unresolved. These include the allocation of the EHDS and GDPR responsibilities for Health Data Intermediation Entities; the practical handling of significant findings; national approaches to fees and incentives; opt-out mechanisms; protection of intellectual property rights and trade secrets; and the relationship between the EHDS consent provisions and national ethical requirements.

The report therefore recommends continued Nordic legal cooperation, with a clear distinction between legal interpretation, policy choices and operational guidance. Cooperation should focus particularly on areas where differing national approaches could create barriers to cross-border

access or make the Nordic User Journey less predictable. Where appropriate, Nordic findings and questions should be brought jointly to the European level.

The ethical mapping demonstrates significant differences among the Nordic countries concerning whether ethical review is required. In Sweden, Norway and Iceland, ethical review is generally required for qualifying scientific or health research where the applicable data-related and territorial conditions are met. Denmark applies ethical-review requirements more narrowly, while Finland generally does not require a statutory ethical review solely because existing health data are used.

The distinction between quality assurance and scientific research, territorial scope, application-language requirements, competent authorities and procedural sequencing can materially affect multinational projects. The VALO2 pilot demonstrated the cumulative practical effect of these requirements. In Norway, classification of the project from quality assurance to scientific research changed the applicable regulatory pathway and contributed, together with subsequent requirements, to a delay of approximately five months.

The report recommends involving ethics committees and ethical expertise early in national and Nordic EHDS implementation. Applicants should have access to clear country-specific guidance on whether ethical review or related national procedures are required, which bodies are competent, what language requirements apply and how ethical procedures relate to the Health Data Access Body process. Continued Nordic exchange on the distinction between quality assurance and scientific research could improve predictability without replacing national law or the independence of competent authorities.

Across all implementation areas, the report recommends viewing the User Journey as a single interconnected process. Metadata publication, data discovery, feasibility assessment, applicant guidance, legal and ethical prerequisites, application processing, access decisions, data preparation, secure analysis, disclosure control and publication of results all depend on one another. A bottleneck in one area can delay or prevent progress in another.

Support functions should therefore be developed for each step of the journey and for all central actors, not only applicants. Health data holders need support in identifying datasets and preparing metadata. Applicants need support in discovering and assessing data, interpreting national requirements and preparing complete applications. Health Data Access Bodies need application-processing, coordination and decision-support capabilities. Secure processing environment operators need reliable procedures for data provision, onboarding, analysis support, monitoring, output control and project closure.

The overall recommendations are that the Nordic countries should jointly:

- maintain a Nordic-Baltic EHDS2 community of practice, building on the trusting environment and working methods established through the Competence Forum;
- map bottlenecks and develop support functions across the full User Journey;
- develop a harmonised health data holder self-assessment approach;

- continue practical HealthDCAT-AP implementation, common mapping, pilot descriptions and work towards more harmonised Nordic metadata practices;
- coordinate legal interpretations and national implementation choices where unnecessary divergence could obstruct cross-border access;
- improve transparency and cooperation concerning the ethical-review requirements, territorial scope, application-language requirements and the distinction between quality assurance and scientific research;
- develop common Nordic applicant-facing information, guidance and training, including English-language material for cross-border users;
- compare national support functions, fee models, secure processing arrangements and implementation costs; and
- monitor emerging concerns about AI, significant findings, opt-out mechanisms, intellectual property rights and trade secrets.

The report also proposes that the VALO outputs can be used as an implementation-readiness, gap-analysis and operational validation framework for secondary use according to the provisions of the EHDS Regulation. By mapping User Journey steps, actors, support functions and recommendations to the relevant EHDS provisions, the work can help national and Nordic actors assess whether the necessary capabilities are being established. Such use does not constitute a formal legal compliance assessment and must be complemented by legal review, technical conformity assessment and the final requirements established through implementing acts.

The report concludes that sustained Nordic-Baltic cooperation would strengthen the region's capacity to implement the EHDS2 in a consistent, trustworthy and effective manner. A continuing community of practice – linked where appropriate to the proposed Nordic Health Data Competence Forum and wider Nordic Model – could connect policy makers, Health Data Access Bodies, secure processing environment operators, metadata specialists, legal advisers, ethics experts and other stakeholders. This would support cross-border research and innovation, reduce avoidable duplication and help ensure that Nordic and Baltic implementation experience contributes constructively to continuing European-level development.

1 Introduction and background

The Value from Nordic health data (VALO project), funded by the Nordic Council of Ministers (NCM), aimed to strengthen Nordic cooperation and support the implementation of the European Health Data Space (EHDS), more specifically in the secondary use of health data (the EHDS2 dimension). In addition to the active Nordic participants in VALO (Denmark, Finland, Iceland, Norway and Sweden) two of the Baltic countries – Estonia and Lithuania – joined as observers in the project extension (VALO2). Workstream 2 (WS2) has focused mainly on establishing the Nordic EHDS2 Competence Forum, coordinating national progress reporting, and fostering collaboration on metadata, legal, and ethics frameworks, as well as technical and organisational infrastructure. During the period September 2024 to September 2026 in total eight quarterly Competence Forums have been held in all the Nordic countries. These quarterly forums, which are by invitation only, have brought together representatives from the concerned ministries and authorities of the Nordic and Baltic regions to share experiences, identify challenges, and explore harmonisation opportunities in the preparations and implementation of EHDS2.

Overall, the initial VALO project and WS2 laid a strong foundation for Nordic-Baltic collaboration in EHDS2 implementation. The project has demonstrated the value of structured dialogue, shared tools, and coordinated strategies in navigating complex regulatory and technical landscapes. The extension, VALO2, has built on these achievements to further enhance regional leadership in the secondary use of health data.

1.1 Scope and method of consolidation

This consolidated final report of WS2 is a synthesis of the outcomes of the Competence Forums and their three breakout sessions (HDAB, Legal including ethical², and Metadata), as well as the work carried out in the groups' regular meetings. The principal content of interim source documents from these different work groups, organising the material around their corresponding connected themes: i) the Competence Forum and the User Journey framework³, ii) organisational and HDAB (Health Data Access Body) readiness, iii) metadata and metadata catalogues, iv) legal interpretation and ethical governance. Detailed country mappings and other supporting material are provided as annexes to this report, to improve readability.

This report should be seen as an interim synthesis rather than a final legal or policy position.

² Although the EHDS establishes a common framework for secondary use, Article 54(1)(e) preserves the application of ethical provisions laid down in national law, meaning that national requirements continue to affect access to and use of health data. Because these requirements differ and ethical expertise had been only marginally involved in EHDS implementation, a separate expert group was established to map the Nordic ethical-review frameworks, identify cross-border bottlenecks and explore opportunities for greater transparency and cooperation.

³ Concept from the TEHDAS and TEHDAS2 projects ([TEHDAS identifies user journey for cross-border health data sharing - Tehdas](#))

1.2 Previous outcomes and current deliverable

Key outcomes of WS2 presented in the previous report of the initial VALO⁴ project – initiated in 2024, hereafter named VALO1, to separate from the VALO2 extension from September 2025 – included:

- National progress reports on EHDS2 readiness and HDAB status across countries,
- Summary and analysis of breakout sessions (working groups),
- Harmonisation aspects (Legal, Metadata, other)
- Recommendation for VALO2 WS2 to focus on identifying and mitigating bottlenecks relating to the health data access process.

According to the latter, the continued work of WS2 in the VALO2 extension – resulting in this deliverable – was to a high degree based on the User Journey framework, especially with regard to providing recommendations for support functions to smoothen the journey towards health data access and secondary use.

1.3 Purpose of this final report

This “Nordic guide to EHDS2” (full working title: *Towards a Nordic guide to efficient and secure access to health data for secondary use according to the European Health Data Space Regulation*) is intended primarily to support the national authorities responsible for preparing for EHDS2 implementation, however also benefiting health data applicants, health data users, health data holders and other key stakeholders. As seen later in this report certain measures may even benefit more than one step or stakeholder of the User Journey at the same time.

Throughout the VALO project, WS2 also had specific tasks to identify EHDS2-relevant calls (EU and other potential funding programmes), as well as ongoing related projects in which any of the Nordic or Baltic countries were participating. This was regularly reported within the project, and is out of scope for this concluding external deliverable.

⁴ Value from Nordic health data – the VALO project Nordic EHDS2 Competence Forum – final report November 2025. [VALO WS2 Final Report.pdf](#)

2 Nordic cooperation for EHDS secondary use

2.1 Nordic EHDS2 Competence Forum

The Competence Forum, a regular by invitation-only workshop for national representatives from concerned ministries and government authorities, has been a central part of the WS2 of the entire VALO project. The overall objective has been to create and maintain an environment of trust for candid discussions on the challenges and unclarities of EHDS2 preparations and implementation. The concept was implemented as quarterly gatherings, preferably onsite but also with the possibility for online participation. Optimally the Forum had national representation from all countries to contribute to the information exchange and discuss relevant aspects, with the most valuable part being the three parallel breakout sessions named i) *HDAB*, ii) *Metadata*, and iii) *Legal* (subsequently *Legal/Ethical*).

At one occasion these breakout sessions were complemented with OMOP CDM⁵ as discussion theme, this as a consequence of national OMOP maturity mappings, as part of Workstream 3 (WS3), in the beginning of the VALO project. OMOP has also been a theme of the open VALO Stakeholder Forum, with the objective to increase awareness about terminology and data model standards, but also to examine more in depth the advantages and disadvantages of implementing such a data model.

An important basis for the discussions and work of the breakout sessions was the national progress report in survey format which was updated by each country before the Forums (see template in Annex 1). For more information on the Forum concept as a whole, see the report from the first VALO project⁶.

When this final consolidated report is being written, a total of seven Nordic EHDS2 Competence Forums have been held (Helsinki in September 2024, October 2025, and January 2026, Copenhagen in February 2025, Gothenburg in May 2025 and May 2026, and Iceland in September 2025). The last formal Competence Forum of the VALO project (VALO2 extension) will be held in Oslo late September 2026, thereby having had all Nordic countries hosting the event.

Following all of these Competence Forums except the first one, a web-based evaluation was conducted. The response rates have mostly varied around 40-50% (no dropout analysis has been made). Taking the response rate into account, the feedback has nevertheless consistently shown that the forums are appreciated and regarded as a valuable and important part of the EHDS2 preparations (see Table I).

Table I. Extract of average survey results from evaluations of Competence Forums February 2025 till May 2026.

⁵ Observational Medical Outcomes Partnership - Common Data Model

⁶ Nordic EHDS2 Competence Forum – final report. November 2025. VALO Project. [VALO WS2 Final Report.pdf](#)

Survey question	Average (of 5 as maximum/optimal)
How well did the Competence Forum in XX meet your hopes and expectations on a scale from 1-5?	4,2
How satisfied were you with the programme in general?	4,2
How satisfied are you with the breakout sessions?	4,1

A selection of quotes, representative for the overall feedback from the evaluations, can be seen in Table II.

Table II. Representative quotes from evaluations of Competence Forums during the VALO as well as VALO2 project.

- **What did you appreciate the most?**
- *Breakout session discussions* (Copenhagen Feb 2025)
- *Breakout session(s)* (Gothenburg May 2025)
- *The candid and trustful ambiance in the group...* (Gothenburg May 2025)
- *To meet and discuss with Nordic colleagues in a trusted environment* (Reykjavik Sep 2025)
- *The breakout session* (Reykjavik Sep 2025)
- *The discussions in the breakout sessions* (Helsinki Oct 2025)
- *The possibility to discuss with an EC representative* (Helsinki Oct 2025)*
- *The open climate and willingness to share thoughts* (Helsinki Jan 2026)
- *Both presentations and discussions in groups* (Helsinki Jan 2026)
- *An open atmosphere and sharing of thoughts. Being part of a community* (Helsinki Jan 2026)
- *Constructive climate, thoughtful questions, and open discussions* (Gothenburg May 2026)
- *Open and trusted atmosphere for conversation, practical level suggestions and face-to-face discussions* (Gothenburg May 2026)
- *...Alongside the discussions, there is now a stronger focus on producing tangible results* (Gothenburg May 2026)
- **Feedback to improve future breakout sessions**
- *Several responded "More time!"*
- *(Technical) Challenges with hybrid meetings (esp. audio problems)*

**Two Forums had a digital visit of a representative of DG SANTE, European Commission.*

2.2 Value of Nordic cooperation

The VALO project started off with the five Nordic countries, however before entering the extension phase of VALO2, Estonia and Lithuania joined as observers. This provided an additional dimension to the VALO consortium. With all the similarities, yet with retained respect

for national differences, the Nordic and Baltic countries have the potential to support and develop faster and further together rather than doing it all by themselves when it comes to the implementation of EHDS. Please note that in this report, all references to Nordic cooperation can in principle be expanded to encompass **Nordic-Baltic** cooperation. This is implied throughout the rest of the report without being explicitly stated.

Preparations for, and implementation of, the EHDS Regulation, in this case with specific regard to the secondary use of health data (EHDS2), require significant efforts and pose challenges to all Member States and concerned stakeholders. By working together, uncertainties and challenges can be addressed more effectively or avoided altogether, thereby saving time, money and other resources. The outcomes of the Nordic EHDS2 Competence Forum, its breakout sessions and working groups, the national progress reports and other activities under WS2 (as well as other parts of the VALO1 and VALO2 project) demonstrate that this kind of cross-border cooperation is valuable and with regard to EHDS even necessary. In addition to cooperation at a broader European Union level, shared characteristics, geographical proximity and close ties of the Nordic and Baltic countries make it both logical and beneficial to establish and further develop a cooperation on these complex and urgent matters. Thereby guidance, harmonisation, and operational support can be further facilitated on this regional level in relation to EHDS2 implementation. Several outcomes and experiences from VALO2 WS2 presented in this report, underline the importance and value of Nordic collaboration, for instance regarding:

- **Metadata:** The metadata standard of EHDS, HealthDCAT-AP, is not easy to understand and interpret by each respective country's experts independently. A joint understanding is foundational. In this way, the Nordic-Baltic community can contribute even more constructively to implementation at EU level.
- **Regulatory aspects:** Legal interpretations and national adaptation in relation to the EHDS Regulation have been important topics for discussion and work in WS2. One example is to reach consensus on the definition of statistical bodies as health data holders, with potential efforts for a Nordic self-assessment support to help organisations identify whether they qualify as health data holders or not.
- **Ethical aspects:** Article 54(1)(e) EHDS preserves the application of ethical requirements laid down in national law, making differences in national ethical-review requirements an important consideration for EHDS implementation. Where required, ethical review forms part of the User Journey, affecting the data-access process as a whole and its timeline. VALO2 therefore mapped the Nordic ethical-governance frameworks to identify differences, potential bottlenecks and opportunities for greater transparency and cooperation.
- **Harmonisation:** Possibilities for Nordic harmonisation have been discussed in depth in the project, e.g. with regard to legal interpretation and adaptation of national legislation, ethical review requirements and process, harmonised implementation of HealthDCAT-AP in national metadata catalogues and possibilities to create extensions in as harmonised way as possible ("Nordic HealthDCAT-AP extension"), HDAB and SPE (Secure Processing Environment) organisation.
- **Support functions:** Comparison of national organisational strategies (e.g. HDAB, SPE) and different support functions for a smooth, yet secure User Journey for secondary use of

health data. A collection of recommendations on support functions presented in this report is to a high degree an outcome of the VALO and VALO2 project (see chapters 4-7).

2.3 Sustainability beyond the VALO project

This report is being finalised and published right after the VALO project, with its extension VALO2, concluded in September 2026. The final Competence Forum of the project took place in Oslo late September, followed the next day by the final stakeholder event, the Nordic Health Data Summit 2026. This Competence Forum provided a final opportunity to have a project-internal discussion about the value of these forums in total and to discuss the need and possibility for continuity in some form after the project end. The subsequent open stakeholder event provided in its turn a possibility to present the work and outcomes of the Competence Forums (including this report), as well as the other work carried out within WS2 and other parts of the entire VALO project (WS1 and WS3). It also provided an opportunity to collect input and feedback from stakeholders with regard to the questions of which EHDS2-preparatory activities should continue beyond the project, and in which form.

WS2 has had a clear focus on continued networking, sharing EHDS2-related news and information, and further strengthening the trusting environment that has come to characterise the quarterly organised Competence Forum. According to the evaluations and feedback from the participants, the forum has been a valuable resource for supporting the complex process of preparing, organising for, and implementing the respective national authority functions as well as conducting the legal interpretations and adaptations in relation to the EHDS Regulation. This indicates a potential need for bridging over from the VALO project outcomes to long-term continuity and sustainability of this Nordic collaboration.

However, since the VALO project comprises three distinct yet complementary workstreams (WS1, WS2 and WS3), it is important to clarify and optimise how these workstreams could contribute through their respective objectives to the overall preparation for the joint Nordic implementation of EHDS2:

WS1: Ensuring the continuity of joint Nordic EHDS2 collaboration on secondary use of health data and addressing the identified need for a driver/orchestrator, leading to the proposal for a Nordic Model.

WS2: Finding a suitable way to continue with the established forum and trusting environment for a collective dialogue and collaboration on the complex matters related to preparing for and implementing EHDS2.

WS3: Advancing practical and research-oriented preparations, exploration and implementation of cross-border access to Nordic health data through federated analysis pilot studies.

The three workstreams all contribute to a common approach for a joint, and to some extent also harmonised, Nordic implementation of EHDS2. Therefore, the VALO2 project could be seen as a well-motivated investment for cross-border collaboration.

The outcomes of VALO provide an opportunity to build on the proposal developed in WS1 for a Nordic model to support the implementation of EHDS Regulation⁷. A key element of this proposal is the establishment of a Nordic Health Data Competence Forum, building on the experience and network created through the VALO Competence Forum. Such a model could provide a structured framework for continued Nordic collaboration, knowledge exchange, capacity building, and coordination related to the secondary use of health data under EHDS.

⁷ Nordic model for collaboration on the secondary use of health data: *steps towards implementation*. Value from Nordic health data – VALO project. September 2026

3 The User Journey as a common framework for EHDS2 services deployment

The User Journey provides a common framework for analysing the services and support required for the secondary use of health data under the EHDS. Building on the applicant- and data user-oriented journey developed in TEHDAS⁸ and TEHDAS2⁹ Joint Actions, VALO2 expands this framework to reflect Nordic implementation needs, including activities undertaken before data discovery and the organisational support required across the journey.

The thematic findings (Metadata, Legal and Ethical) underpinning the User Journey are presented in Chapters 4 to 6, while Chapter 7 and Annex 2 provide a synthesis of the detailed journey, bottlenecks and recommended support functions.

3.1 Overview of the User Journey

The TEHDAS projects (including the current TEHDAS2 Joint Action), also led by Sitra which has been the coordinator of the VALO projects, have presented and elaborated on the User Journey¹⁰, from the applicant's and secondary user's perspective (Figure 1 and Annex 2).

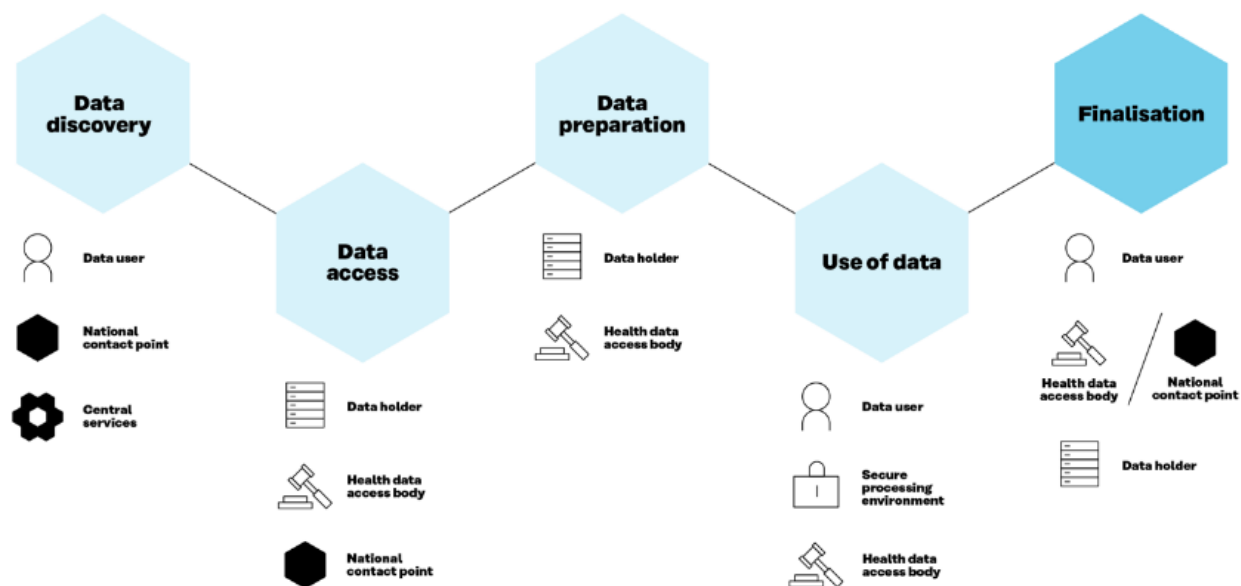


Figure 1. The User Journey of secondary use of health data, according to TEHDAS2 (M8.4 Draft guideline for data users on handling research outcomes), April 2026.

In WS2 of the VALO1 and VALO2 projects we saw a need to develop this concept further to increase the granularity of the different steps and sub-steps and make visible the supportive services required to be deployed in advance. Each sub-step could be described in greater detail

⁸ [Joint Action Towards the European Health Data Space – TEHDAS1 - Tehdas](#)

⁹ [Second Joint Action Towards the European Health Data Space – TEHDAS2 - Tehdas](#)

¹⁰ [Results by user journey - Tehdas](#)

based on a more in-depth analysis. An example is provided for the *Data discovery* step, with sub-steps as seen in Figure 2, and further details are provided in sections 3.3, 7 and Annex 2.

User Journey:

Data discovery

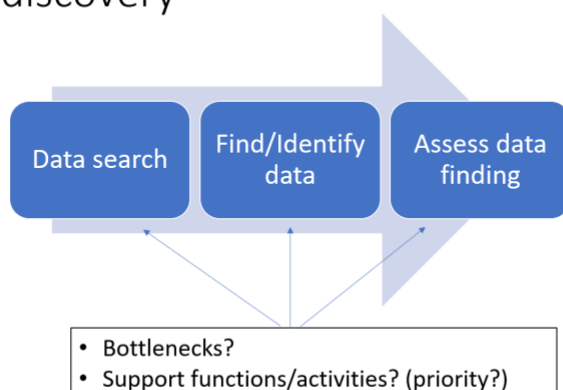


Figure 2. A draft model for a detailed mapping of the different sub-steps of the User Journey's main steps such as Data discovery, together with identification of bottlenecks and (priority) support functions and activities.

For instance, the sub-step *Data search* (under Data discovery), could be described more in detail according to the following proposal:

- **Brief description**
- **Priority**
- Responsible actor ("driver" of process progress)
- Supporting actor(s)
- **Support activity(ies)**
- EHDS Article(s)
- (Other information)

This proposal has been developed based on discussions within the overall HDAB-focused working group of WS2. The discussions led to a consensus to focus initially on the most important items above (in bold), and to start collecting that specific information for all the sub-steps of the User Journey (Annex 2).

Essentially, the work undertaken in VALO2 Competence Forums and dedicated sub-groups work has revealed that the currently prominent view of the User Journey is not sufficient as tool in view of deploying, maintaining and developing the expected national HDAB infrastructures.

Instead, a more useful reference framework seems to be the one presented earlier by WP7 of the first TEHDAS JA (see Figure 3)^{11,12}

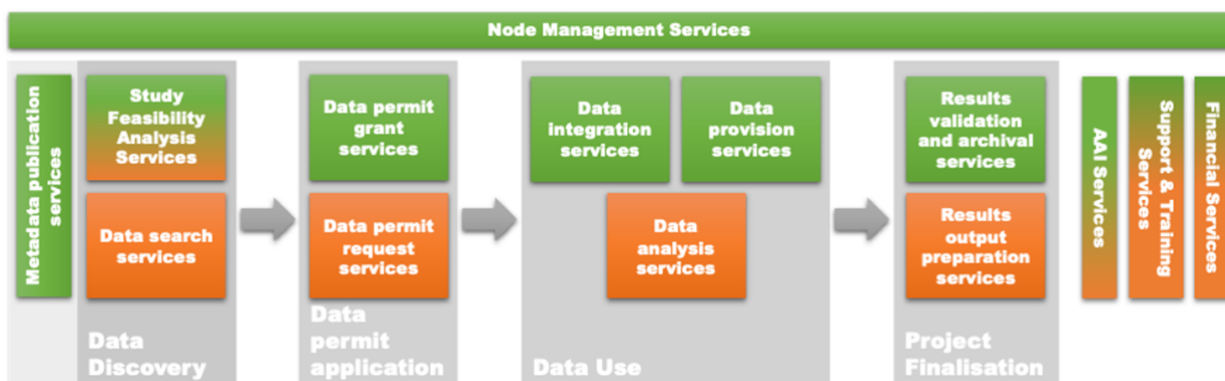


Figure 3. Revisited Users' Journey according to the first TEHDAS project: "...Green boxes represent those services that are related to the EHDS2 point-of-view, i.e., the services that are conceived to involve data controllers, data permit authorities and other actors than data users. The orange boxes represent those services purely related to the EHDS2 data users' point-of-view, i.e., where data users interact with the EHDS2. The grey boxes represent the actual phases of the User Journey itself." (AAI: Authentication, Authorisation & Identification).

VALO2 comment: Notice the Metadata publication services, as a (partial) pre-phase to the User Journey.
Source: TEHDAS Deliverable 7.2 Options for the services and services architecture and infrastructure for secondary use of data in the EHDS. 4 July 2023.

The earlier version of the User Journey captures successfully – albeit on a crude level – the requirement for extensive back-office services and infrastructure development primarily on the side of data holders and HDABs, as well as the need to perceive the Journey as a joint undertaking between different combinations of stakeholders, rather than purely from the perspective of the applicant/health data user (as in the TEHDAS2 User Journey version). VALO2 WS2 has developed this model further and provided concrete examples of its operationalisation steps and requirements.

3.2 Objectives

Based on the above, the Competence Forum decided to apply the Objectives and Key Results (OKR) framework as a way of giving the work concrete direction. Rather than tracking progress through abstract aspirations, OKR helped setting clear shared objectives alongside specific,

¹¹ TEHDAS Deliverable 7.1 Options for the minimum set of services for secondary use of health data in the EHDS. April 2022

¹² TEHDAS Deliverable 7.2 Options for the services and services architecture and infrastructure for secondary use of data in the EHDS. July 2023

measurable key results over a defined period. The HDAB breakout session formulated the following draft OKRs:

A. Support functions

Key objectives

- Identify bottlenecks for secondary use
- Identify support functions in relation to these bottlenecks

Key results

- Mapping of bottlenecks
- List of support functions (incl objective of support function)
- Identify/define concerned step of secondary use process for support function
- Estimated priority and effect of respective support function
- Identifying responsible body (e.g. HDAB)

B. Mappings and compiled outputs of WS2

- National guidance/support (in relation to User Journey)
- Nordic guidance/support (if applicable)
- List of appointed HDABs (or formal candidates)
 - Including national HDAB organisation models (responsibility and functions)
- List of national SPE candidates (national mappings/questionnaires)
- (Possibilities for creating a Nordic portal with mappings and support functions?)

C. Potential for harmonisation

A central ambition of the VALO/VALO2 project has been to aim for and identify the possibilities for Nordic harmonisation in the EHDS2 preparations and implementations. Possible areas of harmonisation include legal matters, such as opt-out, fair and justified Intellectual Property (IP) rights and trade secrets. Similarly, metadata, and other areas could be harmonised, for instance with regard to a Nordic extension of the standard HealthDCAT-AP.

Following the engaged discussions in the first VALO Project, the OKR model was used for VALO2 as a tool to facilitate the definition of the most important objectives and expected key outputs of WS2. The result is presented as integrated parts of the following chapters.

3.3 Integrated view of bottlenecks and support functions

Analyses in Competence Forums and breakout sessions showed that the User Journey should be extended upstream (of Data Discovery) to include also mapping health data holders and their readiness to identify datasets, communicate legal restrictions, and prepare metadata. The latter critical not only at the national level for health data discovery but also across borders to other Member States, through the dataset catalogue provided by the HealthData@EU Central

Platform¹³. This extension upstream was named *pre-discovery and metadata publication* (partially aligned with the User Journey of TEHDAS deliverable D7.2).

Downstream, it should include data preparation, secure processing, analytical support and output release. Legal, ethical and metadata requirements are therefore not separate workstreams from the applicant and data user perspective, but represent dependencies within a single end-to-end process.

Chapter 7 presents a more detailed account of the User Journey in relation to identified bottlenecks for health data access, together with recommendations for facilitating and time-saving support functions and activities. However, prior to that the following chapters on Metadata as well as Legal/Ethical aspects contribute to setting the scene.

¹³ [HealthData@EU Central Platform - HealthData@EU](#)

4 Metadata and metadata catalogues

The following is a summary of the metadata work in the VALO2 project. A more detailed report can be found in Annex 4a (*Metadata and metadata catalogues – full report*).

4.1 Background and objectives

The metadata work in the VALO2 project focused on supporting the implementation of EHDS by strengthening Nordic cooperation on health data metadata and metadata catalogues. Building on previous Nordic initiatives and the first VALO project (VALO1), the work aimed to:

1. Develop a common Nordic understanding of the HealthDCAT-AP metadata specification¹⁴.
2. Improve understanding of the Nordic health data landscape under EHDS Article 51¹⁵.
3. Explore the metadata requirements for effective use of artificial intelligence (AI).

The overall objective was to promote harmonised implementation of EHDS metadata requirements across Nordic countries and improve cross-border discoverability and usability of health data.

4.2 Key findings of the metadata work

4.2.1 HealthDCAT-AP implementation: progress and remaining challenges

4.2.1.1 Key findings

HealthDCAT-AP specification has somewhat matured during the recent years, and participating countries have improved their understanding of the specification. However, implementation readiness remains uneven in and between the countries, and several fundamental challenges persist.

The most important challenge is the lack of a consistent understanding of the HealthDCAT-AP information model. Countries continue to struggle with questions such as:

- What constitutes a dataset?
- How should dataset series or distributions be used? How to interpret the class Catalogue?
- How should datasets from different EHDS data categories be represented?

In addition, the HealthDCAT-AP property definitions are not yet clear enough. There is not yet unified view among the Nordic countries regarding the interpretation of various dataset level mandatory properties, which was demonstrated through a practical exercise (see summary of the pilot descriptions and questions regarding the interpretation of properties in the Annex 4b *HealthDCAT-AP pilot descriptions*). These unresolved issues present a risk to harmonised implementation and could undermine cross-border data discoverability.

¹⁴ <https://healthdataeu.pages.code.europa.eu/healthdcat-ap/releases/release-7/>

¹⁵ Minimum categories of electronic health data for secondary use

The project's mapping exercises showed that countries seeking to adapt existing catalogues, particularly Finland and Norway, will need substantial modifications to become fully compatible with HealthDCAT-AP. Decisions and plans should be made soon, but ongoing uncertainty regarding the correct interpretations is currently hindering rapid progress.

A shared conclusion among all participating countries was that the current HealthDCAT-AP draft's mandatory properties alone are insufficient to describe Nordic health data adequately. Additional metadata elements are required to support meaningful dataset descriptions and effective data discovery, especially at variable level.

4.2.1.2 Main development needs

The metadata group identified several priority areas for further development, which should be addressed at the EU level:

- Clear guidance and practical examples on the HealthDCAT-AP information model.
- More precise definitions of datasets across all EHDS Article 51 data categories.
- Improvement of the HealthDCAT-AP property definitions and resolution of any ambiguities between properties.
- Further development of many vocabularies used in HealthDCAT-AP.
- Detailed, data category specific implementation guidance.
- More EU-level training, examples, and implementation exercises.
- Easier publication of pilot metadata descriptions within HealthData@EU Dataset catalogue to support communication of the issues, and the integration of feedback from various stakeholders.

4.2.1.3 Country HealthDCAT-AP implementation status

HealthDCAT-AP implementation approaches vary across countries:

- Denmark has developed a HealthDCAT-AP-based national health data catalogue prototype and launched it as an internal catalogue.
- Finland plans to adapt its existing national health data catalogue but faces challenges related to information model alignment.
- Iceland is preparing to establish a HealthDCAT-AP-based catalogue and has applied for funding.
- Norway is planning to implement HealthDCAT-AP in the current national catalogue and has made progress in developing metadata platform, validator tool for data holders, and enhanced metadata discovery services.
- Sweden has chosen to build a new HealthDCAT-AP based catalogue with lessons learned from earlier national catalogue for registry data and a prototype catalogue developed in a direct grant project.

Common challenges in implementation include uncertainty regarding information model and implementation requirements; limited resources and lack of metadata or technical expertise; lack of awareness, capabilities or resources of data holders, and inconsistent metadata quality among data holders.

4.2.2 Understanding the Nordic health data landscape

4.2.2.1 Key findings

EHDS broadens the categories of health data that must be made available for secondary use. Many participating countries currently lack a comprehensive overview of these data assets and their holders. The current EHDS definition of a health data holder would need practical clarification, and many countries have not yet established national processes of EHDS health data holder identification.

The Metadata group performed an initial mapping exercise of health data holders and datasets across EHDS Article 51 data categories (*minimum categories of electronic health data for secondary use*, see in Annex 4c *Nordic health data analysis tables*). The exercise showed that uncertainty remains regarding:

- Which Nordic organisations qualify as health data holders;
- Which datasets exist in the countries corresponding to specific data categories, especially those that have not yet been described in the current catalogues;
- Which data are actually covered by certain categories;
- How these data should be organised and presented in catalogues, and how granular should the dataset division be.

4.2.2.2 Main development needs

It is important to seek to clarify the health data holder definition in the Nordics and create tools or other support for data holders to help them identify if they are health data holders according to EHDS. Communication about EHDS and metadata requirements for data holders is essential, and if it fails, it can potentially complicate the secondary use of health data by:

- Potential data holders not recognising their obligations under EHDS;
- HDABs facing difficulties identifying organisations that fall within the scope;
- Cataloguing efforts being inconsistent between countries;
- Data users not being aware of all the datasets that should be available.

4.2.3 Preliminary understanding of the needs AI places on metadata

The project also explored connections between metadata and effective utilisation of AI applications in connection to secondary use of health data.

A preliminary analysis was made on how well a high-risk AI model developer could potentially assess the quality of data following the requirements set out in the Article 10 of the EU AI Act (*Regulation (EU) 2024/1689¹⁶ laying down harmonised rules on artificial intelligence*), if a dataset was described based on the current EHDS requirements on metadata descriptions and data quality and utility labelling (HealthDCAT-AP Release 7 metadata specification and the data quality and utility label metrics¹⁷ developed by the QUANTUM project). When discussing the outputs of the QUANTUM project, it is worth noting that they will serve as the basis for the

¹⁶ [EUR-Lex - 02024R1689-20260727 - EN - EUR-Lex](#)

¹⁷ [Deliverable 1.1 Specification of the data sets' quality and utility label | Zenodo](#)

implementing act on data quality and utility label, but there is no guarantee that the final EU requirements will align with them in the end.

In addition to this, the Norwegian team shared their findings of a project on exploring metadata-driven AI for variable discovery, application support and case processing in the Norwegian Institute of Public Health (FHI) called AI-Powered Metadata Discovery for Health Data Applications and Case Processing. Findings related specifically to metadata quality were discussed.

4.2.3.1 Key findings

The preliminary analysis concluded that metadata quality is a critical enabler of trustworthy AI use in health data environments.

AI Act requirements versus EHDS requirements

High-quality HealthDCAT-AP based metadata descriptions and data quality reporting most likely can help AI developers to assess certain required dataset quality related aspects, such as dataset provenance, data collection processes and original purpose of data collection. They can also help in assessing the availability, quantity, suitability and representativeness of the data that are needed. In particular up-to-date variable-level data quality and availability reporting – if provided by data holders – are likely to provide plenty of useful information to support the assessments.

However, current HealthDCAT-AP metadata and QUANTUM data quality and utility label requirements might provide only a starting point for the deeper assessment. For high-risk AI development, it may be that more detailed information and analysis will often be required especially for the examination of potential biases and identification of relevant data gaps and shortcomings. It may also be necessary to consult the data experts at the data holder's end to gain in-depth knowledge of these aspects.

Lessons from Norway on the use of AI in variable discovery

Norwegian experiences using generative AI for metadata discovery demonstrated that AI performance on assisting variable discovery depends heavily on metadata quality. Effective AI-assisted discovery requires metadata that are structured, standardised, complete, semantically harmonised, consistently maintained and frequently updated.

Poorly documented or inconsistent metadata can prevent AI systems from identifying datasets or variables relevant to a particular study. Variable-level metadata was found to be particularly important for AI-supported data discovery and reuse.

4.3 Summary of recommendations

Following is a summary of recommendations for the Nordic countries:

1. Continue and seek expanding Nordic cooperation

- Maintain close collaboration on interpretation and implementation of EHDS metadata requirements.
- Share lessons learned, best practices, tools, support models and identified national needs for metadata.



- Coordinate Nordic input into EU-level discussions and developments.
- Continue pursuing long-term harmonisation of metadata standards, metadata catalogues, and data quality reporting.

2. Continue practical implementation and piloting

- Make pilot metadata publicly visible when possible and collect feedback from different data holders and communities of data holders, researchers and other data users, HDAB personnel, and other stakeholders.
- Publish pilot dataset descriptions across diverse EHDS data categories.
- Use pilot implementations to identify interpretation issues and to support EU-level discussions.

3. Strive for improved guidance and definitions in the EU level

- Bring Nordic findings in a consolidated manner to the EU level discussion.
- Highlight the particular needs to:
 - Clarify the HealthDCAT-AP information model and the concept of datasets.
 - Develop practical examples and implementation guidance for different EHDS data categories.
 - Improve HealthDCAT-AP property definitions, vocabularies, and instructions.
 - Add new necessary dataset-level properties.
 - Clarify EHDS data category definitions and their metadata implications.

4. Ensure metadata quality and governance

- Invest in metadata quality, completeness, consistency, and long-term maintenance. Establish sustainable metadata governance processes.
- Invest in data holder support and guidance in resource-efficient manner.
- Especially to strengthen AI readiness:
 - Pay attention to structured, detailed and harmonised variable-level metadata.
 - Pay attention to documentation of dataset provenance, collection processes, original purpose of data collection, population coverage, classifications used, and data quality characteristics.
- Establish mechanisms for collecting and using metadata quality and data quality-related user feedback.
- Examine ways to utilise AI to support the production of high-quality metadata.

5. Ensure adequate resources and technical support

- Allocate resources for metadata and data quality and utility labelling implementation, maintenance, and support.
- Ensure sufficient technical expertise in HDABs and the ability to support health data holders in technical issues.
- Explore opportunities to leverage common technical tools in European or Nordic level.



6. Strengthen understanding of the Nordic EHDS landscape

- As part of broader Nordic cooperation, develop and publish a Nordic self-assessment tool or other support material to help data holders identify their role as a health data holder.
- Continue mapping health data holders and datasets across all EHDS Article 51 categories.
- Share methodologies, examples, and findings among Nordic countries.
- Publish practical examples of datasets belonging to different data categories.

7. Explore developing a common Nordic metadata framework

- Explore the need to continue building a “Nordic HealthDCAT-AP extension” consisting of agreed additional important HealthDCAT-AP properties, supplementary metadata elements required for Nordic health data, and harmonised variable-level metadata specifications. This is necessary especially if developments at the EU level are not considered sufficient to meet the needs of the Nordic countries.
- Strive for as harmonised dataset definitions as possible.
- Strive for common approaches to data quality and utility labelling and data quality reporting.

The above recommendations have effect on the User Journey for secondary use of health data and will be discussed at least partly also in Chapter 7.

5 Legal interpretation and implementation issues

The VALO2 Legal Group included participants from all Nordic countries, although the level of participation varied, and received some contributions from Estonia and Lithuania. Due to these differences in participation, the group's conclusions reflect the views of the participating experts from Denmark, Finland, Iceland and Norway. The group examined selected EHDS provisions that were considered particularly relevant or challenging, at the time of working, from the perspective of Nordic implementation. The work identified areas where a common Nordic interpretation could reduce unnecessary divergence, practical implementation issues that may create bottlenecks, and legal questions that remain unresolved and may require further clarification. Unless expressly stated and attributed otherwise, the interpretations and recommendations reflect views developed within the expert group and do not represent official positions of the participating countries, national authorities or the experts' organisations. Where the report describes national legislation, official proposals or formally adopted positions, this is identified separately. **The full reasoning, legal analysis and national implementation context are provided in the *Nordic Interpretation of Specific EHDS Articles (Annex 5)*.**

5.1 Areas where the legal group reached a common interpretation

The Legal Group reached common interpretations on several EHDS provisions where divergent national approaches could create unnecessary complexity.

5.1.1 Statistical bodies – health data holders

The group identified strong textual, systematic and functional grounds for considering statistical bodies that hold and process electronic health data for health-related official statistics to be health data holders under Art. 2(2)(t). However, this status is not automatic. Each statistical body must be assessed individually based on its activities, the intended purpose and users of its statistical products or services, its role in relation to the data concerned and all the conditions laid down in Art. 2(2)(t).

5.1.2 Health data intermediation entities

The group also developed common interpretations on several aspects of Health Data Intermediation Entities (HDIEs). The group considered that national implementation should allow organisational flexibility, including the possibility for public or private legal entities to act as HDIEs and for HDIE arrangements to be organised in relation to different categories of health data holders or datasets. The group also considered that the practical allocation of duties between a health data holder and an HDIE can be specified contractually, within the framework established by the EHDS and applicable national law. This would allow the health data holder to select and use one or more HDIEs and to define the practical division of tasks between them, while the relevant HDAB should be informed of the arrangement.

5.1.3 Fees

Regarding fees under Art. 62, the group agreed on several aspects of how the provision should be interpreted, including that the EHDS fee rules apply from the submission of an application under Arts. 67–69. At the same time, the analysis identified a structural concern with the current framework. The EHDS provides limited financial incentives for health data holders to invest in

systems and infrastructure that could make data extraction and provision more efficient, since such investments cannot generally be recovered through fees charged to applicants.

Differences in national fee policies, combined with these limited incentives, may affect the cost and attractiveness of accessing data in different countries. This illustrates why continued Nordic cooperation remains important even where the underlying EHDS fee rules are relatively clear, as different implementation choices may still create practical barriers to cross-border access. The group therefore considered that these issues should remain on the Nordic and European implementation agenda.

5.1.4 Application assessment

The group also developed a common interpretation of the scope of the HDAB assessment under Art. 68(1)(b). Assessing whether the data requested in a data permit application are necessary, adequate and proportionate may, where relevant, require consideration of the scientific appropriateness of the proposed use and basic ethical aspects. This interpretation is particularly relevant in countries where national law does not require or allow a separate ethical review for the proposed secondary use, as it provides a means for relevant ethical concerns to be considered within the data permit assessment. This does not create a separate ethics review by the HDAB, but means that its assessment need not be limited to a purely formal or administrative exercise.

5.2 Bottlenecks and implementation issues

The legal group identified several issues where national implementation choices or the absence of established procedures may create practical bottlenecks for secondary use, particularly for cross-border projects.

5.2.1 Opt-out

A clear example is the implementation of the right to opt out. Member States have considerable discretion in designing their national mechanisms, including their level of granularity. Different Nordic approaches could result in differences in the data available for secondary use, affecting the representativeness and comparability of datasets and potentially making multinational studies more difficult. The group therefore considered opt-out implementation primarily an operational and policy issue that would benefit from continued Nordic cooperation, particularly between HDABs.

5.2.2 Significant findings

The handling of significant findings under Arts. 58(3) and 61(5) may constitute another bottleneck. Similar mechanisms already exist in some Nordic countries, but practical experience is limited and differences exist between national approaches. A particular challenge is that the EHDS refers to “any significant finding related to health” without specifying whether the finding must also be actionable, for example through treatment or prevention. This raises difficult questions concerning what should qualify as a significant finding, how significance and actionability should be assessed, which actors should be involved, and how information should

ultimately reach the individual concerned. The legal group therefore considered that further multidisciplinary guidance is needed and recommended addressing the issue at European level.

5.2.3 IP rights and trade secrets

The protection of intellectual property rights and trade secrets raises both legal and operational questions concerning how safeguards should be applied in practice. HDABs will need workable procedures for identifying and protecting commercially sensitive information without creating unnecessary restrictions on secondary use. The legal group considered that further work would require specialised expertise and coordination with the HDAB group, including a decision on the level of Nordic cooperation sought in this area.

5.3 Questions that remain unresolved

The Legal Group did not reach a common interpretation on all of the legal questions examined.

5.3.1 Consent

The most significant unresolved issue concerns the relationship between Recitals 52 and 62 and Art. 54(e) EHDS, particularly the role of consent. It remains unclear whether the reference in Recital 62 to ethical provisions relating to consent concerns only consent requirements connected to the GDPR legal basis for processing or may also extend to informed consent requirements under national research ethics frameworks. The relationship between this provision and the possibility of maintaining certain stricter national safeguards under the EHDS also remains unclear. The group considered that clarification at European level would be valuable to avoid divergent national interpretations.

5.3.2 Legal responsibilities of HDIEs

Another unresolved question concerns HDIEs and the allocation of legal responsibilities. Different views were expressed within the Legal Group on the extent to which responsibilities under the EHDS may be allocated to an HDIE under national law and how this relates to the HDIE's possible role as a controller, joint controller or processor under the GDPR. The group did not reach a common interpretation on this relationship and considered that the allocation of responsibilities under the EHDS and the determination of roles under the GDPR require further clarification.

These unresolved questions illustrate areas where continued Nordic legal cooperation and, where necessary, European-level guidance would be particularly valuable. Maintaining a Nordic forum for legal interpretation could help the countries exchange views as national implementation progresses, identify emerging differences at an early stage and, where appropriate, formulate common questions or positions for discussion at European level.

5.4 Legal implications for the User Journey and support functions

The findings of the legal group have direct implications for the User Journey for secondary use of health data. Divergent legal interpretations may result in different requirements, procedures and costs and thereby create unnecessary bottlenecks, particularly for cross-border data access. Several issues examined by the legal group are directly linked to the User Journey,

including the **identification of health data holders** and **use of HDIEs**, **HDAB assessments**, **opt-out**, **fees**, **IP rights and trade secrets**, and **significant findings**.

An efficient User Journey therefore depends not only on consistent interpretation of the EHDS, but also on similar or harmonised approaches in areas where the Regulation leaves Member States national discretion. This concerns, for example, how the right to opt out is implemented, whether reduced fees are available, and the extent to which ethical aspects may be considered as part of the HDAB assessment under Art. 68(1)(b). Legal advice is also an important support function where the interaction between the EHDS and national legislation remains unclear.

More broadly, unnecessary legal and implementation divergence within the Nordic region could weaken the Nordic countries' position as forerunners in the secondary use of health data. Nordic cooperation should therefore seek to avoid unnecessary differences both in legal interpretation and in the exercise of national discretion, supporting a predictable User Journey and maintaining the region's attractiveness for health data research and innovation. These considerations provide the legal context for the more detailed examination of the User Journey and related support functions in Chapter 7.

5.5 Recommendations for continued cooperation

The legal group identified several matters that would benefit from continued Nordic cooperation following the VALO2 project. The following recommendations reflect the views of the participating experts and indicate possible areas for further legal, operational and policy-related work.

- Continue the legal group's analysis of the relationship between the EHDS provisions on consent and national research ethics requirements, with the aim of developing a shared expert interpretation while monitoring Union-level guidance and case law. Examine how "healthcare or care sectors" should be interpreted under Art. 2(2)(t), including whether sectoral affiliation should be assessed primarily on an institutional or functional basis.
- Explore, together with the metadata group and building on relevant national work such as Sweden's decision-tree initiative, whether a common Nordic assessment tool or interface could support the assessment of individual organisations as potential health data holders.
- Support the HDAB group in comparing national approaches to opt-out granularity and the exception under Art. 71(4), including through legal interpretation where needed.
- Continue Nordic examination of HDIE models and seek further clarification of the relationship between responsibilities under the EHDS and controllership under the GDPR.
- Develop Nordic cooperation on the practical protection of intellectual property rights and trade secrets, with the level and form of cooperation first considered by the HDAB group and legal support provided where appropriate.
- Promote multidisciplinary European guidance on the handling of significant findings, including clear procedures, responsibilities and criteria for assessing significance and actionability.



- Prepare a joint expert opinion when the draft implementing act on fees is opened for public consultation, addressing incentives for health data holders and the effects of fee levels on cross-border access.
- Consider whether the interpretation of Art. 68(1)(b) should form the basis of a common Nordic approach and, if supported by the participating countries, promote that approach in discussions with the European Commission and other Member States.

6 Ethical governance of secondary use

The ethical expert group was established in response to Article 54(e) EHDS, which preserves the application of ethical provisions laid down in national law. Consequently, although the EHDS establishes a common European framework for secondary use, relevant national ethical requirements continue to affect the conditions under which health data can be accessed and used. Because these national requirements may differ and ethical expertise had so far been only marginally involved in EHDS implementation, it was decided that a separate ethical experts' group was needed to map the Nordic ethical-review frameworks, identify potential cross-border bottlenecks and considered opportunities for greater transparency and cooperation.

Against this background, the VALO2 ethical expert group examined national ethical review requirements relevant to secondary use in the Nordic countries and considered where differences between national systems may create barriers to cross-border use and where greater Nordic harmonisation or practical alignment could be beneficial. The work also sought to distinguish between differences that could be addressed through common guidance, procedures or other forms of practical alignment and those that are more closely connected to national legislation and structures.

The work identified four particularly relevant themes: i) differences in national ethical review requirements and procedures; ii) the distinction between quality assurance (QA) and scientific research; iii) the practical impact of ethical and related national requirements demonstrated through the VALO2 pilot; and iv) the need for continued Nordic cooperation as the EHDS is being implemented.

The full national mappings, comparative analysis and recommendations are provided in *Ethical Governance of Secondary Use of Health Data in the Nordic Countries – Challenges, Comparisons and Future Collaboration under the EHDS*, see Annex 6.

6.1 National differences and opportunities for Nordic alignment

The national mappings demonstrate that the role of the type of data used as a trigger for ethical review differs considerably between the Nordic countries. For example, in Finland, secondary use of existing health data does not generally require statutory ethical review solely because health data are used. In Denmark, data-only register-based research is generally outside the statutory ethical review system, but certain sensitive bioinformatic data, currently genome and imaging data, may trigger ethical review. By contrast, in Iceland, where the activity constitutes scientific research in the health sector, the ethical review requirement is not limited to particular categories of health data: research using identifiable or pseudonymised health data may require review across all the EHDS Art. 51 data categories. Sweden also uses the type of data as an important trigger, as scientific research involving special categories of personal data, including health data, falls within the Ethical Review Act. In Norway, the type of data is not in itself the primary trigger; the central question is whether the project constitutes medical and health research within the scope of the Health Research Act.

These examples illustrate that the same type of health data does not necessarily trigger the same ethical review requirements across the Nordic countries. In some countries, particular data

categories are relevant to whether review is required, while in others the decisive factor is primarily the purpose and legal classification of the activity. For cross-border projects, the applicable ethical review pathway therefore cannot be determined from the fact that health data are being used alone.

Other differences between the Nordic systems were also identified in the mapping, including territorial applicability of national ethical review legislation, application-language requirements, the competent bodies and applicable procedures, processing times, the validity and amendment of ethical approvals, and other national requirements connected with the ethical review pathway. These differences may affect cross-border projects and the overall User Journey.

6.2 Quality assurance and scientific research

The distinction between QA and scientific research emerged as one of the main cross-cutting issues. In this section, QA refers to the classification of an activity as quality assurance rather than scientific research when determining whether national ethical-review requirements may apply. It should not be confused with the separate metadata-related discussion of data quality and the EHDS data quality and utility label. Although organisational quality-assurance processes may affect how data are produced and documented, the concepts are used here in different regulatory and analytical contexts.

The classification is important because, depending on national legislation, whether an activity constitutes scientific research may affect whether ethical review needs to be considered. The mapping nevertheless indicates that the boundary between QA and scientific research is not always straightforward. The mapping did not identify a shared Nordic legal definition or a single common interpretation of QA. It nevertheless identified certain recurring characteristics: QA commonly aims to monitor, evaluate or improve healthcare or healthcare services, supports patient safety and quality management, and focuses on existing practice or organisational development rather than primarily seeking to generate new, generalisable knowledge. These characteristics provide practical points of comparison but do not constitute a uniform Nordic legal test. Importantly, interpretations may also differ within the same country, for example between individual ethics committees, organisations or other competent authorities. Consequently, similar activities may follow different regulatory pathways depending on how they are classified in practice.

The group therefore also considered the Nordic approaches against the broader European framework. Art. 53(1)(e) EHDS recognises scientific research as a permitted purpose for secondary use, including certain development and innovation activities and the training, testing and evaluation of algorithms and AI systems. The TEHDAS2 JA Guideline and the EDPB Guidelines 01/2026 provide relevant points of reference for interpreting scientific research under the EHDS and GDPR framework. The analysis supports focusing on the purpose and scientific characteristics of the activity, including whether it pursues genuine scientific objectives and uses recognised scientific methodology, rather than assuming that a particular technology or type of data use automatically constitutes scientific research.

Greater common understanding of the distinction between QA and scientific research could therefore improve predictability both between and within the Nordic countries. This does not

necessarily require identical national legal definitions. Exchange of practices, discussion of borderline cases and, where feasible, common Nordic guidance could support greater consistency while respecting national legislation and the independence of the competent authorities.

6.3 Practical impact demonstrated by the VALO2 pilot

The importance of these questions was demonstrated directly through the VALO2 pilot. The experience showed that the classification of a project and the national ethical and related requirements following from that classification can have a major practical impact on the User Journey, including the competent authority, the procedures that must be completed and the time required before data can be accessed.

In the Norwegian part of the pilot, a project that had initially been submitted to the same local hospital ethics committee that had assessed the earlier VALO pilot as QA, was instead classified as scientific research. This changed the applicable regulatory pathway and required ethical review by the Regional Committee for Medical and Health Research Ethics (REC). The timing of that determination meant that the next REC submission deadline had already passed. Following ethical approval, the project also required an exemption from the duty of confidentiality. The exemption was subjected to additional conditions requiring living participants to be informed and given an opportunity to opt out before access to the data could be provided. The combined effect of these sequential procedural requirements resulted in a delay of approximately five months, in data access, compared with the original project timetable.

Importantly, the delay was not caused by ethical review alone. The pilot demonstrates how the classification of an activity can change the regulatory pathway as a whole and trigger several sequential national requirements. In this case, the conditions attached to the exemption from the duty of confidentiality, rather than the ethical review itself, became the most time-consuming part of the approval process.

The pilot therefore provides a concrete example of why differences in ethical governance are highly relevant to the implementation of the EHDS. Requirements that may appear relatively limited when considered individually can have substantial cumulative effects on cross-border projects. Applicants should therefore be able to identify the applicable ethical and related national requirements at an early stage of project planning, before project structures, responsibilities and timelines are finalised.

6.4 Ethical implications for the User Journey and support functions

The findings of the ethical expert group have direct implications for the User Journey for secondary use of health data. The national requirements relevant to ethical review should be identified early, as they may affect the applicable procedures, project design, responsibilities and timelines. As demonstrated by the VALO2 pilot, addressing these questions only after the project and data request have been finalised may result in additional procedural steps and significant delays.

Applicants should therefore have access to clear country-specific information before or at the beginning of the data-access phase. This should enable them to identify whether ethical review

or other related national requirements apply, which bodies are competent, and how the relevant procedures relate to the data-access process. For cross-border projects, information on differences such as territorial applicability, application-language requirements and procedural sequencing should be readily accessible.

Particular support may be needed where the classification of the activity is uncertain. As discussed above, the distinction between QA and scientific research can affect the regulatory pathway, and interpretations may differ both between and within countries. Practical guidance and access to appropriate ethical and legal expertise could help applicants identify these questions early and seek clarification from the competent national bodies where necessary.

Ethical requirements should therefore not be treated as an isolated approval step, but as one of the issues that may need to be considered throughout the User Journey.

6.5 Conclusions and recommendations

The work of the ethical expert group demonstrates that national ethical governance remains an important source of differences in the Nordic secondary-use environment under the EHDS. These differences concern both the circumstances in which ethical review is required and the procedures surrounding it. The VALO2 pilot demonstrated that their practical consequences can be substantial when national requirements form part of a sequence of procedures that must be completed before data can be accessed.

A further important finding concerns the involvement of ethics committees in EHDS implementation. Ethics committees will continue to play an important role wherever national legislation requires ethical review and may also provide ethical expertise within the EHDS governance framework. Despite this, ethics committees have so far been only marginally involved in broader EHDS implementation activities, and awareness of the EHDS and its implications for ethical review processes appears to remain limited among some committees. The VALO2 work itself therefore also served to familiarise participating ethical experts with the EHDS and to connect this expertise with the wider Nordic implementation work.

This points to a need to involve ethics committees and ethical expertise in EHDS implementation at an early stage, rather than only once the first secondary-use applications are submitted. Early involvement would allow questions concerning the interaction between existing ethical review procedures and the EHDS to be identified before the system becomes fully operational and would support cooperation between ethics committees, HDABs and other actors involved in secondary-use governance.

Continued Nordic cooperation should therefore focus on distinguishing between differences that follow from national legislation and structures, areas where greater practical alignment or common guidance is possible, and areas where greater harmonisation may be beneficial. The objective should not be to replace national decision-making or require identical ethical review systems, but to reduce unnecessary divergence and make the remaining national differences sufficiently transparent and predictable for applicants.



Recommendations:

- Involve ethics committees and ethical expertise in national and Nordic EHDS implementation at an early stage, including in discussions concerning the interaction between ethical review and HDAB procedures;
- Improve applicant-facing information on national ethical review requirements and related procedures, including the applicable review triggers, competent authorities, procedural steps and expected timelines;
- Support greater consistency in distinguishing QA from scientific research, including through exchange of practices and discussion of borderline cases;
- Strengthen cooperation between ethics committees, HDABs and other relevant authorities involved in secondary-use governance;
- Use practical cases and future cross-border projects to identify bottlenecks and areas where Nordic alignment or common guidance could improve the User Journey;
- Continue examining emerging questions concerning AI and algorithm development, including possible gaps in ethical assessment and the risk that different national responses could create unnecessary divergence; and
- Maintain a Nordic forum for ethical governance under the EHDS, enabling ethics committees and other ethical experts to exchange experiences and remain connected with the wider legal, technical and policy implementation work.

7 The User Journey, bottlenecks and support functions

This chapter, complemented by Annex 2, emanates from the User Journey described by the TEHDAS Joint Actions^{18,19}, elaborating on that concept and discusses related bottlenecks as well as recommended support functions and activities to avoid or mitigate these. The chapter's content is based on the output of all three WS2 work groups, combined and presented in conjunction to the User Journey step it concerns.

It must be emphasised that this report should not be seen as final and exhaustive with regard to the User Journey in relation to bottlenecks and facilitating recommendations. This is a first Nordic version of a guide of this kind, and it may be followed in the future by updated and complemented versions. Conditions as well as recommendations described here may also differ from those applicable for other European Union Member States.

7.1 User Journey and recommended support functions

Here the different steps as well as sub-steps of the User Journey are described, together with examples of identified barriers or bottlenecks as well as recommended support functions and activities to avoid these. It is an effort to describe at least the basic requirements and prerequisites for making the User Journey as smooth, yet secure, as possible, especially from the perspective of the applicant or health data user. For the sake of simplicity, the term *health data user* will be used almost consistently throughout the following text, including at stages prior to data access.

Most steps of the User Journey are introduced using quotes from the description presented by TEHDAS2.

7.1.1 Pre-discovery and metadata publication

- Data holder identification
- Dataset identification
- Metadata and data quality and utility label

The pre-discovery step is actually not part of the original User Journey described by TEHDAS2, and is not a noticeable step for the health data user. Nevertheless, since this step — along with the appropriate supporting functions — forms the foundation for carrying out the subsequent steps (Data discovery, etc.), it has been included here to make the guidance for EHDS2 preparations more complete.

Relationship to the TEHDAS data lifecycle

VALO2's pre-discovery phase operationalises and expands the metadata-publication prerequisite identified in the TEHDAS User Journey and the publication phase of the TEHDAS

¹⁸ TEHDAS: Deliverable 7.2 - Options for the services and services architecture and infrastructure for secondary use of data in the EHDS. 4 July 2023

¹⁹ TEHDAS2: M8.4 Draft guideline for data users on handling research outcomes), April 2026

data lifecycle. It comprises the back-office activities required before a data user can discover data, including the identification of health data holders and datasets, preparation and validation of metadata, publication in national dataset catalogues, maintenance and updating of catalogue records, and synchronisation with the EU Dataset Catalogue. Metadata publication does not in itself involve transferring the underlying electronic health data or personal data.

7.1.1.1 Data holder identification

Data holders may experience difficulties assessing whether or not they are health data holders according to the EHDS Regulation, and if their data fall under the minimum categories of electronic health data in Article 51. Failing to do these assessments may delay a data holders' preparations for EHDS.

The VALO2 legal group has considered the definition of a health data holder under Art. 2(2)(t) and concluded that statistical bodies should, as a general rule, be considered health data holders under the EHDS. This common interpretation provides one example of how Nordic legal cooperation can support more consistent identification of health data holders and could be reflected in practical guidance and assessment tools.

With the aim to empower organisations in these assessments for identifying health data holders, one suggested strategy is to provide practical support through accessible self-serve digital tools. In this case, a decision tree and an assessment list.

The decision tree would be an interactive tool structured to guide data holders through the different steps of the assessments, e.g. by context on demand from regulatory and related texts, definitions and examples. Data holders would document their assessments at each step, also capturing negatives, i.e. if data holders conclude they are not a health data holder according to EHDS, or their data does not belong to the minimum categories.

The assessment list would (could?) generate a dynamically populated repository over time as organisations complete their decision tree journey. By using this list, data holders should be able to benchmark their assessments against those of other data holders.

The list could also benefit identification of discrepancies and differences in assessments (e.g. missing datasets in similar data holders) and used as a basis for discussions on consensus between data holders and the HDAB, as well as to provide a structured basis to guide HDAB supervision and harmonising supervision with other member states.

If these or similar tools are developed in the Nordic countries, co-operation may bring joint learning and sharing the tools may bring value for process development.

Recommendation: Offer self-assessment tool for facilitating health data holder identification.

7.1.1.2 Dataset identification

According to Article 60 of the EHDS Regulation the health data holder is obliged to provide the HDAB with the necessary, and updated information about its dataset(s), including potential data quality and utility label documentation. Most likely health data holders will need support for being able to comply to these requirements.

Since the provision of datasets is in principle mandatory for all health data holders, there is also an element of supervision here. This supervisory role is part of HDAB's areas of responsibilities.

Recommendation: Support to health data holders to identify relevant datasets.

7.1.1.3 Metadata and data quality and utility label

For the health data holder to provide the mandatory information to the HDAB and the national dataset catalogue, there is a need to comply to the rules for using HealthDCAT-AP. As described earlier in this report, the structure and function of this standard – still under development – is not easily understood. In addition, countries most probably have their own, more detailed metadata requirements, particularly regarding detailed variable descriptions. Data holders also must produce a data quality and utility label for data collected with public funding, in the manner specified later in an implementing act. Therefore, the health data holders (and other concerned stakeholders) must have good guidance and support available, in order to be able to use HealthDCAT-AP and data quality and utility label in the way it is intended and provide metadata and data quality and utility label with a sufficient level of accuracy.

Recommendation: Support to health data holders to provide correct and comprehensive metadata.

7.1.2 Data discovery

- Data search
- Find/Identify data
- Assess data findings

7.1.2.1 Data search

TEHDAS2 describes this step as follows:

“Before requesting access to electronic health data, the data user identifies whether relevant datasets exist and whether they are suitable for the intended purpose. This phase involves consulting dataset catalogues, metadata repositories, and other discovery tools made available through national dataset catalogues and the EU dataset catalogue connected to the HealthData@EU infrastructure. Through these tools, data users can assess dataset availability, structure, quality, and conditions for access. Once suitable datasets have been identified, the data user may proceed to the data access phase.”

The health data user may need guidance for where to start the search, how to use different search tools (perhaps depending on the type of data wanted), and how to save the result of the search.

Recommendation: Support to health data user to initiate a correct and efficient data search.

7.1.2.2 Find/Identify data

For efficient data discovery several search modalities may be developed and used in the national catalogues as well as in the EU dataset catalogue. Support should be developed for both basic and more advanced use cases and users.

With regard to searches in the EU dataset catalogue, this has been touched upon in TEHDAS2:

- “Search Mechanisms: Users are introduced to basic keyword retrieval for initial exploration and advanced, property-based SPARQL queries for technical users requiring precise, repeatable results.
- Iterative Refinement: These search tools are augmented by dynamic filtering mechanisms—mapped directly to EHDS data categories, population characteristics, and coding systems—alongside multi-faceted sorting options to prioritise relevance and currency.”

When the health data user has completed the data search it is important that the search result is saved properly and that the data user can find the source of the identified data.

Recommendation: Support to health data user to identify health data of relevance in national as well as in EU catalogue, and save search result for further analysis and use.

7.1.2.3 Assess dataset suitability and study feasibility

To support a well-founded application and avoid unnecessary administrative work, the results of the initial, and where appropriate iteratively refined, data search should be thoroughly assessed before proceeding to the formal application procedure. According to TEHDAS2 recommendations, guidance on interpreting dataset records should enable prospective applicants to use metadata as structured decision support. The assessment may cover, among other things:

- Provenance and governance: Identification of the organisations responsible for creating, maintaining and making the data available, as well as the relevant HDAB or HDABs responsible for the application process.
- Content and coverage: Assessment of the geographic scope, time coverage, population, level of detail and categories of electronic health data represented in the dataset.
- Technical interoperability: Review of the standards, terminologies, such as ICD-10 or SNOMED CT, classifications, formats and data models used.
- Variable-level information: Use of non-disclosive resources, such as data dictionaries, variable lists, summary statistics and synthetic or proxy datasets, to assess whether the data could support the proposed purpose and methodology without requiring access to the underlying electronic health data.
- Data availability and expected cohort: Non-disclosive information about the availability of relevant observations, variables or individuals, such as the approximate number of individuals meeting specified criteria.
- Data quality and known limitations: Information on completeness, accuracy, consistency, timeliness, coding practices, changes over time, known quality issues and other limitations that could affect the proposed use.
- Linkage and preparation requirements: Preliminary information about possible linkages, expected data preparation, harmonisation or transformation needs, and foreseeable methodological or technical constraints.



In straightforward cases, prospective applicants may be able to complete the assessment using information available through the dataset catalogue and associated documentation. In more complex cases, a feasibility or prestudy service may be required to determine whether the available data can support the proposed purpose, methodology and study population.

Detailed knowledge of a dataset often resides with the health data holder or experts close to the data. The HDAB should therefore provide or facilitate a controlled channel through which prospective applicants can obtain appropriate support from relevant data experts without disclosing personal electronic health data or other protected information. Depending on the circumstances, this support may include structured feasibility queries, availability reporting, data-quality information, written clarification, or direct communication with the health data holder or relevant data experts.

The level of support should be proportionate to the complexity of the proposed use and the information already available through the dataset catalogue. The assessment should enable the prospective applicant to decide whether to proceed with an application, refine the proposed study or data specification, identify additional datasets, or discontinue the planned application. Where possible, relevant information generated during the assessment should be reusable in the subsequent application process, thereby reducing duplication for the applicant, HDAB and health data holders.

Recommendation: Support prospective applicants in assessing dataset relevance, suitability and study feasibility before submission of a formal application. The HDAB should provide or coordinate an identifiable and proportionate feasibility-support service, including access to non-disclosive availability and data-quality information and, where necessary, controlled communication with health data holders or experts close to the relevant datasets.

7.1.3 Data access

- Legal assessment
- Ethical requirements assessment
- Application submission
- Application processing
- Application supplements
- Application decision

According to TEHDAS2: “In the data access phase, the user fills in and submits a dedicated and standardised **data access application** form or a **data request** to an HDAB. The user must complete the information required in the form, upload necessary documents, and provide justifications as needed.”

Data access application form is used when the user seeks to use personal level data. A granted application results in a data permit and access to health data within an SPE. **Data request** is for cases when the user wants to apply for anonymised statistical data. Approval of the latter results in an anonymised statistical answer rather than access to underlying data.

The data access application must describe:

- the purpose of the secondary use,
- the datasets requested,
- the intended methodology,
- compliance with applicable safeguards and legal requirements.

The Data access phase is supported by two related but distinct categories of digital services.

Application-side services support the applicant in preparing, submitting, supplementing and monitoring an application or data request. **Grant-side services** support HDABs and, where applicable, trusted health data holders in reviewing, coordinating, documenting and deciding the case. Distinguishing these service categories helps clarify responsibilities, access rights, interoperability needs and the handling of cross-border applications.

The application-side support should explicitly cover:

- application drafting and validation;
- saving a draft;
- submission;
- status tracking;
- messaging and clarification;
- supplementation;
- viewing the decision and conditions;
- application and permit history.

The grant side should include:

- completeness checks;
- routing to responsible bodies;
- cross-border coordination;
- requests for information;
- legal, ethical and proportionality assessment;
- decision logging;
- permit generation;
- audit trail;
- appeal or review information, where applicable.

7.1.3.1 Legal assessment

With regard to legal ground for data access, prospective applicants should have access to clear guidance on the permitted purposes under Article 53 and the prohibited uses under Article 54. Early guidance could help applicants assess whether a proposed use is eligible before preparing an application and reduce unnecessary work for both applicants and health data access bodies.

Clear guidance should be provided alongside the relevant forms. It should explain that a **health data access** application under Art. 67 may result in access to anonymised or, where sufficiently justified, pseudonymised data under a data permit issued pursuant to Art. 68. A **health data request** under Art. 69 provides only an anonymised statistical response and does not give the applicant access to the underlying data.

Applicants should also be able to identify at an early stage where additional legal considerations may arise, including national opt-out arrangements, applicable fees and requirements concerning intellectual property rights or trade secrets. Where the applicable requirements or the interaction between the EHDS and national law are unclear, access to appropriate legal guidance should be available

Recommendation: Provide health data user (applicant) with clear and accessible guidance on the applicable EHDS access pathway and relevant national legal requirements, with access to legal support where interpretation or national requirements may affect the application or subsequent data access.

7.1.3.2 Ethical requirements assessment

Before submitting an application, the health data user should also be clearly informed about the ethical requirements applicable in the country (or countries) concerned. National rules differ considerably across the Nordic countries, including as to when ethical review is required and which projects fall within its scope (i.e. QA or scientific research). The health data user should therefore be able to determine at an early stage whether a separate ethical review is required under national law and which procedure applies.

Applicants should also be informed whether the national HDAB considers basic ethical aspects as part of its assessment based on Art. 68(1)(b) when assessing whether the requested data are necessary, adequate and proportionate. The applicant should identify and address relevant ethical aspects already when preparing the data access application and provide sufficient justification for the proposed use and the data requested. This assessment by the HDAB would not constitute a separate ethical review.

Recommendation: Provide health data user (applicant) with clear country-specific guidance on special national ethical review requirements and on whether and how the HDAB considers basic ethical aspects based on Art. 68(1)(b), including guidance on how relevant ethical aspects should be addressed in the data access application.

7.1.3.3 Application submission

The health data user is responsible for submitting a correct and complete application. With the importance of this sub-step in the application process as a whole, there should be appropriate and sufficient support available already during the preparation of the application. The experience of the current Nordic health data permit authorities is in general that guidance and support is frequently needed for this sub-step. An investment in this, with a suitable combination of supporting format and modalities (see below), will save time and resources, not the least for the HDAB and perhaps also for the (trusted) health data holder.

Adequate support at this stage also significantly reduces the risk of the application requiring supplementation, which is otherwise a common additional element in the case volume.

Recommendation: To have HDAB functionalities in place for needs-based support and guidance to health data user in application writing and submission.

7.1.3.4 Application processing

As soon as the data application has reached the HDAB, the application processing should be initiated. For this the HDAB needs to have the proper resources and efficient organisation in place.

A first step of the process is to assess whether the application is complete, containing all the necessary information. If this is not the case, this should be communicated promptly to the applicant with clear information about what is missing in the application. If possible with an offer for a guiding telephone call or digital meeting.

The HDAB should strive to complete the assessment of the application as soon as possible within the time limit stipulated in the EHDS Regulation. If, for some reason, this cannot be met, then the HDAB must communicate this to the applicant, with further information about the process.

An alternative procedure for handling applications is for HDAB to appoint a trusted health data holder (EHDS Article 72) to assess the application (in cases where it concerns only the holder's own health data) and submit a recommendation for the HDAB's final decision on the matter. Furthermore, they should be able to provide access to health data via an SPE. All in all, this would relieve the burden on HDAB and potentially save time in the process.

Recommendation: To have HDAB functionalities in place for prompt and efficient application processing, and if applicable, the same for trusted health data holders.

7.1.3.5 Application supplement

This is a part of the application process that becomes relevant only if there are deficiencies in the original application. Since this is a time-consuming sub-step for all the central actors it should be avoided as far as possible. However, when it comes to the need for supplementing the application, this should be processed as swiftly as possible and with clear communication from the HDAB about what is still needed.

Again it is recommended to use the appropriate format and modalities for communication and support, in order to have the application completed as soon as possible.

Recommendation: Clear and prompt information and support from HDAB to health data user to supplement and complete the deficient application.

7.1.3.6 Application decision

“The HDAB assesses the application and may issue a data permit or approve a data request if the conditions set out in Chapter IV of the EHDS Regulation are fulfilled.”

The HDAB decision in an application matter should be clearly formulated and promptly communicated to the applicant, without delay. If the decision is granting a data permit to the

applicant it should be accompanied by clear information about the subsequent process for health data access, and where the health data user can find all the necessary information and support for this.

Recommendation: Timely decision by HDAB followed by prompt and clear communication to applicant.

7.1.4 Data preparation

- Data curation and integration
- Data provision and SPE onboarding

“Once access has been granted, the relevant health data holder(s) provide the requested datasets to the HDAB or the designated infrastructure responsible for preparing the data for secondary use. During this phase, datasets may undergo technical and organisational preparation measures, including:

- pseudonymisation or anonymisation where appropriate,
- application of data minimisation principles,
- preparation of the dataset according to the conditions specified in the data permit.

These measures ensure that the data made available to the data user comply with the safeguards established by the EHDS Regulation.”

7.1.4.1 Data curation and integration

Data curation is the process of selecting and collecting the data authorised by the HDAB for secondary use. Depending on the application and the clarity of the data permit, in combination with the characteristics of the dataset in question, the curation can be a more or less laborious procedure. The permit decision, with its information about the authorised dataset, should of course be formulated in such a way that the health data holder can interpret and apply this as easy as possible for the curation.

Data curation and integration comprise the following:

- extraction and selection according to the permit;
- data minimisation;
- harmonisation of formats and coding;
- data cleaning and transformation;
- record linkage where authorised;
- treatment of identifiers;
- pseudonymisation or anonymisation at the appropriate point;
- validation that the prepared data correspond to the permit;
- documentation of transformations and provenance.

These measures are required to make the authorised data usable and compliant with the permit. Where authorised record linkage is required, it must occur before irreversible anonymisation.

The location and responsibility for integration should be defined in advance, taking account of data expertise, scalability, security and the roles of the data holder, HDAB and SPE operator.

To reduce administrative burden and in light of effectiveness and efficiency principles, Member States may require in their national law that *health data intermediation entities* carry out the duties of certain categories of health data holders, particularly for the secondary use of health data. They help centralise data access, compliance, and secure data exchange, thereby reducing the burden on individual data holders. However, they are distinct from trusted health data holders.

Recommendation: Clear and supportive HDAB decision for health data holder to easily collect and curate the authorised dataset.

7.1.4.2 Data provision to SPE

This step comprises loading the permitted health data into the SPE, according to the HDAB decision. Data provision is the controlled transfer of the prepared dataset from the data holder to the designated SPE. It should use secure and, where feasible, automated machine-to-machine mechanisms, with confidentiality and integrity protection, transfer logging, and verification that the deposited data conform to the data permit. The SPE should offer suitable and approved analysis tools for the curated health data.

Recommendation: As part of the HDAB functionality the SPE operator should ensure prompt and secure health data provision to a designated and suitable SPE.

7.1.4.3 SPE onboarding of data users

This step comprises providing access for the authorised health data user(s) to the SPE, according to the HDAB decision. Data user onboarding is the separate process of verifying the identity and authorisation of each permitted user, providing project-specific training and access, and ensuring that the user understands the applicable conditions and security requirements. The authorised health data user(s) shall well in time be provided clear information on how to log in to the correct SPE, for getting access to the permitted health data in de-identified format.

Recommendation: As part of the HDAB functionality the SPE operator should ensure prompt and secure onboarding to the designated SPE for authorised users.

7.1.5 Use of data

- Data analysis

“During this phase, the data user performs the authorised analysis using the electronic health data. Where personal-level data are involved, the analysis must take place within an SPE or another authorised processing environment. The data user must conduct the analysis strictly in accordance with:

- the conditions of the data permit,
- the approved purpose of processing,

- the applicable data protection and security requirements.”

7.1.5.1 Data analysis

Following a correct and completed onboarding the health data user should be able to initiate the data analysis according to the HDAB decision. It is recommended that the health data user is properly informed and trained to correctly operate the SPE and the permitted data, so that there is no risk for data breach or compromised data. Ongoing technical support should be available for the data user, should there be a need for that.

Access permissions should be linked to the authorised project and data permit. Where a user participates in several projects, each project environment should remain technically and logically isolated unless combination of the data is explicitly authorised. Access should expire automatically when the permit ends. The SPE should provide approved tools, controlled procedures for introducing additional code or data, logging and monitoring, and sufficient computational capacity for the approved analysis.

Analysis support should address:

- a standard set of approved analysis tools;
- a controlled process for requested amendments/changes, e.g additional tools or libraries;
- controlled upload of the user's own software, code, models, or data;
- malware scanning or quarantine;
- project-specific isolation;
- access rights linked to the **project and permit**, not merely to the person;
- automatic expiry of access;
- logging and monitoring;
- support for reproducible analysis, including version control and containers;
- sufficient CPU, memory, GPU, storage, and specialist resources;
- federated analysis where relevant;
- common data models and machine-readable API²⁰ where appropriate.

Federated analysis²¹: Where federated analysis is used, the journey may involve several SPEs and an orchestration function rather than transfer of all data into one SPE. The permit, technical preparation, execution controls, validation of partial outputs, and final disclosure review must nevertheless form one coordinated project workflow.

Recommendation: Support for health data user to quickly, correctly and securely initiate the approved data analysis (information, SPE analysis tooling). Sufficient HDAB logging and monitoring of correct SPE operation and data use.

²⁰ Application Programming Interface

²¹ Federated analysis is a form of distributed analysis in which data remain under the governance and control of their original custodians, while analysis is performed through coordinated execution across multiple data-holding sites.

7.1.6 Finalisation

The finalisation step is where the health data user needs to ensure a proper disclosure of its findings, following the FAIR principles²². This step comprises the following:

- Results validation and release;
- Archiving and reproducibility;
- Publication and FAIRification;
- Significant findings and feedback;
- Return of enriched data;
- Closure, retention, and deletion.

Including Reporting and communication of outcomes (support/inform health data user about this).

7.1.6.1 *Results validation and controlled release*

Before any output leaves the SPE, it should undergo a documented disclosure-control review to verify that it contains no personal electronic health data and complies with the permit. The review may combine automated controls with risk-based manual inspection. Roles, review criteria, processing times, revision procedures and the audit trail should be communicated to the data user before analysis begins.

TEHDAS treats export control as both a technical and organisational process. Controls may include virtual-desktop restrictions, disabled copy/paste, thresholds, file-type and size checks, quarantine, manual review, automated screening, and four-eyes review.

Recommendation: HDAB ensures (monitors) that the health data user has successfully retrieved (only) the analysis results from the SPE, in a timely manner.

7.1.6.2 *Archival and reproducibility*

Project closure should include a reproducibility and archival package, where applicable, containing approved outputs, protocols, queries, code, software and package versions, data-transformation documentation and sufficient provenance information. Any future access to personal or pseudonymised data for validation or reproduction must follow the applicable permit process.

This sub-step comprises:

- archiving of permitted outputs;
- retention of code, queries, protocols, software versions, and metadata;
- a reproducibility strategy;
- controlled re-access where permitted;

²² Wilkinson, M., Dumontier, M., Aalbersberg, I. et al. The FAIR Guiding Principles for scientific data and stewardship. Sci Data 3, 160018 (2016)

- clarity on whether data, synthetic data, subsets, or only code and provenance are retained.

7.1.6.3 FAIR-compliant output preparation

TEHDAS explicitly mentions FAIR-compliant disclosure and preparation of outputs for cataloguing and repositories. Health data users should receive guidance on preparing reusable and FAIR-aligned project outputs, including appropriate metadata, persistent identifiers, documentation, ontologies, and deposition in suitable repositories where this is legally and ethically permissible.

Recommendation: HDABs should support health data users in publishing anonymous results as required by Article 61(4), and should implement that obligation in a FAIR-aligned manner through metadata, provenance, identifiers, documentation and clear reuse conditions.

7.1.6.4 Significant findings, incidental findings, and data-quality feedback

Where a permitted analysis produces a potentially significant health-related finding (see 5.2.2 Significant findings, in Legal chapter above), the data user should have a clearly defined channel for reporting it to the HDAB. The HDAB should coordinate assessment and any subsequent communication according to applicable law and national procedures. A separate channel should allow data users to report errors, inconsistencies or potential improvements in the source data and metadata.

Recommendation: HDAB support health data user how to report significant findings, or other concerns stipulated in the Regulation.

7.1.6.5 Deletion and retention

At permit expiry or project closure, access should be withdrawn and the HDAB (SPE operator) should delete or retain the deposited data in accordance with the permit and applicable law. Completion of deletion or authorised retention should be recorded and auditable. The deletion procedure can be automated.

Recommendation: Assured (automated?) HDAB routine for deleting (or retaining) within time limit the analysed dataset from SPE.

7.2 Support functions – format and modalities

Different support functions and activities, as discussed in the previous section, can be provided in varying formats and through various modalities (“channels”).

In most cases these support functions address the applicant and data user. However, for certain steps and sub-steps of the User Journey the key actor (with potential need for support) can be the health data holder or another actor taking an important part of the User Journey process.

The format and/or modality of the support may differ depending on the target group.

Suitable formats can be: Live human support, guidance, regularly organised training, training tailored to specific needs, chatbot or other interactive AI/algorithm support, FAQ (Frequently Asked Questions), user community, video, self assessment.

Potential modalities can be: HDAB office visit, telephone call, digital meeting, website, email.

Needs-based innovation is of course welcome, and the number of (good) examples at Nordic and Baltic level will most likely increase in the years ahead. At the same time the discussions and initiated benchmarking of the WS2 work clearly indicate that for several of these support functions there are benefits in sharing concepts, or even jointly develop support tools of different kinds. A Nordic harmonisation of support functions and activities should be beneficial.

Since communication is key for an optimal User Journey, language is a fundamental factor. All, or at least most support functions will probably be necessary to offer in the national language of each country. However, as part of the preparations for EHDS the same information will be needed in English, and perhaps also in other EU languages. The development of Large Language Models (LLMs) and other AI tools may be valuable in making translational activities more or less automated, in line with other similar translational procedures connected to the EHDS preparations and implementation.

Data from the Nordics: A joint Nordic overview for data users

Nordic cooperation between authorities involved in the secondary use of health data is currently not very visible to data users during the application process. One simple way to improve this would be for Nordic health data authorities to contribute to a shared, supportive “Data from the Nordics” web information service.

The section should be short, easy to scan, and focused on helping users quickly understand how data access works in each Nordic country. Rather than replacing national guidance, it would provide applicants a shared Nordic overview of access models, application routes, relevant authorities, and links to detailed national instructions. The content could remain largely stable over time, making it easy to maintain while supporting a more visible and coherent Nordic User Journey. While small in scope, the approach could serve as a starting point for further user-facing Nordic collaboration as the implementation of the EHDS progresses. An illustration of the concept is included as Annex 7a.

The same page could also offer the possibility to book a joint online consultation with representatives of the countries from which an applicant is considering requesting data. To minimise the workload for participating authorities, consultations should be offered on a fixed schedule.

7.3 Prioritised recommendations and conclusions

This consolidated synthesis emanating from the work of the different work groups of VALO2 WS2 presented above demonstrates that smooth secondary use of health data under the EHDS depends on coordinated implementation across organisational, technical, metadata, legal and ethical domains. Bottlenecks in one area can prevent progress in another. Nordic cooperation is therefore most useful when it produces common practical tools, examples and transparent descriptions without attempting to replace national competence.

7.3.1 Nordic cooperation

WS2 of VALO and VALO2 has had a clear focus on continued networking, sharing of EHDS2-relevant experiences, news and information, further strengthening the trusting environment that has come to characterise the quarterly held Competence Forum. According to the evaluations and feedback from the participants this is a valuable resource for supporting the complex

process of preparing, organising for, and implementing the respective national authority functions as well as conducting the legal interpretations and adaptations in relation to the EHDS Regulation. Therefore, we see a potential need to bridging over from the VALO project outcomes to long-term continuity and sustainability of this Nordic collaboration.

The VALO project is also comprising three different, however in a way complementary, workstreams. The three workstreams have all contributed to a common approach for a joint, and to some extent also harmonised, Nordic implementation of EHDS2. That way the VALO2 project could be seen as an investment for a tangible example of cross-border collaboration saving time and money for the participating countries in the long run.

The outcomes and feedback accounted for in this report leads to a general recommendation to maintain a Nordic – or preferably, Nordic-Baltic – cooperation based on the successful basic structures and procedures established by the VALO2 project. The challenges of EHDS, and in this case EHDS2 specifically, are in most cases suitable to address jointly on a cross-border level. A regional level such as the Nordic can be optimal for this, situated between the national level (which is too limited and isolated), and the EU level, the latter often being too vast and too multifaceted to enable effective and purposeful cooperation within a very limited timeframe. However, a joint Nordic progress on EHDS2 would most certainly contribute constructively also to the efforts and results at EU level.

The cooperation should continue to be focused on practical solutions and recommendations such as summarised in 7.3.2, including a shared effort towards harmonisation and standardisation.

7.3.2 A smoother User Journey

The Nordic cooperation proposed here should be needs-based and focus primarily on the following:

- Maintain a Nordic-Baltic EHDS2 community of practice (such as the Competence Forum) for continued sharing and developing the highest-impact support functions in relation to the User Journey.
- Develop and implement a Nordic harmonised health data holder self-assessment, in order to facilitate a faster transition to realisation of EHDS2 with accessible health data.
- Legal/Ethics support:
 - Continue the selected-article legal analysis and distinguish clearly between legal interpretation, policy options and operational guidance.
 - Clearly describe for the applicants when an ethical review is required in each Nordic country and finalise practical guidance on quality assurance versus scientific research.
 - As part of a continued Nordic cooperation described above, establish a permanent forum for ethical governance linked to HDAB and legal implementation networks.
- Metadata guidance:
 - Continue the work on common HealthDCAT-AP mappings (towards a “Nordic HealthDCAT-AP extension”), pilot descriptions and the health data landscape analysis.
 - Coordinate national implementation experience and European-level feedback on metadata, data quality and utility, and catalogue governance.

- Use events such as the Competence Forum and Nordic Health Data Summit as stepping stones to test continuously refined recommendations with all stakeholders of the health data ecosystem.
- Develop common applicant-facing information, support, and training material, preferably complemented by English-language guidance (this could include a joint Nordic supportive web information service as described in 7.2 above).
- Continue comparison and benchmarking of national support functions, fee models, SPE arrangements and implementation costs.
- Monitor emerging issues concerning AI, algorithm development, significant findings, opt-out, IP rights and trade secrets.

7.3.3 Additional conclusions

7.3.3.1 *The VALO project as validation layer for EHDS2 implementation*

This report (and other deliverables of the VALO and VALO2 Projects) may be used as a supporting implementation-readiness and validation framework for Chapter IV of the EHDS Regulation and its associated Implementing Acts. By mapping its findings, the User Journey steps and recommendations to individual EHDS provisions, the report can help identify whether the necessary actors, processes, support functions, metadata capabilities and technical environments are in place. Such use does not constitute a formal assessment of legal compliance and should be complemented by legal review, technical conformity assessment and the final specifications established in implementing acts.

This VALO2 report relates to a significant degree to the EHDS Regulation as well as its (future) Implementing Acts; similarly and at least in part also to the work and outcomes of the TEHDAS2 Joint Action. A mapping of selected earlier VALO1 deliverables, together with this report, to the EHDS2 legal framework was conducted, based on complementary reports from the initial VALO project covering organisational HDAB, SPE and other preparations, metadata, legal and ethics, governance, and practical experience from federated analysis. Together, they provide a Nordic implementation perspective relevant to several EHDS provisions and implementing acts.

The report *VALO Metadata catalogues – final report* aligns most directly with Articles 77 and 78, while also supporting the broader context of Article 60, through its focus on national catalogues, HealthCAT-AP, harmonised dataset definitions, and data quality and utility labelling.

Lessons Learned from Multi-Site Federated Analysis in VALO NSCLC pilot study is mapped to Articles 52–54 and is particularly relevant in practice to implementing acts on SPEs (Article 73), HealthData@EU (Article 75).

Nordic model for collaboration on the secondary use of health data – a proposal is reflected in Articles 62, 67–69 and 75 through its emphasis on governance, access procedures, permits and cross-border cooperation.

Also this final report of VALO2 WS2 can be used as a similar supporting validation and readiness layer for national and Nordic preparations for EHDS, as seen in Annex 7b. It translates many legal requirements into operational questions concerning actors, workflows, metadata, ethics, support functions, secure processing environments and cross-border cooperation.

It should not be presented as a formal legal compliance framework or conformity assessment, rather as an implementation-readiness, gap-analysis and operational validation framework for EHDS secondary use.

The report appears to touch, explicitly or substantively, on most of Articles 50 to 78, particularly Articles 51 to 62, 66 to 73, 75, 77 and 78. Coverage of enforcement, penalties, opt-out mechanisms, third-country access, complaints and some formal governance provisions is less complete.

In this context, the matrix in Annex 7b functions as an evidence-based validation layer for EHDS implementation. It enables the consolidated findings, recommendations and emerging implementation approaches to be tested against documented thematic work and practical multi-country experience from VALO and VALO2. It does not constitute a formal legal compliance assessment, audit or validation of conformity with Regulation (EU) 2025/327.

Together, mappings of this kind show that the VALO project may function as a practical validation layer for EHDS secondary use implementation (see proposal in Annex 7b).

7.3.3.2 Extended Nordics

In conclusion, the New Nordics or Extended Nordics is an evolving regional concept that expands the traditional Nordic definition to include the Baltic states (Estonia, Latvia, and Lithuania). An additional term is the Nordic-Baltic Eight (NB8), comprising a powerhouse ecosystem of over 35 million people, characterised by global tech leadership, top-tier technical talent, and digital government infrastructure.

The VALO project was initially established as a collaboration among the five Nordic countries. Before the project entered its extension phase, VALO2, Estonia and Lithuania joined as observers, bringing a valuable Baltic perspective and broadening the basis for regional cooperation. Building on shared characteristics and common interests, while fully respecting national differences, the Nordic and Baltic countries have considerable potential to advance their preparations together. A continued closer cooperation, in accordance with the proposal for a Nordic Model²³, can help accelerate implementation, strengthen national capabilities and support the development of more coherent approaches to the secondary use of health data under the EHDS.

²³ Nordic model for collaboration on the secondary use of health data: steps towards implementation. Value from Nordic health data – VALO2 project. 2026

ANNEXES

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**

Annex 2. Proposal for a User Journey support guiding matrix

Proposal aligned with Chapter 7 of this report.

Purpose and scope. This matrix translates the extended User Journey into an operational overview of the principal actors, bottlenecks and priority support functions. It covers the path from pre-discovery and metadata publication through discovery, access, preparation, secure use and project closure. Each step depends on adequate completion of preceding steps, while some activities may run iteratively or in parallel. The matrix primarily concerns data access applications leading to use of data in a secure processing environment (SPE); where relevant, it also distinguishes data requests that produce only an anonymised statistical response.

How to use the matrix: “Lead/support actors” identifies the operational driver and key contributors. “Priority estimate” reflects the importance of having the support function available for a predictable and efficient User Journey, not a legal ranking. National law, final implementing acts and formal legal assessment prevail.

Phase	Sub-step and intended outcome	Lead / support actors	Key bottlenecks or failure risks	Recommended priority support functions and preventive measures	Priority estimate	Key references / implementation notes
1. Pre-discovery and metadata publication	1.1 Data holder identification Organisations can determine whether they fall within the EHDS definition and understand their obligations.	Lead: HDAB Support: potential health data holders, sector authorities, legal experts	Unidentified holders; inconsistent interpretation of the holder definition; organisations unaware of obligations; fragmented supervisory overview.	• Offer a harmonised self-assessment or decision-tree tool with definitions, examples and documented reasoning. • Maintain an assessment repository/list to support benchmarking, supervision and resolution of divergent classifications. • Provide targeted communication and Community of Practice support, including sector-specific examples.	High	EHDS Art. 2(2)(t), Arts. 55-57. Link to Nordic legal work on statistical bodies and a recommended common assessment approach.
1. Pre-discovery and metadata publication	1.2 Dataset identification Relevant datasets and Article 51 categories are systematically mapped.	Lead: health data holder Support: HDAB, HDIE where relevant, metadata experts	Datasets remain unknown; uncertainty about Article 51 coverage and dataset granularity; inconsistent dataset definitions; missing internal inventories.	• Provide category-specific examples and guidance for identifying datasets. • Continue national and Nordic mapping of holders and datasets across all Article 51 categories. • Establish internal data inventories and named dataset stewards; connect identification to HDAB supervision.	High	EHDS Arts. 51 and 60. Dataset definition and granularity should be coordinated with HealthDCAT-AP implementation.
1. Pre-discovery and metadata publication	1.3 Metadata and Data quality and utility label Catalogue records are complete, current and synchronised nationally and at EU level.	Lead: health data holder Support: HDAB/catalogue operator, metadata experts	Missing, incomplete or outdated metadata; weak variable-level descriptions; inconsistent vocabularies; difficult tooling; poor alignment with HealthDCAT-AP; no sustainable maintenance process.	• Provide practical HealthDCAT-AP guidance, mappings, examples, training, helpdesk and validator tools. • Support data quality and utility labelling, provenance and variable-level metadata. • Use user-friendly editors and automated import where feasible; validate before publication. • Establish ownership, update cycles, feedback channels and synchronisation with the EU Dataset Catalogue.	High	EHDS Arts. 60, 77-78; HealthDCAT-AP; future DQUL implementing act. Metadata publication does not itself transfer underlying health data.

Phase	Sub-step and intended outcome	Lead / support actors	Key bottlenecks or failure risks	Recommended priority support functions and preventive measures	Priority estimate	Key references / implementation notes
2. Data discovery	2.1 Data search – initiate and document The prospective user knows where and how to search and can preserve the search trail.	Lead: prospective health data user Support: HDAB/catalogue operator	Low awareness of catalogues; difficulty selecting the correct national/EU entry point; limited search literacy; searches and sources not documented.	• Provide concise “start here” guidance, tutorials and worked examples for national and EU catalogues. • Enable saving/exporting search strategies, results and dataset identifiers. • Offer English-language, cross-border guidance, including a joint Nordic overview of access routes.	High	National catalogues and HealthData@EU EU Dataset Catalogue. Support basic and advanced users.
2. Data discovery	2.2 Find/Identify data Search results for relevant datasets are precise, traceable and comparable across countries.	Lead: prospective health data user Support: catalogue operator, HDAB	Underdeveloped search/filtering; disharmonised metadata; multilingual terminology; weak variable discovery; unclear dataset series/distributions; AI search degraded by poor metadata.	• Provide keyword, faceted and property-based search, including advanced repeatable queries where appropriate. • Harmonise metadata, vocabularies and dataset descriptions; expose variable-level information. • Test AI-assisted discovery only with transparent controls and sufficiently structured, maintained metadata.	High	HealthDCAT-AP and catalogue usability. Search should support EHDS categories, population, geography, time, coding systems and recency.
2. Data discovery	2.3 Assess data findings The user assesses dataset suitability and study feasibility in order to decide whether to apply, refine or discontinue the planned use.	Lead: prospective health data user Support: HDAB, health data holder/data experts	Metadata insufficient for fitness assessment; no cohort/availability information; limited knowledge of quality, linkage or transformations; premature applications; protected information disclosed during feasibility work.	• Provide guidance for assessing provenance, coverage, interoperability, variables, quality, limitations, linkage and preparation needs. • Offer non-disclosive resources such as dictionaries, variable lists, summary statistics, synthetic/proxy data and approximate availability counts. • HDAB should provide or coordinate a proportionate feasibility/prestudy service and controlled contact with dataset experts. • Reuse feasibility information in the later application where possible.	High	Feasibility support must not disclose personal electronic health data or protected information.
3. Data access	3.1 Legal assessment – legal pathway and permitted purpose The correct application or request route and legal prerequisites are identified early.	Lead: applicant Support: HDAB, legal adviser, data holder where relevant	Ineligible or prohibited purpose; confusion between data access application and data request; unclear national requirements; opt-out, fees, IP/trade secrets or consent issues identified too late.	• Provide early eligibility guidance on permitted and prohibited uses and the distinction between applications and data requests. • Offer accessible legal guidance/advice and country-specific checklists. • Explain fee principles, opt-out implications, safeguards for IP/trade secrets and any supporting documentation required.	High	EHDS Arts. 53-54, 62, 67-71. Application may lead to access in an SPE; a data request leads only to an anonymised statistical response.
3. Data access	3.2 Ethical requirements assessment Identification of potential national requirements so that applicable ethical review, classification and sequencing are known before submission.	Lead: applicant Support: ethics committee, HDAB, legal/ethical experts	Unclear QA versus scientific research classification; different national triggers, territorial scope, language and competent bodies; sequential procedures; major delays when requirements are identified late.	• Publish country-specific guidance on triggers, competent bodies, language, documents, sequence and expected timelines. • Provide early access to ethical/legal expertise and routes for authoritative clarification. • Clarify whether and how the HDAB considers basic ethical aspects in the Art. 68(1)(b) necessity, adequacy and proportionality assessment. • Support Nordic exchange on borderline cases without replacing national law or independent decisions.	High	EHDS Arts. 67(2)(j), 68(1)(b) and 68(1)(f). The VALO2 pilot (WS3) showed that cumulative national procedures can materially delay access.

Phase	Sub-step and intended outcome	Lead / support actors	Key bottlenecks or failure risks	Recommended priority support functions and preventive measures	Priority estimate	Key references / implementation notes
3. Data access	3.3 Application submission The applicant provides a complete, validated, correctly scoped application and attachments.	Lead: applicant Support: HDAB applicant-side service	Incomplete/incorrect application; excessive or poorly justified data request; inconsistent project information; missing documents; inability to save drafts or track submission.	• Provide guided forms, inline explanations, validation checks, examples and needs-based human support. • Enable draft saving, pre-submission review where appropriate, secure submission and receipt confirmation. • Carry forward catalogue selections and feasibility outputs to reduce duplicate data entry. • Provide common applicant-facing material and training, including English-language guidance.	High	EHDS Arts. 57(1)(e) and 67–69. Application-side services should cover drafting, validation, submission, tracking, messaging, supplements and history.
3. Data access	3.4 Application processing The responsible body performs a complete, coordinated and timely assessment; triage, routing and processing the case.	Lead: HDAB Support: trusted health data holder, other HDABs, data holders, legal/ethical/technical experts	Backlogs and insufficient resources; unclear routing; fragmented cross-border assessment; inconsistent completeness checks; weak audit trail; applicant not informed of delay.	• Ensure adequate human, technical and financial capacity and clear case ownership. • Implement grant-side workflow for completeness checks, routing, coordination, requests for information, assessments, decision logging and audit trail. • Use standard operating procedures, dashboards and service targets; communicate status and foreseeable delay. • Where applicable, use trusted health data holders under clear governance while retaining the HDAB decision role.	High	EHDS Arts. 55–57, 67(3), 68, 72 and 75. Cross-border cases require coordinated routing and communication.
3. Data access	3.5 Application supplement If need for supplement or clarification of the application, deficiencies are resolved rapidly and transparently.	Lead: applicant and HDAB	Vague or repeated requests; slow applicant response; fragmented communication; version confusion; unresolved deficiencies causing closure or delay.	• Send a consolidated, specific and prioritised request explaining what is missing and why. • Provide secure messaging, version control, deadlines and visible case status. • Offer a call or digital meeting for complex deficiencies; keep contact information current.	High	Supplementation should be minimised through strong pre-submission support but processed promptly when necessary.
3. Data access	3.6 Application decision A clear, timely and operationally usable decision is issued and communicated.	Lead: HDAB Support: trusted health data holder where applicable	Delayed or unclear decision; dataset scope cannot be translated into curation tasks; conditions, duration, users or SPE not specified; appeal/review information missing.	• Use clear decision templates that specify purpose, datasets, users, duration, conditions, SPE and output obligations. • Communicate the decision promptly with next steps, contacts, fees and review/appeal information where applicable. • Make permit information machine-readable where feasible to support downstream provisioning and access control.	High	EHDS Art. 68 and related national procedure. Decision quality directly affects data preparation and use.
4. Data preparation	4.1 Data curation and integration The prepared dataset corresponds to the permit and is usable.	Lead: health data holder / designated preparation function Support: HDAB, HDIE, SPE operator	Ambiguous permit; delayed extraction; limited data expertise; non-standard formats/coding; linkage problems; excessive data; premature anonymisation; undocumented transformations.	• Translate the permit into an unambiguous technical specification and delivery plan. • Support extraction, minimisation, cleaning, harmonisation, authorised linkage, identifier treatment and pseudonymisation/anonymisation at the appropriate point. • Validate conformity with the permit and document provenance, transformations and quality limitations. • Define roles and location for integration in advance; consider HDIEs where nationally provided.	High	EHDS Arts. 57(1)(b), 60 and 73. As an implementation principle, authorised record linkage needs to take place before irreversible anonymisation where linkage is required.

Phase	Sub-step and intended outcome	Lead / support actors	Key bottlenecks or failure risks	Recommended priority support functions and preventive measures	Priority estimate	Key references / implementation notes
4. Data preparation	4.2 Secure data provision to the SPE Prepared data are transferred to SPE, verified and available without unnecessary delay.	Lead: data holder / SPE operator Support: HDAB	Manual or insecure transfer; incompatible interfaces; delayed loading; integrity failure; no transfer log; dataset differs from permit; inadequate approved tooling.	• Use secure and, where feasible, automated machine-to-machine transfer with confidentiality and integrity protection. • Log and verify receipt, completeness and permit conformity; resolve exceptions quickly. • Pre-provision the approved analysis environment and required capacity based on the permit and project plan.	High	EHDS Arts. 60(1)–(2) and 73, and future SPE implementing requirements. Data provision and user onboarding are related but distinct processes.
4. Data preparation	4.3 SPE onboarding of data users Each user is identified, trained and granted project-specific access.	Lead: SPE operator / HDAB Support: applicant organisation	Identity or authority cannot be verified; training and agreements incomplete; access granted too broadly or too late; conditions misunderstood; access not linked to permit.	• Provide timely identity verification, authorisation, project-specific training and acceptance of conditions. • Issue clear login and support instructions; test access before planned analysis starts. • Link permissions to project, role and permit; apply least privilege and automatic expiry.	High	SPE access must be attributable, auditable and isolated by project unless combination is explicitly authorised.
5. Use of data	5.1a Data analysis in the SPE Authorised analysis is secure, technically feasible and compliant with the permit.	Lead: health data user Support: SPE operator, HDAB, technical/data experts	Missing tools or compute; slow approval of libraries/code; insecure uploads; cross-project data mixing; limited support; weak logging; analysis diverges from permit.	• Provide a standard approved toolset and controlled processes for additional software, code, models or data, including malware scanning/quarantine. • Ensure adequate CPU, memory, GPU, storage and specialist support; use containers/version control where appropriate. • Maintain project isolation, role-based access, monitoring and audit logs; support reproducible workflows. • Coordinate multi-SPE workflows for federated analysis, including execution controls and validation of partial outputs.	High	EHDS Art. 73. Access rights should be linked to the project and permit, not merely to the person.
5. Use of data	5.1b Manage changes during data analysis Legitimate amendments are assessed without uncontrolled scope drift.	Lead: health data user and HDAB Support: data holder, SPE operator	Need for additional variables, users, tools or time emerges; informal changes bypass controls; amendment processing stops work; permit and SPE configuration diverge.	• Provide a transparent amendment route with criteria for minor versus material changes. • Synchronise approved amendments with data preparation, SPE access, tooling and expiry dates. • Maintain versioned permit conditions and notify all affected actors.	Medium	Operational addition derived from the need for project/permit-linked access and reproducible, auditable analysis.
6. Finalisation	6.1 Results validation and controlled release Only compliant, non-disclosive results leave the SPE in a predictable timeframe.	Lead: SPE operator / HDAB Support: health data user, disclosure-control expert	Personal data leakage; unclear export rules; long review queues; inconsistent decisions; repeated rework; no audit trail.	• Define output rules, review criteria, file restrictions, service times and revision procedures before analysis begins. • Combine automated screening with risk-based manual or four-eyes review; quarantine outputs pending approval. • Document reviewer, decision and released version; prevent bypass through copy/paste or uncontrolled channels.	High	EHDS Art. 73; controlled output release is both technical and organisational.
6. Finalisation	6.2 Archival and reproducibility A proportionate project package preserves methods, provenance and approved outputs.	Lead: health data user Support: HDAB/SPE operator, repository/records function	Code, versions and transformations lost; future validation impossible; retention basis unclear; sensitive data retained informally; no controlled re-access route.	• Define an archival and reproducibility package: approved outputs, protocols, queries, code, software/package versions, transformations and provenance. • Clarify what is retained, where, for how long and under which legal basis. • Require a new or applicable permit route for later access to personal or pseudonymised data.	Medium	Apply proportionality: not every project requires the same package, but decisions should be explicit and auditable.

Phase	Sub-step and intended outcome	Lead / support actors	Key bottlenecks or failure risks	Recommended priority support functions and preventive measures	Priority estimate	Key references / implementation notes
6. Finalisation	6.3 FAIR-compliant output preparation Publication obligations are met and reusable outputs are adequately documented.	Lead: health data user Support: HDAB, repository/publisher support	Results not published or poorly documented; identifiers/provenance missing; unclear reuse conditions; confidential or protected information exposed.	• Provide guidance and templates for Article 61(4) publication of anonymous results. • Support metadata, provenance, persistent identifiers, documentation, ontologies and suitable repositories where permissible. • Check consistency with permit conditions, disclosure control, ethics, IP and trade-secret safeguards.	High	EHDS Art. 61(4); FAIR-aligned implementation should support findability and reuse without compromising safeguards.
6. Finalisation	6.4 Significant findings, incidental findings and data-quality feedback Potential health-related findings and source-data issues follow defined channels.	Lead: health data user Support: HDAB, data holder, clinical/ethical/legal experts	No reporting route; uncertain significance/actionability; unclear responsibilities; direct contact with individuals; data errors not fed back to metadata/data owners.	• Provide separate, clearly documented channels for potentially significant findings and for data/metadata quality feedback. • HDAB should coordinate multidisciplinary assessment and any lawful onward communication. • Define responsibilities, triage, documentation and feedback loops; avoid direct re-identification or contact by the user.	High	EHDS Arts. 58(3) and 61(5). Further European and national guidance is needed on significance and actionability.
6. Finalisation	6.5 Deletion and retention Closing the project by revoking access and deleting or retaining data. Closure is timely, evidenced and auditable.	Lead: SPE operator / HDAB Support: health data user, records function	Access persists after expiry; original data remain beyond the authorised period; deletion not evidenced; unresolved outputs; retention inconsistent with permit/law.	• Trigger a closure checklist covering final outputs, reporting, access withdrawal, retention and deletion. • Automate expiry and deletion where feasible, with exception handling and authorised retention controls. • Record completion and provide auditable evidence; communicate closure to the user and relevant data holders.	High	Permit conditions and applicable law determine deletion/retention. Automatic controls reduce residual-risk and administrative burden.

Abbreviations: DQUL = Data Quality and Utility Label; EHDS = European Health Data Space; HDAB = Health Data Access Body; HDIE = Health Data Intermediation Entity; IP = Intellectual Property; QA = quality assurance; SPE = Secure Processing Environment.

Source basis: Consolidated VALO2 WS2 Final Report, especially Chapters 3-7. This annex is an operational synthesis and is not a formal legal compliance assessment.

Annex 3a. List of Nordic-Baltic national EHDS2-relevant authorities and bodies



National EHDS authorities – Key stakeholders in Nordic EHDS2 Competence Forum

Introduction

This document presents the public authorities in the Nordic countries as well as Lithuania and Estonia, which play a role in the national EHDS organisation, specifically related to secondary use of health data.

The organisations have primarily been identified based on their participation in the VALO project and presence at the Nordic Competence Forum meetings.

The document provides a brief general introduction to each organisation, as well as more specific information on their current role in secondary use of health data and in the implementation of the EHDS Regulation (secondary use), to the extent that has been determined.

Considering the upcoming VALO2 extension together with pending government decisions in several countries to designate various HDAB functions, this list should not be seen as exhaustive and definitive.

Denmark

Danish Health Data Authority

The Danish Health Data Authority provides high-quality health data and digital solutions to support patient care, research, and administration. It manages national health registers, develops medical classifications, and ensures secure data infrastructure. The authority plays a key role in Denmark's digital health strategy and international data cooperation.

Finland

Finnish Ministry of Social Affairs and Health

The Ministry of social affairs and health is responsible for planning, steering, and implementing Finland's health and social policy. Its mission is to ensure equal opportunities for well-being, promote healthy living and working environments, and secure access to social and healthcare services throughout life.

The Finnish Innovation Fund, Sitra

Sitra is an independent future fund operating under the Finnish Parliament. It anticipates societal changes and develops solutions to Finland's challenges through foresight, experimentation, and collaboration. Its mission is to promote Finland's well-being and accelerate sustainable economic growth within the limits of nature's carrying capacity. In addition to leading the VALO/VALO2 project, Sitra is also in parallel leading the TEHDAS2 Joint Action (and earlier the first TEHDAS project).

Finnish Institute for Health and Welfare (THL)

THL is an independent expert and research institute under the Finnish Ministry of Social Affairs and Health. It promotes the welfare, health, and safety of the population by producing research, statistics, and policy recommendations. THL also serves as a statistical authority and holds national registers in its field. THL is legally mandated to steer national information management in social welfare and health care services, including the development of systems aimed at processing the health and welfare data of the Finnish citizens (<https://thl.fi/en/about-us/what-we-do>).

Findata – Finnish Social and Health Data Permit Authority

Findata is the national data permit authority for the secondary use of health and social care data. It grants permits, compiles and processes data securely, and ensures privacy protection. Findata operates independently but in conjunction with THL, and is guided by the Ministry of Social Affairs and Health.

Iceland

Ministry of Health

The Ministry of Health is responsible for shaping national health policy, overseeing healthcare services, and promoting public health and prevention. It also coordinates health-related legislation, bioethics, and international cooperation in the health sector.

Directorate of Health

The Directorate of Health supervises healthcare services in Iceland and promotes public health through prevention, licensing of professionals, and oversight of health data. It also manages health statistics and coordinates responses to communicable diseases. The Directorate recently applied for an EU direct grant, in collaboration with Digital Health to establish an HDAB in Iceland.

Digital Health

Digital Health is a centre for development and innovation in healthcare services, established on 1 January 2026. It is responsible for the development and governance of Iceland's national digital health infrastructure and services. The centre coordinates digital health initiatives, promotes interoperability, and enables secure exchange of health data across the healthcare systems. Digital Health is expected to play a central role in the implementation of the European Health Data Space (EHDS) in Iceland, including the development of technical capabilities for

cross-border health data exchange and cooperation with national authorities and European partners.

University of Iceland, Faculty of Law

Supporting other authorities in legal matters.

Norway

Norwegian Ministry of Health and Care Services

The Ministry of health and care services is responsible for ensuring good and equal health and care services for Norway's population. It directs healthcare policy through legislation, budgeting, and oversight of subordinate institutions like the Directorate of Health.

Norwegian Directorate of Health

The Directorate of Health promotes public health and coordinates sustainable, equitable health and care services in Norway. It implements government policies, manages health registers, and guides digitalisation efforts in the health sector.

Norwegian Institute of Public Health (NIPH)

NIPH monitors population health and conducts research in areas such as infectious diseases, mental health, and epidemiology. It provides evidence-based advice for health promotion and prevention, and manages national health data registers.

Sweden

Swedish Ministry of Health and Social Affairs

The Ministry of Health and Social Affairs oversees Sweden's welfare policies, including public health, healthcare, social services, and social insurance. It coordinates national strategies, legislation, and funding to ensure equitable and effective care across the country.

Swedish eHealth Agency

The Swedish eHealth Agency (E-hälsomyndigheten) coordinates national e-health initiatives and develops digital solutions for healthcare, pharmacies, and social services. It manages key registers and IT services, including digital prescriptions and the Medicine Check service.

The National Board of Health and Welfare

Socialstyrelsen is Sweden's central authority for health and social care. It ensures equal access to high-quality services, maintains health data registers, and publishes official statistics. The agency also develops national guidelines and supports decision-makers across the healthcare and social sectors. Socialstyrelsen is an appointed candidate for having the role as coordinating HDAB.

The Health and Social Care Inspectorate (IVO)

The Health and Social Care Inspectorate (IVO) is a government agency responsible for supervising health care, social services and activities under the Act concerning Support and

Service for Persons with Certain Functional Impairments (LSS). IVO is a formal candidate for having future HDAB responsibilities with regard to data use supervision.

Statistics Sweden

Statistics Sweden SCB is the national statistical agency responsible for producing official statistics to support decision-making, research, and public debate. It collects, analyses, and publishes data on areas such as population, labour market, economy, health, and education. SCB had the government assignment to investigate the prerequisites for how a system of secure processing environments should be organised and developed in Sweden within the framework of the EHDS.

The Swedish Ethical Review Authority

The remit of Etikprövningsmyndigheten is to protect participants involved in research, doing this by examining applications for ethical review.

Estonia

Ministry of Social Affairs of Estonia

The Ministry of Social Affairs is responsible for shaping Estonia's policies in health, social protection, and employment. It promotes public health, ensures access to healthcare services, and supports vulnerable groups through welfare programmes. The ministry also plays a key role in digital innovation and international cooperation in health and social systems.

Lithuania

Ministry of Health of the Republic of Lithuania

The Ministry of Health formulates national health policy, oversees healthcare institutions, and promotes public health. It supports disease prevention, health education, and the development of health information systems.

State Data Agency

The State Data Agency (Valstybės duomenų agentūra) appears to be the designated national lead authority preparing to assume HDAB functions. Through the EU4Health-funded LiDAS project, it is developing the national health-data catalogue, secure processing environment and HealthData@EU connectivity required by the EHDS.

Annex 3b. Secure Processing Environment candidates

The following information about Secure Processing Environment (SPE) candidates is from the National progress reports of VALO2, in combination with desktop research:

DENMARK

Data from the national health registers at the Danish Health Data Authority is only distributed via The Secure Research Platform. This Platform is a database that contains a duplicate of most of the Danish Health Data Authority's registers. It provides remote access to the data, allowing the secondary user to access it online from their own workplace.

[The Secure Research Platform - The Danish Health Data Authority](#)

FINLAND

There are several SPEs in Finland for analysing social and health data. According to the Finnish Act on Secondary Use, Findata has issued a regulation on the requirements set for these environments. The analysis of data at individual level is only permitted in environments that meet the requirements of the regulation. The Finnish Supervisory Agency maintains the public Astori register that lists registered regulatorily compliant operating environments: [Astori register under the Client Data Act and the Secondary Use Act - Finnish Supervisory Agency](#)<https://lrv.fi/en/healthcare-and-social-welfare/operating-environments>

- **Auria's Atolli**
 - Provider of the environment: Auria Health Data Services of The wellbeing services county of Southwest Finland (Varha).
 - Read more: <https://www.auria.fi/tietopalvelu/en/atolli/>
- **FIMM Sandbox**
 - Provider of the environment: University of Helsinki
- **FinnGen Sandbox**
 - Provider of the environment: University of Helsinki
 - Read more: <https://sandbox.finnngen.fi/>
- **FIONA**
 - Provider of the environment: Statistics Finland
 - Read more: <https://stat.fi/en/services/services-for-researchers/instructions-for-researchers/using-the-datasets/fiona-remote-access-system>
- **HUS Acamedic**
 - Provider of the environment: HUS Helsinki University Hospital.
- Read more: <https://acamedic.fi/en/Kapseli>
 - Provider of the environment: Findata – Finnish Social and Health Data Permit Authority
 - Read more: <https://findata.fi/en/kapseli>
- **SD Desktop**
 - Provider of the environment: CSC – IT Center for Science



- Read more: <https://research.csc.fi/sensitive-data/sensitive-data-sd-services-for-research/>
- **SECDATA**
 - Provider of the environment: Aalto University
 - Read more: <https://www.aalto.fi/en/services/secure-operating-environment-for-sensitive-data>
- **SPESIOR**
 - Provider of environment: ESior Oy
 - Read more: <https://esior.fi/en/spesior-3/>
- **T3 Tutkijan työtila**
 - Provider of the environment: Istekki Oy
 - Read more (in Finnish only): <https://pirha.fi/ammattilaiselle/tutkimus/tutkimus-ja-opinnaytetyoluvat/rekisteritutkimukset/kuinka-tilaan-tutkijan-t3-tyotilan>

ICELAND

Statistics Iceland provides access to microdata on the Icelandic economy and society for statistical research purposes. Access is granted to researchers from Icelandic research entities with extensive capacity and needs for research and analysis – such as universities, research institutions or research departments in public administration, the Central Bank of Iceland, statistical institutes etc. Since all data collected by Statistics Iceland is confidential, access to anonymised microdata is always granted via remote connection to a secure virtual machine hosted by Statistics Iceland

[Microdata service - Statistics Iceland](#)

NORWAY

There are several infrastructures available in Norway today: HUNT Cloud (Norwegian University of Science and Technology), SAFE (University of Bergen), TSD (University of Oslo). These are all part of the NORTRE collaboration (Norwegian Trusted Research Environments), funded with support from the Ministry of Education and Research and the Ministry of Health and Care Services.

The purpose of NORTRE is to provide secure analysis rooms and services for the collection, storage, processing and sharing of sensitive data. NORTRE will provide services for both research and public administration. But how such infrastructures are to meet the EHDS requirements on SPE is still to be determined.

[Frontpage - Norwegian Trusted Research Environments \(NORTRE\)](#)

SWEDEN

This information about Swedish SPE candidates comes from the final report of the government assignment to Statistics Sweden (SCB)²⁴.

²⁴ Uppdrag till Statistiska centralbyrån att utreda förutsättningar för att tillhandahålla säkra behandlingsmiljöer enligt EHDS, S2025/00975 (delvis), Slutrapport.

Brief facts about the respective environment

Vesta

Principal of the environment: Uppsala University

VESTA is a university-affiliated secure research environment for storing, processing and analysing sensitive research data. The environment is particularly focused on health data, but is also used in other research areas where there is a need for a user-friendly and controlled analysis environment. VESTA 2.0 is under development and possibly the same hardware as in MAJA will be used to provide a Windows environment.

AIDA Data Hub

Principal of the environment: Linköping University

AIDA Data Hub is a national e-infrastructure for data-driven precision health, with a special focus on AI, medical imaging and life sciences. The environment combines secure data management with computational resources and support for advanced research and innovation projects.

MIMER

Principal of the environment: Linköping University (NAISS)

MIMER is a Swedish AI factory and supercomputing infrastructure under construction, with the aim of strengthening Sweden's and the EU's capacity in AI and high-performance computing. The environment is focused on computationally intensive use cases and large data sets in areas such as health and life sciences.

Arrhenius SENS

Principal of the environment: Linköping University

Arrhenius SENS is a European supercomputing infrastructure located in Sweden and intended for computational intensive cutting-edge research in several areas. The environment is relevant for research projects that require very high computational capacity and can handle sensitive data through special secure solutions.

BIANCA

Principal for the environment: Uppsala University

BIANCA is a secure cluster and compute environment for projects that handle sensitive data within UPPMAX and will be replaced by MAJA. The environment is designed for research where high safety requirements need to be combined with high computational capacity and flexibility in the analysis work.

GMS (NGP) – Genomic Medicine Sweden (National Genomics Platform)

Principal of GMS: Region Skåne ; Principal of NGP: Västra Götaland Region

GMS is a collaboration between Sweden's seven regions with university healthcare and the seven universities with medical faculties in Gothenburg, Linköping, Lund, Stockholm, Umeå, Uppsala and Örebro. The National Genomics Platform (NGP) is Genomic Medicine Sweden's initiative to store, analyse and share genomics data in a secure and efficient way. The

environment is particularly focused on precision medicine diagnostics, decision support, research and development work where genomics data is combined with other health data.

Säker forskningsmiljö (SFM)

Principal of the environment: Västra Götaland Region

SFM (Secure Research Environment) is a regionally anchored secure research environment for the management of research data throughout the life cycle. The platform has been developed for research within VGR, but is designed to be able to support collaboration with external research actors and future requirements for secure health data management.

Microdata online Access (MONA)

Principal of the environment: Statistics Sweden SCB

MONA is Statistics Sweden's platform for processing and analysing microdata. In MONA, users can make processing via the internet without microdata leaving Statistics Sweden.

An extended presentation is available in the SCB report. In the final report to the Swedish Government, SCB points at significant gaps in MONA in relation to expected requirements for an SPE according to the EHDS Regulation. SCB therefore advises against aiming for MONA as a formal SPE.

LITHUANIA

Lithuania already has a secure environment for secondary use of health data operated by the State Data Agency within the national State Data Lake infrastructure. Through the EU4Health-funded 2026-LT-LiDAS project, this environment is currently being expanded and adapted to fulfil the requirements of EHDS and to serve as Lithuania's future HealthData@EU-connected SPE.

[The State Data Agency \(Statistics Lithuania\) Is Implementing the Project “2026-LT-LiDAS”, Aimed at Developing the Infrastructure for Secondary Use of Health Data in Lithuania - Valstybės duomenų agentūra](https://duomenys.stat.gov.lt/sveikatos-duomenys/)
<https://duomenys.stat.gov.lt/sveikatos-duomenys/>

Annex 4a. Metadata and metadata catalogues – full report

Condensed summary in Final consolidated WS2 report above

Introduction to the metadata work in VALO2

The task *Metadata and metadata catalogues in relation to EHDS* was part of WS2 in VALO2 project. The aim of the task was to continue the work done in the first VALO project (VALO1) on collaboration around health data catalogues and implementation of EHDS2 metadata requirements in the Nordics (and possibly also Baltics).

The objectives of the metadata work of VALO2 were to develop:

- common understanding of the HealthDCAT-AP metadata specification to support its implementation in the national catalogues;
- common understanding on Nordic health data landscape (EHDS Article 51), including how to present the data as datasets for secondary use, and
- preliminary understanding on the requirements efficient use of AI sets for metadata.

The metadata work in the VALO projects builds on already longer history of Nordic collaboration around health data catalogues in secondary use. The VALO projects were preceded by two Nordic Commons projects funded by the Nordic Council of Ministers, both of which had a task force on metadata issues. There is also ongoing informal collaboration bridging over from the Nordic Commons to the VALO projects within the framework of the Nordic Health Metadata Network.

The metadata task was advanced through Competence Forum Metadata breakout sessions, engaging with the informal Nordic Health Metadata Network involving monthly meetings, and organisation of some additional meetings to discuss specific tasks.

Previous work and key outcomes

The metadata work during the first VALO project focused mainly on forming a shared understanding of the HealthDCAT-AP metadata specification draft and EHDS2 metadata requirements. The task also actively sought to influence the development of HealthDCAT-AP through the TEHDAS2 HealthDCAT-AP development work, which was underway at the same time. In addition to specific EHDS-related work, a common Nordic variable-level metadata specification was further developed up to version 0.8 and it was also submitted as input from the VALO1 project to the HealthDCAT-AP development work being carried out within the TEHDAS2 project.

The identified key challenges of HealthDCAT-AP draft from the Nordic perspective included:

- lack of shared understanding on the information model,
- lack of hierarchy in the information model (higher “data resource” level missing above the datasets to point out that the datasets are part of the same data resource, e.g. registry or population study),
- ambiguity about how datasets should be defined,
- some technical complexity issues, and

- terminology inconsistencies.

For upcoming work, it was proposed to:

- continue building a shared Nordic understanding of HealthDCAT-AP,
- seek the most harmonised way possible to implement the HealthDCAT-AP in the national health data catalogues.

The proposed solutions included:

- creating possible enrichments of HealthDCAT-AP in the national catalogues in a harmonised way, including common Nordic variable metadata specification,
- implementing data quality and utility labelling in a harmonised way, and
- aiming for harmonised dataset definitions.

For more information, see the previous VALO report on metadata catalogues²⁵.

The metadata work in the VALO2 project built on where the first VALO project ended. All identified objectives were still relevant, as well as most of the identified HealthDCAT-AP related challenges, even though the HealthDCAT-AP draft had evolved since the first VALO. The VALO1 work was based on the HealthData@EU Pilot project's and TEHDAS2 versions of HealthDCAT-AP draft; at the time of writing, HealthDCAT-AP Release 7 published by EU's DG SANTE is in use.

Outcomes of the metadata work

Common understanding of HealthDCAT-AP

The primary objective of the metadata task was to enhance shared understanding of the HealthDCAT-AP specification, with the overall goal to achieve the highest possible level of harmonisation in its implementation in the Nordics.

This objective was promoted mainly through:

- mappings between already existing or emerging Nordic national health data catalogues and the mandatory dataset-level properties of HealthDCAT-AP (using HealthDCAT-AP Release 7 and Implementing Act on Article 77²⁶ draft's mandatory properties);
- pilot descriptions using the mandatory HealthDCAT-AP properties;
- discussions on which non-mandatory HealthDCAT-AP properties the countries would want to encourage their data holders to describe;
- testing the HealthDCAT-AP Release 5 and the Dataset Description Assistant provided in the HealthData@EU Central Platform and sending shared feedback with questions to DG SANTE;
- collecting information on the status of HealthDCAT-AP understanding and implementation in the countries;
- sharing experiences with the EU project Cancer Watch Joint Action metadata work;

²⁵ VALO Metadata catalogues – final report. 2025. <https://www.sitra.fi/en/publication/valo-metadata-catalogues-final-report/>

²⁶ EHDS Article 77: *Dataset description and dataset catalogue*

- showcasing the development made in the national catalogues.

In addition, shared feedback on the EHDS Article 77 Implementing Act on dataset descriptions was compiled and submitted on behalf of the VALO2 project in the implementing act public consultation (see: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/15673-European-Health-Data-Space-dataset-descriptions/F33400889_en).

Summary of findings

The HealthDCAT-AP specification has evolved in a positive direction to some extent, and understanding of it has also increased in the participating countries during the VALO2 project. However, the specification is still considered mature enough only in certain respects to support planning for its national implementation, and the understanding of HealthDCAT-AP across VALO2 participant organisations is perceived as uneven. Most of the challenges identified during the VALO1 project (introduced above under the title *Previous work and key outcomes*) remain valid and still require further clarification, despite the continued evolution of the HealthDCAT-AP specification and the important revisions that have been made.

The identified key needs to support the national implementation of HealthDCAT-AP include:

- **Clear guidance with examples on the information model:** What is a dataset? What is a Catalogue in the information model? And how should dataset series or distributions be used?
- **Clear guidance on datasets in different data categories:** The key concept dataset should be defined more precisely, and concrete examples should be given of what a single dataset could be for different EHDS Article 51²⁷ data categories. There are currently very different views on the matter in the community. Inconsistent implementation can jeopardise the ability to gain a harmonised understanding of the available data in different countries.
- **Development of property definitions and vocabularies, taking into account different data categories:** HealthDCAT-AP is still in the development stage, and in particular specific mandatory properties' definitions and vocabularies should be developed to enable both the correct understanding and also the possibilities to comprehensively and with sufficient accuracy describe datasets from all different concerned data categories.
- **Detailed instructions taking into account different data categories:** More detailed EHDS Art. 51 data category specific guidelines are needed for dataset descriptions in order to make them harmonised and ensure the findability of similar data from different countries.
- **Possibility to publish pilot descriptions:** In addition that the HealthDCAT-AP pilot descriptions can be made using the Commission's Dataset Description Assistant, a possibility to also publish the descriptions in the HealthData@EU Central Platform's EU Dataset catalogue more easily is needed. Currently, the descriptions can only be published via national infrastructure, and not all countries have started setting it up yet. Easily accessible pilot descriptions would support the development of common

²⁷ Article 51: *Minimum categories of electronic health data for secondary use*

understanding and allow feedback from different stakeholder groups. Discussions and feedback are needed both at the EU and Nordic level and within individual countries, considering the perspectives of various data holders, communities and different types of data categories, as well as different data user groups and HDAB personnel who process data permit applications – making the descriptions visible and accessible is a prerequisite for progress.

- **Concrete training, examples and exercises in the EU level:** Also, more concrete examples and exercises in the EU level are needed and clarification on how different user needs (e.g. statistic, research, or combined datasets) should be supported.
- **Additional resources:** The need for additional resources and especially technical expertise support was identified as key factors in facilitating implementation in the countries – currently more in the HDAB side, but also in the health data holder side. In general, manual work on metadata is time consuming but automation requires resources and technical investment. The expectations towards metadata are increasing with EHDS due to the implementation of a new common metadata specification and a data quality and utility label, as well as the inclusion of broader data categories within the scope of secondary use regulation.
- **Possible Commission support regarding technical solutions:** Also, the possibility to use the Dataset Description Assistant²⁸ and other possible technical solutions provided by the European Commission as part of national technical metadata solutions in the future was identified as a possible implementation path.

The mandatory dataset level properties' mapping exercise demonstrated that countries primarily aiming to implement the specification into an existing catalogue, Finland and Norway, will need to add several new properties and also adapt some existing ones in order to be HealthDCAT-AP compatible. In general, it seems that building a new catalogue based on HealthDCAT-AP might be easier than adapting an old catalogue and metadata model to it.

The Nordic countries also share the view that the mandatory HealthDCAT-AP properties are not enough to describe Nordic health data consistently and support cross-border discovery. In addition to the HealthDCAT-AP properties, all countries also intend to implement other properties – either by retaining existing ones or by adding others deemed necessary. It is seen important to continue cooperation and explore the possibilities to implement additional properties as harmonised as possible, possibly with the aim of “Nordic HealthDCAT-AP extension”. It should include both other than mandatory HealthDCAT-AP properties the countries consider necessary to be described, and additional properties outside the HealthDCAT-AP specification that are needed to be able to describe Nordic health data in a meaningful manner.

Doing the pilot descriptions (see Annex 4b *HealthDCAT-AP pilot descriptions*) and discussion with the VALO Legal group demonstrated that the HealthDCAT-AP specification has evolved in a better direction, but it still needs further development. To highlight a few examples among others, the following development needs were identified during the work:

²⁸ <https://acceptance.data.health.europa.eu/healthdata-central-platform/datasetDescriptionAssistant?locale=en>

- **Development of vocabularies:** To highlight a few examples, the current version of certain vocabularies (e.g. *Coding systems*), currently have more suitable options for Cancer registry descriptions than biobank data descriptions. The vocabulary in *Has personal data* lacks many key concepts for describing personal data related to health data.
- **Development of instructions:** For example, instructions on how numerical data in properties like *Number of records* and *Number of unique individuals* will be presented for continuously updating datasets, is needed.
- **Addition of new properties:** Also, some missing key properties were identified in the specification, like for example:
 - **Unit of observation:** The mandatory property *Number of unique individuals* would need to be accompanied by the observation unit information to make more sense for the users.
 - **IP rights and trade secrets:** In discussion with the VALO Legal group it was noted that a dedicated property for Intellectual Property (IP) rights would be needed. Data holders must communicate to HDABs if the data includes IP rights or trade secrets, and it would be necessary to have a structured and harmonised way to describe it in metadata.

Differences between countries were observed in the interpretation of properties, as the guidance is not yet sufficient. More pilots with different datasets are needed to be able to highlight more specific needs.

The implementation status of HealthDCAT-AP in Nordics is briefly outlined in the table below. More detailed information on the countries' national health data catalogues can be found in the [Final metadata catalogues report](#) from the earlier VALO project²⁹.

Table: Status of HealthDCAT-AP implementation in the Nordic national health data catalogues.

Country	National health data catalogue exists	Status	Key challenges in HealthDCAT-AP implementation
Denmark	No	• Minimum Viable Product (MVP) for a national health data catalogue based on HealthDCAT-AP Release 6 has been developed in EU funded HDAB Denmark project. • The catalogue MVP was soft-launched in May 2026, with the dataset descriptions visible only internally. It currently contains descriptions on key	

²⁹ <https://www.sitra.fi/en/publication/valo-metadata-catalogues-final-report/>



		population-based health registries in Danish language.	
Finland	Yes	• Goal to implement HealthDCAT-AP in the existing national health data catalogue Data resources catalogue, while also retaining some of the existing characteristics. • The catalogue has been preliminarily mapped to HealthDCAT-AP in the dataset and variable description levels. Quite many HealthDCAT-AP properties are missing and need to be implemented. • Plan for the HealthDCAT-AP implementation will be drawn up during the autumn 2027. • Catalogue usability and search functions were further developed in the EU-funded direct grant FinHITS project during the year 2025.	• Understanding of the HealthDCAT-AP information model. • Adapting the old catalogue's more hierarchical information model (data resource and dataset descriptions vs. dataset descriptions) to the new one. • An additional resource with technical expertise would be needed to assist with planning. • There is funding for the planning, but not yet for the implementation.
Iceland	No	• Applied for a direct grant to start planning a national HealthDCAT-AP based catalogue. • Descriptions of key health registers, including variable description in Excel files, are already published at webpage. Most of the registries are owned by Directorate of Health.	• Understanding of the HealthDCAT-AP information model. • Resources.
Norway	Yes	• The national metadata standard mapped to HealthDCAT-AP. • The national metadata catalogue is currently being developed within MUNIN, a metadata management system that supports both the national metadata specification and HealthDCAT-AP. The platform enables efficient metadata governance and	Norway has established the foundations for HealthDCAT-AP implementation through initiatives such as MUNIN, the Dataset Description Assistant, and the national metadata catalogue. However, the key challenges are: • Limited adoption across the health sector:



		facilitates compliance with emerging European interoperability requirements. • To support EHDS compliance, a HealthDCAT-AP validator has been developed, providing feedback on the quality and completeness of metadata imported from health data registries and helping data providers identify and address compliance gaps. • HealthDCAT-AP will be implemented in the national health data catalogue, helsedata.no, which serves as Norway's public portal for health data metadata managed in MUNIN. In addition, new functionalities, including the Data Source Explorer (Kildeutforsker - Source explorer - Munin) and Variable Explorer (Variable Explorer - Munin), are currently under development and testing, with launch planned for autumn 2026. • The primary motivation for developing new functionalities has been to improve metadata discoverability by enhancing search capabilities, introducing more advanced filtering mechanisms, and enriching metadata records with HealthDCAT-AP properties.	HealthDCAT-AP is still a new and evolving standard, and implementation among health data providers remains limited. • Metadata harmonisation: Health registries and other data holders use different metadata models, terminologies, and code lists, making it difficult to achieve interoperability and consistency. • Metadata quality and completeness: Existing metadata are often incomplete, inconsistent, or outdated, reducing their value for data discovery and reuse. • Unclear implementation requirements: Some uncertainty remains regarding the required level of metadata granularity and the interpretation of certain HealthDCAT-AP requirements. • Awareness and competence among data holders: Many organisations need additional guidance and support to understand their responsibilities under EHDS and to implement HealthDCAT-AP correctly.
--	--	--	---



			• Resource constraints: Creating, maintaining, and continuously improving metadata requires time, expertise, and dedicated resources. • Variable-level metadata: Researchers increasingly expect detailed information at variable level, but such metadata are often not standardised or easily available. • Long-term governance and maintenance: Sustainable metadata management processes must be established to ensure that metadata remain accurate, up to date, and compliant over time.
Sweden	Yes	• Sweden has a national metadata catalogue for registry data. Rather than altering said catalogue to meet EHDS criteria, a new catalogue will be assembled. • A prototype catalogue (POC), which is partially mapped to HealthDCAT-AP, has been developed as part of EU-funded SENASH direct grant project. The POC is not built for launch but has gathered valuable information for creation of a production catalogue. • Sweden's HDAB will now build on all lessons learned in	• Awareness, resources and capabilities among data holders to provide metadata for the catalogue. • The time restraints for development: HealthDCAT-AP is not yet stable, and time is ticking to implement it.

		the direct grant-funded POC catalogue when assembling a national health data catalogue.	
--	--	---	--

Recommendations

- **Making rationale visible and fostering communication:** The next steps should be to move to concrete piloting by publishing pilot descriptions using datasets covering a wide range of different data categories and thereby enabling making the rationale visible to different user groups and asking for feedback. The findings and possible suggestions should be presented and brought for further discussions in the EU level in a consolidated manner, for example in the Community of Practice (CoP) subgroup 2 on dataset catalogue (SG2), to demonstrate open questions in a practical way and to foster the formulation of common guidelines.
- **Explore the need to continue developing a common Nordic metadata framework:** To ensure that Nordic health metadata is as harmonised as possible, a shared metadata specification on additional metadata properties is needed. It should include both other than mandatory HealthDCAT-AP properties the countries consider necessary to be described, and additional properties outside the HealthDCAT-AP specification that are needed to be able to describe Nordic health data in a meaningful way. The group has started the work towards this goal by discussing which other than mandatory HealthDCAT-AP properties would be needed to be filled in in the descriptions and earlier during the previous projects developing the draft of common Nordic variable metadata specification (see as annex in the VALO1 metadata final report³⁰). Confirmation from all countries as to whether this goal is still supported is needed. In addition, it is advisable to first seek to influence developments at the EU level and avoid creating a separate Nordic layer.

Common understanding of the Nordic health data landscape

EHDS expands the field of data categories under secondary use in relation to the current data categories familiar to many in the Metadata group. Many countries already have a national catalogue or sector specific catalogues of health data, but not all data categories (*minimum categories of electronic health data for secondary use*) of EHDS Art. 51 are included in them. Also, many in the metadata group are not familiar with what these data categories are in practice, and which health data holders are found in the countries that fall within the scope of the legislation. Those countries that are already engaging with the future EHDS2 health data holders, like Norway, have reported that the data holders which have not yet described their data in the existing catalogues, are often unfamiliar with the EHDS Regulation and may lack understanding of their role and responsibilities as health data holders under the Regulation. Additionally, the suitability of HealthDCAT-AP to describe data from all data categories has not been tested either.

³⁰ <https://www.sitra.fi/en/publication/valo-metadata-catalogues-final-report/>

Work on building an understanding of the health data landscape and of different data categories according to EHDS Art. 51 was started with a light touch. The metadata group conducted a practical exercise to identify examples of health data holders and datasets belonging to various data categories from each country (see Annex 4c *Nordic health data landscape analysis tables*). The work also included considering in what kind of datasets it would be desirable to offer these data in the catalogues for users. A more detailed reasoning on why to present data in such datasets was gathered and discussed with examples from a couple of different data categories. Also, a joint workshop with the VALO2 Legal group was organised to discuss open questions. The Legal group had discussed preparing a self-assessment template for potential data holders, to help them assess whether they are health data holders according to EHDS, based on work done in Sweden. A shared tool of this kind would be warmly welcomed by the Metadata group.

Disclaimer: The mapping done in VALO2 project is illustrative only and does not constitute a determination that any listed organisation is, or is not, a health data holder under Regulation (EU) 2025/327. Each organisation remains responsible for assessing its status and compliance obligations for each dataset and processing context, including whether it acts as a controller or joint controller for personal electronic health data under Articles 2(1)(a) and 2(2)(t), whether it controls the availability of non-personal electronic health data, and the controllership rules in Article 74. Natural persons and microenterprises are exempt from the Chapter IV health data holder obligations under Article 50(1), unless a Member State extends those obligations pursuant to Article 50(2). Final national legislation, implementing acts, contractual arrangements and actual processing roles may affect the assessment.

Summary of the findings

To summarise the findings and remaining open questions, it can be stated that:

- **Practical clarification of the health data holder definition and a self-assessment tool for data holders is needed:** The health data holder definition in the EHDS Regulation is perceived too vague and would need practical clarification. Furthermore, many Nordic countries have not yet initiated a comprehensive discussion or established a legal interpretation regarding which data holders fall within the scope of the definition. The VALO2 Legal group started clarification of the definition, and such progress is very welcome. A shared more specific definition within the Nordics could be useful and a Nordic self-assessment framework for data holders or other support material would be needed.
- **No clear understanding yet on the Nordic EHDS data landscape:** Based on a brief exercise to identify data resources belonging to different Art. 51 categories, the group found it somewhat challenging to identify examples for many of the less familiar data categories. For example, there is no clear overview yet on the research datasets generated by hospitals and universities, many collaborative research datasets, data from apps and wearables, or health data produced by private companies.
- **Clarification needed for Art. 51 definitions:** Many of the definitions of the minimum data categories set out in Art. 51 of the EHDS Regulation require further clarification. In some cases, it is currently unclear which data are actually covered by these categories. For example, it remains unclear which data held by healthcare providers are included in

the EHR data category and should be provided for secondary use under EHDS, and which are not.

- **More guidance on metadata implications needed:** There is currently no general guideline on how the HealthDCAT-AP health category property should be used. In particular, it is unclear whether it should reflect the original primary data source (e.g., EHR data in case of national registry data) or only the current data category of the dataset. This issue was discussed with the VALO2 Legal group, which concluded that it is a practical dilemma, rather than a legal matter.

The exercise to present the current views on how to divide national cancer registries into datasets demonstrated varied views among Nordic countries. It also demonstrated that the contents of the cancer registries are not similar, or the data are organised differently under different registries in the countries. For example, the National cancer registry in Norway includes quality registries, which in some other countries might be organised as a separate registry. The different views on how to present data as datasets are guided by, among other things:

- views on what the goal and core ambition of the catalogue should be (a starting point to provide a general overview – “a high-level directory”, or a place to get detailed description on specific data),
- already implemented ways of describing data in the catalogues,
- views on how feasible it is to describe the data (e.g. the description of a complex dataset as one single dataset most probably might compromise the accuracy of description),
- views on how feasible it would be to report on the quality of data from the defined entities (data quality and utility label),
- the known data holders’ different views on how detailed metadata they would like to share,
- the level of funding and resources for the metadata work, and
- views on already known user needs.

A good example of the complexity of the subject – and of the specificity regarding data categories and intended use – is that the Cancer Watch Joint Action shared with the group their conclusion on the most optimal dataset division of national cancer registries. Their conclusion was that frozen versions of the entire registry should be described as datasets.

It is clear that the VALO2 project was only able to scratch the surface of the EHDS health data landscape analysis in the Nordics, as well as other relevant metadata issues, and it is important to continue the work.

Recommendations

- **Publishing health data holder self-assessment tool:** A shared Nordic tool should be developed and published to help both the data holders and HDABs in identifying health data holders.
- **Data holder and dataset mapping:** Continuing the mapping of data holders and datasets and sharing the methodology and results among the countries.
- **Forming more detailed descriptions on data categories:** Once the category descriptions are clarified at the EU level, publishing the descriptions including examples

from Nordic datasets in connection with the health data holder self-assessment tool could facilitate the identification of data holders.

- **Publishing HealthDCAT-AP metadata and utilising user feedback:** Continue experimenting with data category selection in the published metadata descriptions and collecting user feedback on the consistent discoverability of specific data categories in the catalogues

Preliminary understanding of needs AI places on metadata

Expectations towards AI have grown greatly in recent years. The potential applications of AI are expanding rapidly, and it has been recognised that it is important to identify and learn about the connections between metadata and effective utilisation of AI applications in connection to health data secondary use.

The topic was approached from two different angles: By examining the AI Act's requirements regarding data quality when training high-risk AI models, and by learning from practical findings regarding the experiences of a Norwegian project exploring metadata-driven AI for variable discovery.

The AI Act Art. 10 states that the data used to train high-risk AI models must meet certain quality criteria. AI training, validation and testing datasets must be subject to data governance and management practices appropriate for the intended purpose of the high-risk AI system. Those practices concern in particular relevant design choices, data collection processes and the original purpose of data collection, relevant data preparation processing operations, formulation of assumptions, assessment of the availability, quantity and suitability of the datasets that are needed, examination in view of possible biases, appropriate measures to detect possible biases, and identification of relevant data gaps. Training, validation and testing datasets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. (<https://eur-lex.europa.eu/eli/reg/2024/1689/oj/eng>)

A preliminary analysis was made on how well the potential users could assess and gain an understanding on the aspects mentioned in the quality criteria by descriptions following the current EHDS metadata and data quality and utility label documentation requirements - HealthDCAT-AP Release 7 metadata specification (EHDS Art. 77) and the data quality and utility label metrics developed by the QUANTUM project^{31,32} (EHDS Art. 78). When discussing the outputs of the QUANTUM project, it is worth noting that they will serve as the basis for the implementing act on data quality and utility label, but there is no guarantee that the final EU requirements will align with them in the end.

The objective was promoted by:

- Seeking to identify criteria among those listed in AI Act Article 10 that could potentially be met through metadata descriptions or data quality reporting.

³¹ Deliverable 1.1 Specification of the data sets' quality and utility label. 2025
<https://zenodo.org/records/14937423>

³² <https://quantumproject.eu/>

- Conducting a preliminary mapping of the equivalent HealthDCAT-AP metadata properties and the QUANTUM data quality and utility labelling dimensions and metrics and analysing the correspondences.

In addition to this, the Norwegian team shared their findings of a project on exploring metadata-driven AI for variable discovery, application support and case processing in the Norwegian Institute of Public Health (FHI) called AI-Powered Metadata Discovery for Health Data Applications and Case Processing, and findings related specifically to metadata quality were discussed. The project was initiated in autumn 2024 through a pilot and evolved during 2025-2026 into a purpose-built AI agent architecture and MCP (Model Context Protocol) based service for structured metadata search and variable discovery. The solution aims to help researchers, other data users and case handlers identify relevant datasets and variables from FHI's health registry metadata, with the objective of reducing the time from data request to data delivery while simultaneously identifying areas where metadata quality can be improved.

Summary of findings

The role of metadata in ensuring the effective and reliable use of AI for the secondary use of health data appears to be central. This very preliminary analysis identified metadata – both metadata describing data and its quality and aiding in assessing the suitability of the data, as well as the quality and coverage of the metadata itself – as key factor.

Regarding the requirements introduced in the AI Act, it appears that:

- Some of the quality-related information needed to assess whether a dataset meets the criteria set out in Art. 10 could potentially be provided through HealthDCAT-AP-compliant dataset descriptions and data quality and utility labelling, including data quality reporting based on the requirements proposed by the QUANTUM project.
- At the very least, the data descriptions and quality labels could provide the AI developers with a starting point for assessing whether the data are worth further consideration and analysis, especially if detailed and up-to-date variable-level data quality reporting is available. For example:
 - Higher level information on the data collection processes, the origin of data and the original purpose of data collection can be provided by the mandatory HealthDCAT-AP property *Provenance* and non-mandatory properties *Purpose* and *Legal basis*. However, the documentation in the HealthDCAT-AP metadata is in free text fields and likely not in a very detailed level, and more detailed information might be needed for the high-risk AI model development. In QUANTUM's data quality and utility label in turn, the data holder needs to indicate whether dataset source and processes and operations are documented or not.
 - For assessment of the availability, quantity and suitability of the datasets that are needed, it seems that accurate and detailed metadata based on HealthDCAT-AP and the related QUANTUM data quality label's metrics could facilitate this assessment. However, in the case of health data for example from national registries or EHRs, providing reporting on the availability of data subjects with specific diagnoses in the data could further support this assessment.

- For the examination of potential biases and identification of relevant data gaps and shortcomings, it might be that deeper analysis and consulting the data experts are needed. Information on all results of such analyses should be made visible in the metadata for subsequent users.

Therefore, it seems that the requirements in the AI Act go deeper than what can be fulfilled by the current HealthDCAT-AP or QUANTUM requirements, and more in-depth information and analysis of data quality are needed to be able to state whether the data used meets the quality criteria. However, well documented metadata and data quality and utility label and reporting provide the necessary starting point for the AI model developers to start digging deeper to evaluate the data quality.

The Norwegian project demonstrated that the effectiveness of AI-assisted discovery depends heavily on the completeness, consistency and standardisation of metadata. The project found out in practice that metadata quality is a key factor in ensuring that generative AI can reliably suggest which variables could be used in a study from among the datasets described in the catalogue, based on the study description. The metadata needs to be well structured, standardised, all necessary information completed and regularly updated. A common problem is that the metadata has not been described with sufficient comprehensiveness or updated regularly. Harmonising variable descriptions that cover the similar content is also very important: if the descriptions are not created consistently, AI may not necessarily recognise the similarity and be able to suggest the needed variables.

Recommendations

- **Aim for detailed variable-level metadata:** Detailed and structured variable-level metadata, along with clear information on classifications and changes to them, is important. The variable-level metadata in the HealthDCAT-AP draft is not yet this detailed and the attention so far has been more in the dataset level metadata – it is important for the Nordic countries to continue developing their own solution and share the lessons learned also in the EU level.
- **Support for data holders:** To ensure sufficient metadata quality, Nordic countries are encouraged to develop metadata support for data holders that is as resource efficient as possible, while remaining comprehensive. Particular attention could be paid on supporting the variable level metadata work of datasets that are most frequently utilised for secondary use or otherwise assessed as key datasets. Especially if the goal is metadata harmonisation, a metadata expert familiar with the metadata of various organisations on a broader scale can offer valuable assistance, as opposed to a deep-level data expert who is skilled at describing precise details of specific dataset. It is advisable to share best practices and lessons learned among the Nordic countries, as well as any support approaches specific to particular data categories and use cases. It is important for the Nordic countries to fund metadata work sufficiently to create the conditions for providing adequate support.
- **Harmonised implementation of EHDS data quality and utility label and data quality reporting:** It is worth investing in the consistent implementation of the EHDS data quality

and utility label across the Nordic countries. Furthermore, it is important to share experiences and strive to find common methods for reporting data quality.

- **Collecting quality related user feedback:** It is recommended to explore enabling a direct customer feedback channel on the metadata and data quality from data users to data holders and HDABs, to enable the continuous development of dataset descriptions especially with regards to quality considerations. In this context, it is also important to share experiences and learn from the experiences of other Nordic countries. The possibility of publishing user feedback on data quality and utility alongside the dataset description should be explored, and potential European developments – such as the possible further development of the fit-for-purpose strategy developed in the QUANTUM project – should be monitored.
- **Examine ways to utilise AI to support the production of metadata:** It would be advisable to explore the possibilities of leveraging AI for supporting generating high-quality variable-level metadata.

The importance of Nordic cooperation

Nordic cooperation around metadata for secondary use of health data has been historically considered important among the national actors. Now, under the EHDS Regulation and the significantly increased requirements and expectations regarding metadata and data quality and utility reporting, such cooperation has become even more important.

The following are some of the identified achievements and future possibilities that would not be possible to achieve without collaboration:

- HealthDCAT-AP, including data quality and utility label, is not easy to understand and interpret. It would not be wise use of resources for the countries to think about implementation solely on their own. The metadata work presented in this report demonstrates concrete examples of the value of Nordic collaboration, in this case the joint interpretation and implementation of HealthDCAT-AP, in an increasingly harmonised way
- Many of the Nordic countries have extensive practical experience with health data catalogues. It is important to leverage this experience to have a constructive influence on the solutions being developed at the EU level. Working together on such efforts is more effective than countries acting individually. This influencing work has been carried out during the VALO projects, among other things, through discussions on the implementing acts on dataset descriptions and data quality and utility labelling, the exchange of national views, and the submission of joint feedback on the implementing act on dataset descriptions and the previous version of HealthDCAT-AP specification.
- Many countries have limited resources for metadata work, and under the EHDS the requirements for metadata catalogues increase significantly. National health data catalogues will need to contain new metadata elements, include data quality and utility labels, and describe a wider range of data categories. In addition, new types of data holders will need to be involved in the work related to metadata. It is valuable to discuss open questions and implementation plans together.



- The first Nordic Commons project established a vision of a common Nordic metadata catalogue. Consistent and harmonised implementation of the EHDS requirements across countries would enhance the feasibility of realising this vision in the future, provided it continues to be considered beneficial also in the EHDS era.

The VALO projects and this report account for several examples of initiated Nordic harmonisation such as developing of a common variable-level metadata specification draft version, aiming for creating possible enrichments of HealthDCAT-AP in the national catalogues in a harmonised way, aiming for implementing data quality and utility labelling in a harmonised way, as well as aiming for harmonised dataset definitions.

Metadata implications for the User Journey

As described in this chapter, metadata – created and used in a standardised manner – is a key prerequisite for making datasets searchable and findable in the User Journey (the Data discovery step, see chapters 3 and 7 as well as Annex 2). Accordingly, there are several steps prior to that (during Pre-discovery) where metadata can make a significant change: The health data holders must first understand their role as a health data holders in EHDS and be able to identify what data subject to EHDS Regulation they hold. Health data holders must provide adequate metadata for their datasets, which in turn must be clearly identified, scrutinised and up to date. The metadata must be of sufficiently high quality. Data holder must also provide the data quality and utility label for all publicly funded datasets.

In addition, the catalogue search features must be adequate, and guidance – as well as support for using the catalogues, if needed – must be available. These matters were not addressed in detail in this report, but sharing good practices related to them within the Nordic countries is important.

Annex 4b. HealthDCAT-AP pilot descriptions

This table compiles the dataset-level mandatory metadata properties mandated by the HealthDCAT-AP Release 7 and the implementing act on dataset descriptions (*Commission Implementing Regulation (EU) 2026/2098 of 18 September 2026 laying down the minimum metadata elements and their characteristics to be provided by health data holders for dataset descriptions for the secondary use of electronic health data under Article 77(4) of Regulation (EU) 2025/327 establishing the European Health Data Space*), their definitions, country-specific pilot descriptions, and questions raised during the joint review of the pilot descriptions. A draft version of the implementing act was used and later the information was verified to match the approved version.

HealthDCAT-AP Dataset property name	Property description in implementing act Art. 77	HealthDCAT-AP Dataset property definition (R7)	HealthDCAT-AP Dataset property usage note (R7)	DE Example description National cancer registry	FI Example description National cancer registry	FI Comments	IS Example description National cancer registry	IS Comments	NO Example description National cancer registry	NO Comments	SV Example description National cancer registry	SV Comments	Unclear / Questions
Title	Provides the official name or title of the dataset.	A name given to the Dataset.	Provide a title(s) for your Dataset, which can be repeated in multiple languages. Example: Healthy Brain Study - Physiological Data RDF example: dct:title	Cancerregisteret	Finnish Cancer Registry		The Icelandic Cancer Register		Kreftregisteret Kvalitetsregister for hjerne- og ryggmargssvulster	Title of the datasource and datacollection	National Cancer Register		Is the name of the country supposed to be added to the title? Or does it come automatically as an attribute from the class Catalogue?
Access rights	Describes the level of access applicable to the dataset (e.g. public,	Information that indicates whether the Dataset is publicly	This property allows you to indicate whether the dataset is publicly accessible, has restrictions,	NON_PUBLIC	Non-public	In our current catalogue: Data permit	Non-public	The dataset has access restrictions; access may be granted under specific conditions for scientific	https://lovdata.no/dokument/NL/lov/2014-06-20-43#KAPITTEL_3	We are going to adopt this property in the future.	Non-public		



	restricted or non public).	accessible, has access restrictions or is not public.	or is not publicly available. This is a mandatory property in HealthDCAT-AP. Use one of the following values :public, :restricted, :non-public, which means: NON_PUBLIC — The dataset is not publicly available and access is subject to restrictions. PUBLIC — The dataset is openly accessible to everyone. RESTRICTED — The dataset has access restrictions but may be available under specific conditions. RDF example: dct:accessRights					research purposes.	20-43#KAPITTEL_4 Non-public			
Applicable legislation	Identifies Union legal acts or national legislation	The legislation that mandates the creation	The ELI of the EHDS Regulation, published in March 2025, can now be	https://www.retsinformation.dk/eli/ta/2018/1049	http://data.europa.eu/eli/reg/2025/327/oj	In our current catalogue: Under secondary use act	The Icelandic Cancer Register <i>Krabbameinskrá Íslands</i>	Most probably the link to EHDS Regulation	https://lovdat.a.no/dokument/NL/lov/2014-06-20-43 https://lovdata.no/dokument	In the national specification, Lovverk and Forskrift	The Cancer Register is a health data register that is regulated by the Health	This needs clarification. What is the difference between Legal basis and



	n that specifically govern the establishment, maintenance or availability of the dataset, where such legal acts or legislation exists.	or management of the Dataset.	used as the applicable legislation where relevant: http://data.europa.eu/eli/reg/2025/327/oj . As multiple legislations may apply to the resource the maximum cardinality is not limited. RDF example: dcat:applicableLegislation				<i>fékk lagagrunn árið 2007 (lög nr 41/2007 og reglugerð nr 548/2008) og er hún því samkvæmt lögum ein af heilbrigðisskráum Landlæknis. Samkvæmt lögum um landlækni og lýðheilsu er tilgangur þess að halda heilbrigðisskrár m.a. sá að nýta gögnin til vísindarannsókna.</i>	will be given here.	ent/SF/forskrift/2001-12-21-1477	are defined as one or more URLs to relevant laws and regulations on lovdata.no that govern the dataset.	Data Register Act (1998:543) and associated regulation (2001:709). The National Board of Health and Welfare's regulation and general advice (HSLF-FS 2016:7), shows in more detail how the healthcare provider's obligation must be fulfilled.	Applicable legislation? Who is this information supposed to serve: the secondary user to know under which legislation the data can be applied for secondary use, or broader use? Does the link to legislation have to be in ELI format or can it be in some other format as well? What to do if national legislation doesn't have ELI?
Code values	Identifies classification systems or controlled vocabularies reflected in the content of the dataset (e.g. disease classifications, procedures classifications), where applicable.	A free- text description of any health classification, terminology, ontology, thesaurus, or coding system used in the dataset.	Use this field to describe, in free text, the code values of the coding systems used that apply to the dataset (e.g. U07.1, Y59.0). No controlled vocabulary is required at this stage. RDF example: healthdcat:hasCodeValues	---	IDC-10: Malignant tumours (C00-C96), Other tumours (D00-D48 and D76), Others (N85, N87, N89- N90).	It is unclear how this HealthDCA T-AP property will actually be utilized.	<i>ICD-10 topography codes: C00– C97 (malignant neoplasms), D00–D09 (carcinoma in situ), D22, D32–D35, D42–D44, D45–D47 (benign and uncertain behaviour neoplasms of CNS, endocrine and haematopoietic tissue); ICD-O-3 topography codes (e.g. C50.9 breast,</i>	Krabbamei nsskráningin er í samræmi við leiðbeiningar Evrópusamtaka krabbameinsskráa (European Network of Cancer Registries, ENCR). Skráð er samkvæmt alþjóðlegri sjúkdómaflokkun (International Classification of	«2» og «Kvinne».		Relevant code values from the coding system listed in Coding System	Is this supposed to be used to reflect the data content (annotation with keywords, like the implementing act definition implies) or the actual code values found in the data? Isn't the connection to the coding system supposed to be mentioned as well - without it user cannot understand which code list do the values belong to? Where do you



							C61.9 prostate); ICD-O-3 morphology codes (e.g. 8500/3 infiltrating duct carcinoma, 9732/3 multiple myeloma); Basis of diagnosis codes: 0 (death certificate only), 1 (clinical), 2 (investigation without histology), 4 (biochemical) , 5 (cytology), 6 (histology of metastasis), 7 (histology of primary tumour); Laterality codes: 0 (not paired organ), 1 (right), 2 (left), 4 (bilateral), 9 (unknown); Sex codes: 1 (male/boy), 2 (female/girl), 7 (non- binary/child); Tumour number codes: 10 (first malignant), 20 (second	Disease, ICD) og ICD-O (Internation al Classificatio n of Diseases for Oncology).					draw the line, how in depth should it be? What use case is this information supposed to serve? It should be connected to the Coding system property, is there a plan for developing that?
--	--	--	--	--	--	--	---	--	--	--	--	--	--



							malignant), 00 (first benign), 07 (diagnosed abroad)						
Codi ng syst em	Identifies standardi sed coding schemes used to encode data elements within the dataset (e.g. ICD 10 CM, SNOME D CT, DRGs), where applicabl e.	Coding systems in use (ex: ICD-10- CM, DGRs, SNOME D=CT).	This property allows you to specify the coding systems used within your dataset. For example, if a dataset uses ICD-10 for disease classification, this property allows data users to search for datasets with the same coding system. As a machine- actionable property, it also facilitates automated processes, making dataset discovery more efficient. Specify the standardised coding systems used in the dataset (e.g. ICD-10- CM, SNOMED- CT). The coding systems controlled	—	International Classification of Diseases, 10th Revision (ICD-10) International Classification of Diseases for Oncology, 3rd Edition (IDC-O-3)		ICD-10, ICD- 03 <i>ICD-10 (International Classification of Diseases, 10th Revision) — for tumour topography and cause of death; ICD- O-3 (International Classification of Diseases for Oncology, 3rd Edition) — for tumour topography (ksicd0) and morphology (ksmeingerd/f smeingerd); Multiple ICD versions historically: ICD-7, ICD-8, ICD-9, ICD- 10 (tracked per record in fsdanorsicdke rfi)</i>		ICD-10 codes referenced in descriptions (e.g. C50, C34)		ICD-7, ICD-9, ICD-O/2, ICD-O/3, UICC TNM, TOPO, PAD/C24.1/hi st SHOULD BE FROM CT ONLY: ICD-O-3	https://hde u- dcat. acce ptanc e.dat a.hea lth.eu ropa. eu/re sourc e/aut hority /codi ng- syste m/	General comment to all vocabularies: We need to have these vocabularies as human readable lists. Now we have been using the Dataset Description Assistant to pick the values from the vocabularies. How to indicate if the national coding system used is not identical to the source coding system? Should the source coding system be then selected or not? NOTE: Not all coding systems listed in the pilot descriptions are yet included in the HealthDCAT-AP vocabulary.



			vocabulary (https://hdeu-dcat.acceptance.data.health.europa.eu/resource/authority/coding-system/) MUST be used. RDF example: healthdcatap:hasCodingSystem										
Contact point	Provides contact details for enquiries related to the dataset.	Contact information that can be used for sending comments about the Dataset.	This property informs about a contact point (Individual, Organization, Location, Group) that can answer questions about the dataset. Details on how to describe these are provided under class vcard:Kind. RDF example: dcat:contactPoint	https://sundhedsdatastyrelsen.dk	Contact Page: https://cancerregistry.fi/information/contacts/ Email: kirjaamo@cancer.fi	Currently in the Finnish catalogue: Elli Hirvonen, Contact person, phone and email. We have currently guided to use (at) instead of @ in the email addresses in the Finnish catalogue, but the Dataset Description Assistant doesn't allow this format.	mottaka@landlaeknir.is		krg.data@fhi.no		cancerregistret@socialstyrelsen.se		
Conforms to	Identifies a standard or technical	An established standard to which	If your data conforms to an established standard or	—						Could be considered in the future	NA		Opportunity to select Non applicable has to be added to the vocabulary.



	specification that defines the structural or syntactic organisation of the dataset as a whole.	the described resource conforms.	specification, use this property to indicate which one. The Health Standards controlled vocabulary (https://hdeu-dcat.acceptance.data.health.europa.eu/resource/authority/standard/) MUST be used. RDF example: <code>dct:conforms To</code>										
Custodian	Identifies the organisation responsible for holding, managing and maintaining the dataset over time (health data holder).	Party that accepts accountability and responsibility for the data and ensures appropriate care and maintenance of the resource [ISO-19115].	Use this property to identify the entity that technically holds and maintains the dataset. In the EHDS context, this field represents the legally defined health data holder, (Article 2(6) EHDS Regulation), i.e. the entity responsible for holding and maintaining the dataset. This entity may differ from the	—	Name: Finnish Institute for Health and Welfare (THL) Type: Public health institute Contact Page: https://thl.fi/en/front-page Email: kirjaamo@thl.fi		Icelandic Cancer Society (Krábbamein sfélag Íslands) — legally responsible for maintaining and managing the registry on behalf of the Directorate of Health (Embætti landlæknis)		Norwegian Institute of Public Health		The Swedish National Board of Health and Welfare		



			publisher. RDF example: geodcatap:cu stodian										
Desc ription	Provides a free text summary describin g the content and purpose of the dataset.	A free- text informati on about the Dataset.	Brief description of the dataset. This property can be repeated for including several language versions of the description. RDF example: dct:description	Cancerregist eret indeholder oplysninger om danske cancerpatient er. Registeret er et incidentsregist er, dvs. at det alene indeholder oplysninger om nye tilfælde af cancer. Cancerregist eret rummer bl.a. oplysninger om: diagnosetidsp unktet for sygdommen, den anatomiske lokalisering, hvilken type kræft det er (histologi), udbredelse af sygdommen og hvordan diagnosen er stillet. Indberetnin g til Cancerregist eret skete på frivillig basis frem til marts 1987,	The Cancer Registry stores information necessary for the Finnish Institute for Health and Welfare (THL) to perform its statutory tasks in terms of the incidence of cancer, prevention, early detection, treatment and medical rehabilitation, and the use of services. Data are collected for statistical and scientific research purposes. Registration of cancers began nationwide in 1953. Since 1961, the submission of cancer reports has been mandatory. The Mass		The Icelandic Cancer Register is a nationwide health registry that systematicall y collects data on all cancer diagnoses in Iceland. It is overseen by the Directorate of Health and operated by the Icelandic Cancer Association. Established with electronic records dating back to 1955, the register's primary purpose is to support healthcare quality control and enable scientific and epidemiologic al research. It compiles data from hospitals, healthcare practitioners, laboratories,	Skráin nær til meir en 99% allra meina sem greinast hjá þjóðinni og er í flokki bestu krabbamein sskráa heims ásamt öðrum Norrænum skráum.	Norwegian Registry of Brain and Spinal Cord Tumors contains variables specific for diagnostics, treatment and follow-up of brain- and spinal cord tumors. The information comes from multiple sources, see information about the Cancer Registry.		The national cancer registry is an incidence based registry that contains information about diagnosed primary tumors. The registry contains information about all malign tumors and a subset of the benign tumors and tumor like conditions.		

[illegible]



				digitale løsninger og forbedrede datainfrastrukturer. In Fra og med årgang 2023 er datastrukturen på Cancerregisteret blevet ændret - læs mere om dette under 'Hovedprincip i datastrukturen'.	cancer screening registries are maintained. Data on the target population of national mass screenings are registered in these mass screening registers. Data is collected from screening invitations and examinations throughout the country.		care in Iceland.						
Distribution	Provides a technical representation or format in which the dataset is made available for secondary use.	An available Distribution for the Dataset.	For Health DCAT Application Profile a distribution is mandatory independently of the access rights. A distribution must include information on the Health Data Access Body supporting data access. RDF example: dcat:distribution	—	Access URL: https://findata.fi/en/ Applicable Legislation: http://data.europa.eu/eli/reg/2025/327/oj	It is unclear how this HealthDCAT-AP property will actually be utilized.	Restricted access; applications submitted to the Directorate of Health	Publicly available cancer statistics from the Icelandic Cancer Register can be freely accessed and reused with proper citation, while customized statistical queries may incur a fee. Publication of data in media requires prior contact with the registry. Access to		To be implemented, could be considered in the future	HDAB-SE	Access to data is conditional on the issuance of a permit by the HDAB after submission of a data request application	Is this supposed to describe the technical format of the data that will be given for secondary use, or only point out to the HDAB website? The data can be given out in many different formats so should all of them be described? It is up to agreement between data holder and user in which format the data is given. Why do we have need to have a distribution to point to HDAB if there already is



								identifiable data for research purposes requires a formal application to the Directorate of Health, including supporting documents and a specified list of requested variables.					another property for that?
Geographical coverage	Indicates the geographic area to which the dataset relates (e.g. Member State, region or EU wide), where applicable.	A geographic region that is covered by the Dataset.	The EU Vocabularies Name Authority Lists MAY be used for continents, countries and places that are in those lists; if a particular location is not in one of the mentioned Named Authority Lists, Geonames URIs MAY be used. RDF example: dct:spatial	DENMARK	Finland	Currently in the Finnish catalogue: National.	Iceland	<i>National coverage</i> <i>Certain data on all cancers diagnosed in Iceland since 1955. Skráin nær til meir en 99% allra meina sem greinast hjá þjóðinni og er í flokki bestu krabbameinsskráa heims ásamt öðrum Norrænum skráum.</i>	Norge		Sweden		



Personal data / Has personal data	Indicates whether the dataset contains personal data within the meaning of Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament and of the Council ² .	Key elements that represent an individual in the dataset, Indicate association with Personal Data.	This property is used to indicate the types of personal data contained in the dataset itself (i.e. the actual data, not the metadata record). The Data Privacy Vocabulary for Personal Data at https://w3id.org/dpv/dpv-pd MUST be used for this property. Examples of allowed values include: Gender → https://w3id.org/dpv/dpv-pd#Gender Age → https://w3id.org/dpv/dpv-pd#Age RDF example: dpv:hasPersonalData	—	Gender, Identifier, Birth Date, Age, Medical Health	It is unclear how this HealthDCA T-AP property will actually be utilized. Not all of the desired terms were found in the vocabulary.	Yes	PIN, Birth year, Gender, residence when diagnosed, diagnosis date, tumour site, morphology, basis of diagnosis, pathology results, causes of death, referring physician speciality, treating physician speciality (these type of terms would be needed to be found in the vocabulary)	1 = Direkte personidentifiserbare opplysninger		Gender, Age, Medical Health, Marital Status, Name, Region, Locality, Birth Date, PIN Code	It is still unclear whether this will be yes/no or to indicate more in depth types of personal data. We expect clarification on this in the next HealthDCAT-AP release. If the vocabulary is adopted, it needs to be further developed to better suit health data.
Health data access body	The competent health data access body responsible for facilitating	Health Data Access Body supporting access to data in the	Member state-designated authority that facilitates the secondary use of electronic health data.	Sundhedsdatastyrelsen	Health Data Access Body Name: Findata - Finnish Social and Health Data Permit Authority					To be implemented	Health Data Access Body Sweden (healthdcatap:hdab-se)	How to provide multiple HDABs, if there are multiple in the country? Currently it looks like only one can be provided.



	g access to the dataset under the European Health Data Space, where the dataset is subject to restricted or non public access.	Member State.	HDABs assess the information provided by the health data applicant and decide on health data requests and access applications, authorise and issue data permits, obtain data from data holders and make data available in Secure Processing Environments . HDABs systematically track the data request and data access applications received and the data permits issued. As per Article 58 of the EHDS, HDABs are required to publicly list information on the data permits issued. (Article 55; Recital 52 of EHDS Regulation). RDF example:		Health Data Access Body Type: Government and Public Sector Organizations Health Data Access Body Contact Page: https://findata.fi/en/ Email: info@findata.fi								
--	--	---------------	--	--	---	--	--	--	--	--	--	--	--



			healthdcatap: hdab										
Health category / Health data category	Identifies the categories of electronic health data contained in the dataset and listed in Article 51(1) of Regulation (EU) 2025/327.	The health category to which this dataset belongs as described in the Commission Regulation on the European Health Data Space laying down a list of categories of electronic data for secondary use, Art.51.	This property indicates the EHDS data category the dataset belongs to, based on Article 51 (https://eur-lex.europa.eu/legal-content/EN/XT/HTML/?uri=OJ:L_20250327#ntr35-L_202500327-EN.000101-E0035) of the EHDS Regulation. Use the controlled vocabulary http://13.81.34.152:1101/resource/authority/healthcategories/ to ensure standardised classification across all datasets RDF example: healthdcatap:healthCategory	PHDR, EINS, EHRS	Data from population-based health data registries such as public health registries		K Data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person			To be implemented	Data from population-based health data registries such as public health registries (k, PHDR) (alternatively, also Data from medical registries and mortality registries)	Also quality registries involved in the registry.	Interpretation of this property is important to be harmonised between countries.
Health theme	Indicates a high level health topic or theme associated with the	A category of the Dataset or tag describing the Dataset.	A dataset may be associated with multiple health themes. The Health Theme	CANCER_DISEASE	Cancer		Cancer		Kreft, forskning, analyse, kvalitetssikring av helsetjenesten, styring, råd	To be implemented	Cancer		



	dataset (e.g. cardiovascular disease, cancer).		controlled vocabulary (http://13.81.34.152:1101/resource/authority/health-theme) MUST be used. RDF example: healthdcatap: healthTheme						og veiledning om helsehjelp				
Identifier	Provides a unique and persistent identifier for the dataset (e.g. uniform resource identifier (URI), digital object identifier (DOI) or catalogue identifier).	The main identifier for the Dataset, e.g. the URI or other unique identifier in the context of the Catalogue.	For Health DCAT Application Profile the identifier is mandatory and its value must be unique from the origin database of the Dataset. In the process of dataset transmission to the next database, the 'identifier' property is overwritten by the new database identifier, and the original identifier becomes the value of the 'other identifier' property. RDF example: dct:identifier	CAR	https://urn.fi/URN:NBN:fi:thl:ak:21085403-7be8-4f93-bf05-231518c642a0				K_KREG.CNS	To be clarified and implemented	URI	We do not have an identifier as of yet. When a catalogue is built, this shall be presented. NBH W uses OIDs for classifications and terminologies, but have not given their	



												data unique identi fiers.	
Stru ctur ed data / Is stru ctur ed	Indicates whether the dataset is structured, meaning that it is organised according to a predefined schema or model that defines its variables, attributes or fields.	Indicates whether the Dataset contains structured data for which a machine-readable description of the data variables can be provided.	Use this boolean property to state whether the dataset contains structured data. Set it to true when a machine-readable description of the data variables can be published, and to false when such structured variables do not apply. When the value is true, at least one healthdatacatap: hasVariables should be provided.	—	Yes		Yes	The dataset is structured according to a predefined schema		To be clarified and implemented, however we are not in favour of unstructured metadata/dataset	True		
Key word	Provides keywords or tags describing the dataset and supporting search and discovery.	A keyword or tag describing the Dataset.	Add keywords to increase dataset discoverability. You can include keywords in different languages, submitting each keyword as a separate entry. Example: Physiological	"Kræft", "Cancer", "Neoplasi", "Neoplasmer", "Onkologi", "Tumor", "Malignitet", "Histologi", "TNM"	cancer, cancerous diseases, registers, screening, mass screening, breast cancer, cervical cancer, colorectal cancer, prevention, national					To be clarified and implemented	Cancer, Tumour, Malignancy, TNM , Pathology, Morfology, Topology, Tumor Stage, Cancer Incidence		



			measures, Heart Rate, Stress Measures. RDF example: dcat:keyword		cancer registry								
Language	Indicates the language or languages in which the dataset content is expressed.	A language of the Dataset.	For this property the values from the EU Vocabularies Languages Named Authority List must be used. If your Dataset contains multiple languages, this property can be repeated. RDF example: dct:language	—	FIN, SWE		Icelandic			To be implemented	Swedish		



Number of records	Indicates the total number of records contained in the dataset, where applicable.	Size of the dataset in terms of the number of records.	Use this property to indicate the total number of records in the dataset, giving users an idea of the dataset's size and whether it suits their analysis or research needs. You can provide the exact count or an approximate average if the exact figure is unavailable. It reflects the total data entries (e.g., consultations, prescriptions, lab results, hospital admissions) according to the dataset's content. RDF example: healthcatap: numberOfRecords	(no metadata provided by data holder)	1 700 000	Information found that there would be roughly 1,7 million registered cancer cases. It is possibly not the same as number of records. The Dataset Description Assistant currently only accepts numbers.				To be implemented	4,927,237 (2024)		What timepoint does this refer to? If we update metadata every year, is this pointing to the latest year? Where does the user see which year this is pointing to?
Number of unique individuals	Provides an estimate of number of unique natural persons represented in the dataset, where the	Number of records for unique individuals.	Use this property to indicate the number of unique individuals represented in the dataset. It helps users understand the dataset's	(no metadata provided by the data holder)	3600000	Information found by Googling: The Finnish Cancer Registry and Mass Screening Registers do not disclose a single,				To be implemented	3,242,090 (2024)		The observation unit needs to be defined as well. It can be different, not necessarily individuals, for example periods of data collection.



	dataset contains personal data and where applicable.		scale and assess whether it meets their needs for secondary use. Provide the total or an approximate count of distinct individuals whose data is included. RDF example: healthcatap: numberOfUniqueIndividuals			static aggregate of all historical unique individuals, as this number is constantly expanding. However, over 3.6 million unique individuals have been registered since 1953, with over 334,000 living Finns previously diagnosed with cancer still on the active roster.						
Provenance	Describe the origin, source or creation process of the dataset.	A statement about the lineage of a Dataset.	Information about how the data was collected, including methodologies, tools, and protocols used, this property can be repeated for different versions of the provenance (e.g. the provenance in different languages). RDF example:	Indsamling af oplysninger til Cancerregisteret sker i henhold til "Bekendtgørelse om lægers anmeldelse til Cancerregisteret af kræftsygdom m.v.". Indberetninger er til og med 2003 foretaget på papirblanket. Fra 2004 er indberetningen fra sygehuse	Regular sources of information in the register: -Healthcare organizations - Municipal data on cancer patients and data on emigration and immigration are obtained from the Population Information System of the Digital and Population		<i>Data originate from three source tables within the registry:</i> (1) <i>kskra_kjarnskra (core registry) — primary tumour data including ICD-10/ICD-O-3 codes, diagnosis date, age, laterality, basis of diagnosis;</i> (2) <i>kskra_frumskra (source/notifi</i>	Upplýsingar til Krabbameinsskrár berast frá rannsóknarstofum í meinafræði og blóðmeinafræði, sjúkradeildum, heilsugæslustöðvum, einstökum læknum og læknaðstofum. Upplýsingar berast að jafnaði	Kreftregistrið fær rapportert og hentar inn opplýsingar frá ulike kilder: kliniske meldinger, patologisvar og kliniske systemer (stråle, medikamente og behandling), samt fra andre registre (NPR, DÅR, Folkeregisteret). Noe data kodes og registreres		Healthcare providers regularly send data about newly diagnosed tumours to the 6 regional cancer centres for coding and registration and after quality control these data are forwarded yearly to National Board of Health and Welfare.	It might be interpreted in many different ways what the level of detail should be. Important to be harmonised.



			dct:provenance	sket gennem Landspatientsregisteret og for primærsektoren gennem Sundhedsdatastyrelsens elektroniske indberetnings system (SEI) fra 2005. \nTil og med 2003 blev alle informationer kodet manuelt af koderne. Fra 2004 sker den primære databehandling af alle oplysninger med relevans eller mulig relevans for Cancerregisteret i den "automatiserede cancerlogik". Denne logik sammenholder nye oplysninger i Landspatientsregisteret og Landsregisteret for Patologi med eksisterende oplysninger i Cancerregisteret og foretager derved den initiale vurdering af, om de nye	Data Services Agency. - The monitoring data of the Mass Screening Register and the data of the target population for mass screenings are also obtained from the Population Information System of the Digital and Population Data Services Agency. - Data on socioeconomic status, occupation and education, as well as data on causes of death, are available from Statistics Finland.		cation registry) — pathology and cytology lab reports, referring institution, physician, autopsy data, morphology, cause of death; (3) kskra_nafnas kra_safn (name/population register linkage) — personal identifier, date of death, linked via Þjóðskrá Íslands (National Population Register). Mandatory notifications are submitted by hospitals, pathology laboratories, and haematology units across Iceland. Death certificate linkage is performed via the death cause register of the Directorate of Health (Embætti landlæknis). The registry follows ENCR	innan tveggja mánaða frá greiningu. Upplýsingar um mein þar sem ekki liggur fyrir meinafræði greining koma til viðbótar úr Dánarmein askrá og Vistunarskrá á heilbrigðisstofnana. Tölfræði krabbameina á ársgrundvelli er birt á heimasíðu Krabbameinsfélagsins www.krabb.is	manuelt, noe importeres fra kildene				
--	--	--	----------------	--	---	--	---	---	-------------------------------------	--	--	--	--



				oplysninger enten skal føre til en ny sygdom i Cancerregistret, om oplysninger skal supplere en eksisterende anmeldt kræftsygdom, eller om oplysningerne ikke tilfører noget nyt. Efter den automatiserede databehandling foretages en manuel vurdering og databehandling i 10 - 20 pct. af tilfældene. Dette kan i nogle tilfælde medføre, at koderne fra Cancerregistret er nødt til at gå tilbage til indberetteren for at få verificeret sygdommen.				<i>data collection and quality assurance standards. Electronic data available from 1955; benign CNS and haematopoietic tumours recorded from 2003 onwards for some categories.</i>					
--	--	--	--	--	--	--	--	--	--	--	--	--	--

[illegible]

[illegible]



				n blive kørt om for de konkrete tilfælde, således at Cancerregistret baseres på de korrekte oplysninger. \nI det moderniserede Cancerregister fra 2004 inddrages yderligere en kilde i forhold til tidligere – patologisk-anatomiske diagnoser (SNOMED-patologi) fra Landsregisteret for Patologi.									
Publisher	Indicates the entity making the dataset available, which may differ from the creator or custodian.	An entity (organisation) responsible for making the Dataset available.	Use this property to identify the agent that publishes the dataset description in the catalogue. In the EHDS context, this may be the data holder or another organisation such as an intermediary entity. RDF example: dct:publisher	Sundhedsdatastyrelsen	Publisher Name: The Finnish Cancer Society Publisher Type: Public health registry Publisher Contact Page: https://cancerregistry.fi/ Publisher Email: kirjaamo@cancer.fi	THL is the registrar of the Cancer Registry. The Finnish Cancer Society is the technical administrator of the Cancer Registry and the processor of personal data, and has also made the metadata description in our				To be implemented	The Swedish National Board of Health and Welfare		



						current catalogue.							
Temporal coverage	Indicates the time period covered by the dataset (e.g. years of data collection), where temporal information exists.	A temporal period that the Dataset covers.	The start and end date of the period that the dataset covers. This property makes use of a Period of Time class. This property makes use of the class dct:PeriodOfTime (more details on PeriodOfTime class tab). The start and end of the interval SHOULD be given by using properties dcat:startDate or time:hasBeginning, and dcat:endDate or time:hasEnd, respectively. RDF example: dct:temporal	1.1.1943-00	1.1.1953-		Start date: 1911-01-01 (breast cancer records); 1955-01-01 (all other tumour types, electronic records). End date: ongoing — registry updated daily. Note: some tumour categories (e.g. myelodysplastic syndromes D45-D47, MGUS D47.2) have later start dates for electronic registration (from 1999–2003).	Only one temporal coverage can be given currently in HealthDCA T-AP.	Opprettet 2019	To be clarified and implemented. It is not really fitting our metadata management praxis.	1958–		
Type	Indicates the general category or nature of the dataset (e.g. registry, administrative)	A type of the Dataset.	A Dataset may be associated with multiple types. The EU Dataset-type controlled vocabulary (http://publica	HVD	Registry (but currently in the Dataset Description Assistant: Statistical data)	The current vocabulary in the Dataset description assistant is not usable and is not in line with the	Register			To be implemented	Register or Statistical		We are expecting the vocabulary to be developed to be more in line with the definition in the implementing act.



	active dataset, research dataset, synthetic dataset).		tions.europa.eu/resource/authority/dataset-type) SHOULD be used. RDF example: dct:type			description in the implementing act draft.							
Variables	A structured description of the variables contained in the dataset, including, where applicable, the variable name, definition, data type, coding system or value domain.	Links the Dataset to a CSVW TableGroup that provides a machine-readable description of the data variables.	Use this property to link a structured dataset to a CSVW TableGroup that documents its data variables, columns, or fields in a machine-readable way. This property becomes mandatory when healthdcatap:hasStructuredData is true. RDF example: healthdcatap:hasVariables	Table title: Cancergrupperring_ICD10 Table keyword: - Variable title: Cancer_diag_grp_ICD10 Variable description: ICD10 - diagnosegrupperring - undergrupper Variable datatype: char (3)	For example: Table URL: https://aineistokatalogi.fi/catalog/studies/21085403-7be8-4f93-bf05-231518c642a0/datasets/ca8a40b0-1e54-447f-9bd2-70cfe82296f4 Table Title: Basic variables Table Keyword: cancer registry, basic variables Column Name: dg_date Column Title: Date of diagnosis Column Description: Date of cancer diagnosis. Column Datatype: date Column Property URL: -		Variables in the Icelandic Cancer Registry (source: Krabbameinskrá breytulisti, February 2023): PATIENT-LEVEL VARIABLES: • kennitala — National ID (pseudonymised research number; source: kskra_nafnas kra_safn) • fæðingarár — Year of birth • kyn — Sex per national register: 1=male/boy, 2=female/girl, 7=non-binary/child (from 2009; source: kskra_nafnskra) • kssveitarfelag — Residence		Dato for robotassistert kirurgi.	We have more advanced use of variable and we expect more converge with HealthDCA T-AP in the future.	name (variabeletikett), definition (variabelbeskrivning), datatype (datatype), coding system (*see comment below. ICD-7, ICD-9, ICD-O/2, ICD-O/3, UICC TNM, TOPO, PAD/C24.1/hist), value domain (värdeområde) *NB: The disease classification is presented alongside the individual variables (e.g. variable name "ICD7") and the coding system is described in the related value domain (värdeområde)	https://www.socialstyrelsen.se/gl-obalanssets/sharepoint/dokument/ment-webbstatistik/register-variabelfor-teknisk-cancerregistret.xlsx	How to interpret the table attributes? What should the table refer to more specifically?



						at diagnosis (health region/municipality; from 2009; note: poorly recorded for benign tumours 1955–2003; source: kskra_kjarnskra) • danardagur — Date of death (delivered as month and year; from 2009; source: kskra_nafnasakra_safn) TUMOUR-LEVEL VARIABLES (CORE REGISTRY — kskra_kjarnskra): • ksdagsfyrstuf aerslu — Date of diagnosis (dd.mm.yyyy; from 2009) • ksnraexlis — Tumour number: 10=first malignant, 20=second malignant, 00=first benign, 07=diagnose						
--	--	--	--	--	--	---	--	--	--	--	--	--



						d abroad, A1/A2=diagn osed before 1955 • ksgral — Age at diagnosis (integer) • ksicd10 — Tumour topography (ICD-10; from 2009) • ksicd0 — Tumour topography (ICD-O-3; from 2009) • kshlid — Laterality: 0=not paired organ, 1=right, 2=left, 4=bilateral, 9=unknown (from 2009) • ksnagr — Basis of diagnosis: 0=death certificate only, 1=clinical, 2=investigatio n without histology, 4=biochemica l, 5=cytology, 6=histology of metastasis, 7=histology of primary tumour (from 2009) • ksmeingerd — Tumour morphology (ICD-O-3;					
--	--	--	--	--	--	---	--	--	--	--	--



							from 2009) NOTIFICATION/PATHOLOGY VARIABLES (kskra_fruitskra): • fssendstofnun — Reporting healthcare institution (text; from 2009) • fssendlaeknir — Referring physician (delivered as medical specialty; from 2009) • fssendnrlaeknis — Treating physician registration number (delivered as specialty; source: professional licence register) • fsdagskomu — Date of sample receipt at laboratory (dd.mm.yyyy; from 2009) • fsrannst — Laboratory performing the diagnosis						
--	--	--	--	--	--	--	---	--	--	--	--	--	--



						(from 2009) • fsgkr — Diagnosed at autopsy: 0=no, 1=yes (from 2009) • fsnrpad — Pathology and/or autopsy number (from 2009) • fsnraexlis — Tumour number (notification-level; from 2009) • fsicd10 / fsicd0 — Tumour topography ICD-10 / ICD-O-3 (notification level; from 2009) • fshlid — Laterality (notification level; from 2009) • fsnagr — Basis of diagnosis (notification level; from 2009) • fsmeingerd — Tumour morphology ICD-O-3 (notification level; from 2009) • fsdanorsicd — Underlying cause of death per						
--	--	--	--	--	--	--	--	--	--	--	--	--



							death certificate (ICD code; from 2009) • fsdanorsicdke rfi — ICD version used for cause of death coding: ICD-7, ICD-8, ICD-9, or ICD-10 (from 2009) ICD-10 TOPOGRAPHY SCOPE: C00–C97 (malignant), D00–D09 (in situ), D22, D32–D35, D42–D44, D45–D47 (benign/uncertain CNS, endocrine, haematopoietic)						
Was generated by	Identifies the activity or process through which the dataset was generated (e.g. registry, clinical study, administrative process).	An activity that generated, or provides the business context for, the creation of the dataset.	The activity associated with generation of a dataset. The Health activity controlled vocabulary (https://hdeu-dcat.acceptance.data.health.europa.eu/resource/authority/health-activity) MUST be used.	—	Registry (but currently in the Dataset Description Assistant: National Health Registries)	The current vocabulary in the Dataset description assistant seems not to be in line with the description in the implementing act draft.	Population-based cancer registration process established in 1955 (breast cancer from 1911) under the Icelandic Cancer Society. Mandatory notifications submitted by hospitals, pathology laboratories (vefjagreining)	Upplýsingar til Krabbameinsskrár berast frá rannsóknarstofum í meinafræði og blóðmeinafræði, sjúkradeildum, heilsugæslustöðvum, einstökum læknum og læknaðstofu		We expect more convergence with HealthDATA-AP in the future.	HOSPITAL_RECORDS, OBSERVATIONAL_DATA		We are expecting the vocabulary to be further developed.



			RDF example: prov:wasGen eratedBy				/histology, frumugreining (cytology), and haematology units across Iceland. Death certificate linkage via the death cause register of the Directorate of Health. Population register linkage via Þjóðskrá Íslands (National Population Register). Registry updated daily. Data consolidation across three internal source tables: core registry (kskra_kjarns kra), notification registry (kskra_frums kra), and population linkage (kskra_nafna skra_safn).	m. Upplýsingar berast að jafnaði innan tveggja mánaða frá greiningu. Upplýsingar um mein þar sem ekki liggur fyrir meinafræði greining koma til viðbótar úr Dánarmein askrá og Vistunarskr á heilbrigðisst ofnana. Tölfræði krabbamein a á ársgrundvel li er birt á heimasíðu Krabbamei nsfélagsins www.krabb. is							
The me		A category of the Dataset.	A Dataset may be associated with multiple themes. The EU data- theme	https://www.retsinformation.dk/eli/ta/2018/1049 HEAL	Health		Health			To be clarified and implemente d	HEAL				

[illegible]

Annex 4c. Nordic health data landscape analysis tables

The following tables contain a preliminary compilation of example datasets that the metadata experts involved in the VALO2 project have suggested to belong to different EHDS Art. 51 data categories. The suggestions do not represent the official position of the countries. This compilation should be viewed as preliminary, and work to identify examples should continue.

Disclaimer: This mapping is illustrative only and does not constitute a determination that any listed organisation is, or is not, a health data holder under Regulation (EU) 2025/327. Each organisation remains responsible for assessing its status and compliance obligations for each dataset and processing context, including whether it acts as a controller or joint controller for personal electronic health data under Articles 2(1)(a) and 2(2)(t), whether it controls the availability of non-personal electronic health data, and the controllership rules in Article 74. Natural persons and microenterprises are exempt from the Chapter IV health data holder obligations under Article 50(1), unless a Member State extends those obligations pursuant to Article 50(2). Final national legislation, implementing acts, contractual arrangements and actual processing roles may affect the assessment.

Denmark

Minimum categories of electronic health data for secondary use (EHDS Art. 51):

- (a) electronic health data from EHRs;
- (b) data on factors impacting on health, including socioeconomic, environmental and behavioural determinants of health;
- (c) aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;
- (d) data on pathogens that impact human health;
- (e) healthcare-related administrative data, including on dispensations, reimbursement claims and reimbursements;
- (f) human genetic, epigenomic and genomic data;
- (g) other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data;
- (h) personal electronic health data automatically generated through medical devices;
- (i) data from wellness applications;
- (j) data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person;
- (k) data from population-based health data registries such as public health registries;
- (l) data from medical registries and mortality registries;
- (m) data from clinical trials, clinical studies, clinical investigations and performance studies subject to Regulation (EU) No 536/2014, Regulation (EU) 2024/1938 of the European Parliament and of the Council (35), Regulation (EU) 2017/745 and Regulation (EU) 2017/746;
- (n) other health data from medical devices;
- (o) data from registries for medicinal products and medical devices;
- (p) data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results;
- (q) health data from biobanks and associated databases.



Publi sher type group	Data holder	Original data source name (ENG)	Original Data source name (national language)	Dataset name (ENG): candidate as entry in nHDC	Po ss ibl e su b- da ta se ts	Comments	Link to further information/metadata	Ques tions/ uncle ar	N A Pr ob ab ly no t in cl ud ed in E H D S	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
Nation al author ity	Sundheds datastyrels en	Danish Patient Registry	Landspati entregistre ret	Danish Patient Registry		This registry will be published in the Danish metadata Catalog with metadata on registry, table and variable level	https://sundhedsdatabank.dk/behandling-og-pleje/ventetid https://sundhedsdatabank.dk/behandling-og-pleje/udredningsret https://sundhedsdatabank.dk/behandling-og-pleje/sygehus													X						
Nation al author ity	Sundheds datastyrels en	Danish Cancer Registry	Cancerre gisteret	Danish Cancer Registry		This registry will be published in the Danish metadata Catalog with metadata on registry, table and variable level	Kræft - Sundhedsdatabanken													X						
Nation al author ity	Sundheds datastyrels en	The Cause of Death Register	Dødsårså gsregister et	The Cause of Death Register		This registry will be published in the Danish metadata Catalog with metadata on registry, table and variable level	Livets afslutning - Sundhedsdatabanken														X					
Nation al author ity	Sundheds datastyrels en	The Clinical Laboratory Information Register	Laboratori edatabas en	The Clinical Laboratory Information Register		This registry will be published in the Danish metadata Catalog with metadata on registry, table and variable level	Findes ikke endnu																			X
Public health institut e	Statens Serum Institut	The Danish Vaccination Registry	Det Danske Vaccinati onsregist er	The Danish Vaccination Registry		This registry will be published in the Danish metadata Catalog with metadata on registry, table and variable level	Tilgængelige data													X						
Public health institut e	Statens Serum Institut	Covid-19 Test Responses	Covid-19 testsvar	Covid-19 Test Responses		This registry will be published in the Danish metadata Catalog with metadata on registry, table and variable level	Tilgængelige data													X						

[illegible]

Finland

Minimum categories of electronic health data for secondary use (EHDS Art. 51):

- (a) electronic health data from EHRs;
- (b) data on factors impacting on health, including socioeconomic, environmental and behavioural determinants of health;
- (c) aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;
- (d) data on pathogens that impact human health;
- (e) healthcare-related administrative data, including on dispensations, reimbursement claims and reimbursements;
- (f) human genetic, epigenomic and genomic data;
- (g) other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data;
- (h) personal electronic health data automatically generated through medical devices;
- (i) data from wellness applications;
- (j) data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person;
- (k) data from population-based health data registries such as public health registries;
- (l) data from medical registries and mortality registries;
- (m) data from clinical trials, clinical studies, clinical investigations and performance studies subject to Regulation (EU) No 536/2014, Regulation (EU) 2024/1938 of the European Parliament and of the Council (35), Regulation (EU) 2017/745 and Regulation (EU) 2017/746;
- (n) other health data from medical devices;
- (o) data from registries for medicinal products and medical devices;
- (p) data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results;
- (q) health data from biobanks and associated databases.

Publi sher type grou p	Data holde r	Original data source name (ENG)	Origin al Data source name (natio nal langua ge)	Dataset name (ENG): candida te as entry in nHDC	Possible sub- datasets	Comments	Link to further information/meta data	Q u e s t i o n s/ u n c l e a r	N A P r o b a b l y n	A	E	C	E	F	G	H	I	J	K	L	M	N	C	P	Q
------------------------------------	--------------------	---	---	---	---------------------------	----------	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

[illegible]



Governments and public sector organisations	Finnish Institute for Health and Welfare (THL)	Finnish Cancer Registry	Suomen Syöpärekisteri	Finnish Cancer Registry	Cancer Registry, Cervical cancer screening, Breast cancer screening, Colorectal cancer screening	Dataset division might need re-evaluation. Cancer Registry, Cervical cancer screening, Breast cancer screening and Colorectal cancer screening described as datasets belonging to the Finnish Cancer Registry in the current catalogue.	https://aineistokatalogi.fi/catalog/studies/210854-03-7be8-4f93-bf05-231518c642a0									X			
Governments and public sector organisations	Finnish Institute for Health and Welfare (THL)	Diabetes register (National quality register)	Diabetesrekisteri (kansallinen laaturekisteri)	Diabetes register (National quality register)			Diabetes register (national quality register)										X		
Governments and public sector organisations	Finnish Institute for Health and Welfare (THL)	HIV-register (National quality register)	HIV-rekisteri (kansallinen laaturekisteri)	HIV-register (National quality register)			https://aineistokatalogi.fi/catalog/studies/ee8391c8-8502-47ef-9934-7636019dafae										X		
Inpatient institution/Hospital	HUS group	HUS quality register on asthma	HUSin laaturekisteri astmasta	HUS quality register on asthma			https://aineistokatalogi.fi/catalog/studies/b12b2716-6a4f-4bc1-ba58-e1c23ea9486f										X		
Governments and public sector organisations	Finnish Institute for Health and Welfare (THL)	FINRISK 2012 study	FINRIKSI - tutkimus 2012	FINRISK 2012 study	Food frequency questionnaire, Cold and hot exposure questionnaire, Bioimpedance measurements etc.	Dataset division might need re-evaluation. Our original hypothesis was that Distribution could have been utilized to describe a sub-dataset in HealthDCAT-AP, but at the moment it doesn't seem possible. All variables can't be described in one file because there will be over 1000 variable descriptions. In the current catalogue FINRISK 2012 study is divided into 8 datasets.	FINRISK 2012 Study , ID:FII_002:collection:FINRISK_K">https://app.fingenius.fi/cohorts/bbmri-eric-ID:FII_002:collection:FINRISK_K					X							X X



Governments and public sector organizations	Finnish Institute for Health and Welfare (THL)	School health promotion study 2025	Kouluterveyskysely 2025	School health promotion study 2025	School health promotion study 2025 in the 4th and 5th grades of basic education; School health promotion study 2025 in 8th and 9th grades of basic education, upper secondary schools and vocational schools	Dataset division might need re-evaluation. Our original hypothesis was that Distribution could have been utilized to describe a sub-dataset in HealthDCAT-AP, but at the moment it doesn't seem possible.	School Health Promotion study 2025													X
Biobank / Government and public sector organization	THL Biobank	Corogene study	Corogene - Sepelvaltimotaudin perimä - tutkimus	Corogene study			Fingenious Catalogue						X						X?	X
Biobank	Auria Biobank	Auria Covid-19 collection	Aurian Covid-19 kokoelma	Auria Covid-19 collection			https://app.fingenious.fi/cohorts/bbmri-eric:ID:F1_001:collection:Auria-Covid					X								X
Biobank	Biobank Borealis of Northern Finland	Borealis Biobank Maternity Clinic collection		Borealis Biobank Maternity Clinic collection			Fingenious Catalogue													X
National authority	Social Insurance Institution of Finland (Kela)	Kanta Patient Data Repository: Key health data	Kantapotilastiedot: Keskeiset terveydet tiedot	Kanta Patient Data Repository: Key health data	Diagnoses, Vaccinations, Laboratory results, Laboratory statements, Microbial discoveries etc...	Dataset division might need re-evaluation.	https://aineistokatalogi.fi/catalog/studies/3e9d936e-ee2a-4e0e-9344-fb2c85b94e0c			X?		X								

[illegible]

[illegible]

[illegible]

[illegible]

Iceland

Minimum categories of electronic health data for secondary use (EHDS Art. 51):

- (a) electronic health data from EHRs;
- (b) data on factors impacting on health, including socioeconomic, environmental and behavioural determinants of health;
- (c) aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;
- (d) data on pathogens that impact human health;
- (e) healthcare-related administrative data, including on dispensations, reimbursement claims and reimbursements;
- (f) human genetic, epigenomic and genomic data;
- (g) other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data;
- (h) personal electronic health data automatically generated through medical devices;
- (i) data from wellness applications;
- (j) data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person;
- (k) data from population-based health data registries such as public health registries;
- (l) data from medical registries and mortality registries;

- (m) data from clinical trials, clinical studies, clinical investigations and performance studies subject to Regulation (EU) No 536/2014, Regulation (EU) 2024/1938 of the European Parliament and of the Council (35), Regulation (EU) 2017/745 and Regulation (EU) 2017/746;
- (n) other health data from medical devices;
- (o) data from registries for medicinal products and medical devices;
- (p) data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results;
- (q) health data from biobanks and associated databases.

Publi sher type grou p	Data holde r	Original data source name (ENG)	Original Data source name (national language)	Dataset name (ENG): candida te as entry in nHDC	Possib le sub- databse s	Comments	Link to further information/metadata	Ques tions/ uncle ar	N A Pr ob ab ly no t in cl ud ed in E H D S	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
Gove rnm ent and publi c secto r organ isatio n	Direct orate of Health	Hospital dischar ge register	Vistunarskrá heilbrigðisstofnan a	Hospital dischar ge register	TBD	Data available for scientific research. Recent law changes will result in the merging of the hospital discharge register, the register of primary healthcare contacts as well as the register of contacts with medical specialists in private practice.	https://island.is/en/gagnas ofn-embattis-landlaeknis Variable list: https://assets.ctfassets.net/ 8k0h54kbe6bj/7wlyljY8Sb aYt8rD7YEFLW/1151f880 801de3de9c3bc439decf8f de/Vistunargrunnur_breytu listi_09.2020.xlsx			X	X (P arti al, the pro visi on of he alt hc are inc lud ed)								X	X						

[illegible]



regist ers	Hospit al																			
Not- for profit organ isatio n	The Icelandic Heart Associ ation	The Reykjav ik Study	Reykjavíkurrannsóknin	The Reykjav ik Study	TBD - Maybe REFIN E, MONIC A Iceland	Prospective cohort 1967– 1996, n=30,795. Six examination stages. Results published.	Information about the research but not really on the metadata https://hjarta.is/en/research/ h/reykjavikurrannsokn/			x										x
Not- for profit organ isatio n	The Icelandic Heart Associ ation	Ages phase 1. AGES Reykjav ik Study: The Reykjav ik Study of Healthy Aging for the New Millenni um	AGES - Reykjavíkurrannsóknin	AGES - Reykjav ik Study	TBD	Extension of Reykjavík Study cohort, 2002–2006, n=5,764 survivors. Adds genetic, imaging and biobank data.	https://hjarta.is/en/research/ h/ages-phase-1/										x			x
Admi nistra tive institu tion	Iceland Health (Sjúkr atrygg ingar Íslands)	Healthc are reimburs ement and claims data	Greiðslubátttökugögn og kröfugögn	Healthc are reimburs ement and claims data	TBD	Iceland Health is the universal health insurance agency for Iceland, whose main task is to contract and pay for all healthcare covered by the insurance — including hospitals, primary healthcare, nursing homes, medical specialists, dentists, and other healthcare professionals. Its drug reimbursement records also complement the Prescription Medicines Register already in the inventory.	https://island.is/en/o/iceland- d-health						X							
Admi nistra tive institu tion	Social Insura nce Admin istrati on (Trygg ingars)	Social insuran ce and disabilit y data	Gögn um almannatryggingar og örorku	Social insuran ce and disabilit y data	TBD	Administers disability pensions, sickness cash benefits, and rehabilitation payments	https://island.is/en/o/social- insurance-administration						X							

[illegible]

[illegible]

[illegible]

Norway

Minimum categories of electronic health data for secondary use (EHDS Art. 51):

- (a) electronic health data from EHRs;
- (b) data on factors impacting on health, including socioeconomic, environmental and behavioural determinants of health;
- (c) aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;
- (d) data on pathogens that impact human health;
- (e) healthcare-related administrative data, including on dispensations, reimbursement claims and reimbursements;
- (f) human genetic, epigenomic and genomic data;
- (g) other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data;
- (h) personal electronic health data automatically generated through medical devices;
- (i) data from wellness applications;
- (j) data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person;
- (k) data from population-based health data registries such as public health registries;
- (l) data from medical registries and mortality registries;
- (m) data from clinical trials, clinical studies, clinical investigations and performance studies subject to Regulation (EU) No 536/2014, Regulation (EU) 2024/1938 of the European Parliament and of the Council (35), Regulation (EU) 2017/745 and Regulation (EU) 2017/746;
- (n) other health data from medical devices;
- (o) data from registries for medicinal products and medical devices;
- (p) data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results;
- (q) health data from biobanks and associated databases.

Public type group	Data holder	Original data source name (ENG)	Original Data source name (national language)	Dataset name (ENG): candidate as entry in nHD C	Possible sub- datasets	Comments	Link to further information/metada ta	Questions/unclear	NA	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
Governments	Norwegian	Norwegian	Norsk pasientregister	About the		We share subdatasets as distributions today	https://helsesdata.no/en/variables/?dataset=1	Maybe the dataset name would need to include "Norwegian Patient Registry" for more clarity?						X						X						

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]



Governments and public sector organizations	Norwegian Institute for Public Health	Norwegian Patient Registry	Norsk pasientregister	Personal injury and accident data		We share sub datasets as distributions today	https://helsedata.no/en/variables/?dataset=K_NPR.FMD_S	The register contains health information on everyone who has been referred for or has received treatment in the specialist healthcare services. NPR has personal, administrative, social, and medical information from the following service areas: Somatic hospitals and clinics Mental healthcare for adults Mental healthcare for children and adolescents Private contract specialists, somatic disciplines Private contract specialists, mental healthcare Interdisciplinary specialized treatment for substance abuse In addition, NPR has information about: Waiting list and patient rights Injury and accident data Emergency medical communication centers (AMK) Mapping of substance abuse situation at the start of treatment (within substance abuse treatment) Private rehabilitation clinics Nursing homes in Finnmark NPR has personally identifiable information from 2008.		X	X						X			
---	---------------------------------------	----------------------------	-----------------------	-----------------------------------	--	--	---	--	--	---	---	--	--	--	--	--	---	--	--	--



Gove rne nt and publi c secto r orga nisati on	Nor wegi an Instit ute for Publ ic Heal th	Nor wegi an Patie nt Regi stry	Nor sk pasi entr egis ter	Activi ty- base d finan cing		We share subdatasets as distributions today	https://helsedata.no/en/variables/?datasetling=K_NPR.INNSATSSTYRTFINANSIERINGISF	The register contains health information on everyone who has been referred for or has received treatment in the specialist healthcare services. NPR has personal, administrative, social, and medical information from the following service areas: Somatic hospitals and clinics Mental healthcare for adults Mental healthcare for children and adolescents Private contract specialists, somatic disciplines Private contract specialists, mental healthcare Interdisciplinary specialized treatment for substance abuse In addition, NPR has information about: Waiting list and patient rights Injury and accident data Emergency medical communication centers (AMK) Mapping of substance abuse situation at the start of treatment (within substance abuse treatment) Private rehabilitation clinics Nursing homes in Finnmark NPR has personally identifiable information from 2008.				X					X			X	
Gove rne nt and publi c secto r orga nisati on	St. Olav s hos pital HF	The Hear ing Regi stry for Child ren	Hør sels regi ster et for barn	The Heari ng Regis try for Child ren	Førstegan gsregistre ring		https://helsedata.no/en/variables/?datasetling=K_HFB.FRSTEGANGSREGISTERING					X					X	X			
Gove rne nt	St. Olav s	The Hear ing	Hør sels regi ng	The Heari ng	Oppfølgin gsskjema		https://helsedata.no/en/variables/?datasetling=K_HFB.FRSTEGANGSREGISTERING					X	X				X	X			

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]



Research organization	UiT – The Arctic University of Norway	The Tromsø Study	Tromsø undersøkelsen				https://helsedata.no/no/variabler/?datasamling=K_TR.TR4&page=search																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																															
-----------------------	---------------------------------------	------------------	----------------------	--	--	--	---	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

[illegible]

[illegible]

[illegible]

[illegible]

☒

Minimum categories of electronic health data for secondary use (EHDS Art. 51):

- (a) electronic health data from EHRs;
- (b) data on factors impacting on health, including socioeconomic, environmental and behavioural determinants of health;
- (c) aggregated data on healthcare needs, resources allocated to healthcare, the provision of and access to healthcare, healthcare expenditure and financing;
- (d) data on pathogens that impact human health;
- (e) healthcare-related administrative data, including on dispensations, reimbursement claims and reimbursements;
- (f) human genetic, epigenomic and genomic data;
- (g) other human molecular data such as proteomic, transcriptomic, metabolomic, lipidomic and other omic data;
- (h) personal electronic health data automatically generated through medical devices;
- (i) data from wellness applications;
- (j) data on professional status, and on the specialisation and institution of health professionals involved in the treatment of a natural person;



- (k) data from population-based health data registries such as public health registries;
- (l) data from medical registries and mortality registries;
- (m) data from clinical trials, clinical studies, clinical investigations and performance studies subject to Regulation (EU) No 536/2014, Regulation (EU) 2024/1938 of the European Parliament and of the Council (35), Regulation (EU) 2017/745 and Regulation (EU) 2017/746;
- (n) other health data from medical devices;
- (o) data from registries for medicinal products and medical devices;
- (p) data from research cohorts, questionnaires and surveys related to health, after the first publication of the related results;
- (q) health data from biobanks and associated databases.

Pu bli sh er ty pe gr ou p	Data holde r	Original data source name (ENG)	Original Data source name (national language)	Dataset name (ENG): candidat e as entry in nHDC	Possible sub- datasets	Comments	Link to further information/ metadata	Questio ns/uncle ar	NA Pr ob abl y not inc lud ed in EH DS	A	E	C	D	E	F	G	H	I	J	K	L	N	O	P	Q	
Natio nal au tho ri ty	Swedi sh Natio nal Board of Health and Welfar e	National Patient Register	Patientregistret	National Patient register, In- patient care	Maybe split into historic (pre 1987) and current (nationwide coverage from 1987) for more clear metadata description	We are contemplating to share each subregister within a register as a dataset on its own and link them through keywords and/or concatenation of title of main and sub dataset, instead of using dataset series or catalogue or distributions	National Patient Register - Socialstyrels en			(X)				(X)					(X)	X						
Natio nal au tho ri ty	Swedi sh Natio nal Board of Health and Welfar e	National Patient Register	Patientregistret	National Patient register, Speciali sed out- patient care		We are contemplating to share each subregister within a register as a dataset on its own and link them through keywords and/or concatenation of title of main and sub dataset, instead of using dataset series or catalogue or distributions	National Patient Register - Socialstyrels en			(X)				(X)					(X)	X						
Natio nal au	Swedi sh Natio nal Board	National Patient Register	Patientregistret	National Patient register, Primary care		Data collection has not begun but will be available during EHDS period	National Patient Register - Socialstyrels en			(X)				(X)					(X)	X						

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]

[illegible]



Annex 5. Full report on Legal aspects

Nordic interpretation of specific EHDS Articles

Report 1.0

Value from Nordic health data – VALO project

1 October 2026

Document info

0.3 Authors

Author	Partner
Jenina Soimala	The Finnish Institute for Health and Welfare (THL)
Sirpa Soini	The Finnish Institute for Health and Welfare (THL)
Vilma Piironen	The Finnish Institute for Health and Welfare (THL)
Florine Wettly	The Norwegian Institute for Public Health (NIPH)
Christina Møllebro	The Norwegian Institute for Public Health (NIPH)
Editors	
Anne Savolainen	National Board of Health and Welfare, Sweden
Hrefna Dögg	University of Iceland, Faculty of Law

0.4 Keywords

Keywords Health data, Nordic, EHDS, legal interpretation

Disclaimer

The content of this report represents the views of the author(s) and do not necessarily reflect the views of the experts interviewed.

Copyright Notice

Copyright © 2026 The contributing VALO2 Parties and authors identified in this report

Contents

Annex 5. Full report on Legal aspects	175
Executive summary	178
1 About the legal group and the countries.....	179
2 Purpose of this document	180
3 Need for harmonisation in the Nordics	181
3.1 The relationship between Recitals 52 and 62 and Art. 54(e) EHDS	181
3.2 Policy and operational overlap with HDAB group	183
3.2.1 Opt-out.....	183
3.2.2 Intellectual property rights and trade secrets.....	184
4 Interpretation and implementation of specific EHDS Articles	185
4.1 Art. 2(2)(t), definition of a data holder, statistical bodies	185
4.2 Art. 50(3), possibilities of Health Data Intermediation Entities (HDIE)	188
4.2.1 Meaning of “certain categories of data holders”	188
4.2.2 Organisation and role of HDIE	189
4.2.3 HDIEs and fees	189
4.2.4 HDIE’s legal responsibility and controllership.....	190
4.2.5 Designation of HDIEs and allocation of duties	191
4.3 Art. 58(3) and 61(5) significant findings	191
4.4 Art. 62, fees	194
4.5 Consideration of ethical aspects under Art. 68(1)(b).....	195
References	197

Executive summary

The European Health Data Space (EHDS) establishes a common legal framework for the secondary use of electronic health data across the European Union. Although the Regulation harmonises many aspects of data access and sharing, several provisions require interpretation before they can be implemented consistently by the Member States.

To support this work, the VALO2 legal group brought together legal experts from the Nordic countries to discuss selected EHDS provisions that have proven particularly important or difficult during national implementation. This report summarises the group's legal analyses, common interpretations and recommendations. It presents (a) legal interpretations for which the group reached a common view, (b) legal questions that remain uncertain and would benefit from further European guidance, and (c) implementation issues that would benefit from continued Nordic cooperation.

First, the legal group developed common Nordic interpretations for several implementation questions. These include the definition of a health data holder, the possible organisation and responsibilities of Health Data Intermediation Entities, the interpretation of the EHDS fee provisions, the implementation of the provisions on significant findings, and the scope of assessments carried out by Health Data Access Bodies (HDAB) when deciding whether to grant access to health data.

Second, the report identifies provisions where the legal group considered the EHDS to remain open to different interpretations. One of the key examples is the relationship between the EHDS provisions on consent and national ethical requirements, where the interaction between Recitals 52 and 62 and Article 54(e) remains uncertain. The report concludes that additional guidance from the European Commission, the European Data Protection Board or, ultimately, the Court of Justice of the European Union would be valuable to support consistent implementation across Member States.

Third, the report discusses implementation issues that are primarily operational or policy-related rather than legal. These include the design of national opt-out mechanisms and the protection of intellectual property rights and trade secrets. The legal group recommends that these topics continue to be developed through the Nordic HDAB collaboration.

A common theme throughout the report is that unnecessary differences in national implementation could make multinational research more complex and reduce the attractiveness of Nordic health data. Continued Nordic cooperation therefore provides an opportunity to exchange experiences, develop common approaches where appropriate and identify issues requiring European clarification.

The legal group concludes that maintaining this collaborative Nordic legal network beyond the VALO2 project would support a more consistent, trustworthy and effective implementation of the EHDS while strengthening the Nordic region's position in cross-border health research and innovation.

1 About the legal group and the countries

The VALO2 legal group included participants from all Nordic countries, although the level of participation varied, and received some contributions from Estonia and Lithuania, as observers in VALO2. Due to these differences in participation, the group's conclusions reflect the views of the participating experts from Denmark, Finland, Iceland and Norway. Nevertheless, the participation of Sweden, Estonia and Lithuania have facilitated valuable knowledge exchange, allowing experiences and implementation approaches to be shared across the region.

Unless expressly identified as an official national position or attributed to an official source, the interpretations and recommendations in this document reflect the views developed by the participating experts within the VALO2 legal group. They do not represent the official positions of the participating countries, national authorities or the experts' organisations.

The legal group was initially established as a discussion forum that met during the VALO2 Competence Forums. As the implementation of the EHDS progressed, the need for more structured legal cooperation became evident. The participants themselves also expressed a wish to move beyond general discussions and establish more concrete objectives, including documenting common interpretations and recommendations in writing. At the beginning of 2026, the group's working methods were therefore revised. Monthly online meetings were introduced between the Competence Forums, supported by recurring agendas that revisited unresolved legal questions until a common understanding could be reached. The development of this document became a standing agenda item, providing a structured basis for discussions and ensuring that the group's conclusions were documented for future use.³³ In addition, each meeting allowed time for ad hoc legal questions arising from ongoing national implementation work.

The collaboration extended beyond the scheduled meetings. Participants regularly exchanged views and draft interpretations by email whenever new legal questions emerged, creating an active Nordic network of legal experts. Many participants had only recently assumed responsibility for EHDS implementation within their respective organisations when joining the project. Thus, there were more questions than answers in the beginning. The legal group has therefore served not only as a forum for legal interpretation but also as a mechanism for building institutional expertise and strengthening Nordic legal capacity in preparation for the implementation of the EHDS.

The Nordic countries currently find themselves at different stages of EHDS implementation. While some countries have already developed national legislative proposals and implementation models, others are still at an earlier stage of analysis. Similarly, the priorities and immediate implementation challenges differ between countries. This diversity has proven valuable, allowing experiences from countries that have already addressed particular legal questions to inform discussions in countries where the same issues will arise later. For example, legal interpretations developed in

³³ The articles and topics were selected because they were considered particularly relevant or challenging for Nordic implementation of the EHDS at the time of the analysis.

one country have enabled other countries to identify potential implementation challenges before reaching the same stage of their legislative process. This has been particularly valuable in areas where national implementation choices may directly affect Nordic cross-border research, such as the definition of health data holders, the granularity of opt-out mechanisms and the scope of assessments carried out by Health Data Access Bodies (HDAB). On this basis, the collaboration has contributed to developing a shared understanding of several legal questions among the participating experts. The participants consider that continued Nordic legal cooperation will remain essential throughout the national implementation of the EHDS and beyond, as many legal and policy questions remain unresolved both nationally and at the European level. Maintaining this network will allow the participating countries to continue exchanging experiences, discussing emerging interpretations and, where appropriate, promoting common Nordic approaches to issues that are left to national discretion.

2 Purpose of this document

The topics addressed by the legal group have arisen directly from the practical needs of its participants. The discussions have focused on questions requiring peer support, legal interpretation and the development of common solutions during the national implementation of the EHDS. While some issues required only brief discussion, others were revisited repeatedly due to their complexity or practical importance.

This document records the legal group's discussions on those issues that were considered sufficiently significant to warrant more extensive analysis. It is not intended to provide an exhaustive interpretation of the EHDS or to establish binding legal positions. Rather, it documents the group's reasoning, interpretations and recommendations in order to support the ongoing implementation of the EHDS within the participating countries and to preserve the work carried out during the VALO2 project.

Many of the questions discussed in this document remain unresolved at both the national and European levels. Consequently, the document should be understood as a record of the legal group's current interpretations and recommendations rather than as a statement of settled law. Where appropriate, the document also identifies legal uncertainties and areas where further guidance from the European Commission, the European Data Protection Board or the Court of Justice of the European Union would be beneficial.

The legal group considers Nordic cooperation particularly important because the EHDS offers significant opportunities for the secondary use of health data but also presents implementation challenges that may reduce the attractiveness of Nordic data if national approaches diverge unnecessarily. The comparative mapping carried out in Work Stream 1 demonstrated that, despite the high quality of Nordic health data, administrative complexity and differences in national implementation may discourage applicants from conducting multinational studies (1). Differences in national interpretations, for example regarding the granularity of opt-out mechanisms, the identification of health data holders or the scope of assessments carried out by HDABs, may affect the comparability of datasets and the practical feasibility of using Nordic data across borders. For example, if one Nordic country interprets a particular registry or public authority as a health data holder while another does not, or if datasets are made available with different levels of

detail, applicants may no longer be able to conduct comparable analyses across all Nordic countries.

The purpose of this document is therefore not to promote complete harmonisation of national implementation. Rather, it seeks to identify areas where a common Nordic understanding may reduce unnecessary fragmentation, improve legal certainty for applicants and authorities, and support the effective implementation of the EHDS while respecting the national discretion left by the Regulation. By promoting well-reasoned and, where appropriate, aligned Nordic interpretations, the legal group aims to help ensure that the Nordic countries continue to be among the leading regions in Europe for the trustworthy and effective secondary use of health data.

3 Need for harmonisation in the Nordics

3.1 The relationship between Recitals 52 and 62 and Art. 54(e) EHDS

The legal group discussed the relationship between Recitals 52 and 62 of the EHDS, Art. 54(e), and the role of consent in the secondary use framework. The group noted that the interaction between these provisions remains difficult to interpret and that further clarification at the Union level is needed.

Recital 52 clearly addresses consent as a legal basis for the processing of personal data under the GDPR. It states that the secondary use framework established by the EHDS provides its own legal basis for processing and that Member States may no longer maintain or introduce, pursuant to Art. 9(4) GDPR, further conditions for the secondary use of personal electronic health data, including requirements to obtain the consent of the natural person. At the same time, however, Recital 52 expressly preserves the possibility for Member States to introduce "stricter measures and additional safeguards at national level aimed at safeguarding the sensitivity and value of certain data as laid down in this Regulation." This exception is further reflected in Art. 51(4), which allows Member States to introduce stricter measures and additional safeguards for the categories of data referred to in Art. 51(1), points (f), (g), (i) and (q), subject to notification to the Commission.

The interpretation of Recital 62 is, however, less straightforward. It provides that the prohibition on secondary use for activities contrary to ethical provisions under national law does not apply to "ethical provisions relating to consent to the processing of personal data and ethical provisions relating to the right to opt out", as the EHDS takes precedence over national law in accordance with the principle of the primacy of Union law. The precise meaning of this exception remains unclear.

The legal group further noted that the concept of consent is not uniform. Depending on the legal and regulatory context, consent may serve different purposes. Under the GDPR, consent may constitute a legal basis for the processing of personal data. In the context of research, however, informed consent may also function as an ethical safeguard, reflecting the autonomy of research participants and the ethical commitments made by researchers and research institutions. Such informed consent may be required

under national research legislation or research ethics frameworks even where it does not constitute the legal basis for processing under the GDPR.

Recent academic literature has also highlighted the ethical challenges that may arise where data originally collected on the basis of informed consent become subject to the mandatory data-sharing obligations introduced by the EHDS, particularly where this may alter the expectations created by the original consent process and potentially affect public trust in research (2).

Against this background, the legal group identified several questions of interpretation. First, it is unclear whether the reference in Recital 62 to "ethical provisions relating to consent to the processing of personal data" concerns the same type of national consent requirements addressed in Recital 52, namely consent requirements maintained or introduced under Art. 9(4) GDPR, or whether it instead refers to ethical requirements governing research, such as informed consent required under national research ethics frameworks. The wording of Recital 62 does not clearly indicate whether it is intended to address the same issue as Recital 52 or a different category of national provisions.

Secondly, it remains unclear how the exception in Recital 52 permitting stricter national measures and additional safeguards, as reflected in Art. 51(4), should be interpreted together with the statement in Recital 62 that "ethical provisions relating to consent to the processing of personal data" cannot prevent secondary use under the EHDS. If such ethical provisions are understood as constituting stricter national measures or additional safeguards within the meaning of Recital 52 and Art. 51(4), the relationship between the provisions is not immediately apparent. Conversely, if Recitals 52 and 62 address different concepts of consent or different categories of national provisions, the EHDS does not expressly explain where the boundary between them lies.

The legal group was therefore unable to reach a definitive conclusion regarding the intended relationship between Recitals 52 and 62 and Art. 54(e). In particular, it remains uncertain whether Recital 62 merely reinforces the rules in Recital 52 concerning consent as a legal basis under the GDPR, or whether it also extends to ethical requirements relating to informed consent in research or other national ethical frameworks governing the processing of personal data. This distinction is of practical importance, as the latter interpretation could affect existing consent-based governance models used by research infrastructures and other data holders. Moreover, overruling ethical commitments will diminish the trust of the Nordic people. Further clarification from the European Commission or, ultimately, the Court of Justice of the European Union would therefore be valuable.

As a next step, the legal group could continue its analysis with the aim of developing a shared expert interpretation of the relationship between Recitals 52 and 62, Art. 51(4) and Art. 54(e), including through comparison of the relevant national consent and research ethics requirements. Any interpretation developed by the group should be kept under review in light of subsequent guidance from the European Commission or the European Data Protection Board and relevant case law of the Court of Justice of the European Union.

3.2 Policy and operational overlap with HDAB group

The legal group discussed both the implementation of the EHDS opt-out mechanism and the protection of intellectual property rights and trade secrets (IPR&TS) under the EHDS framework. While certain legal considerations were identified, the group concluded that both topics are primarily operational and policy-related in nature and therefore could fall within the remit of the VALO2's HDAB group. The following chapters summarise the discussions held within the legal group, the considerations identified, and the information shared with the HDAB group at the second-to-last Competence Forum in Gothenburg in May 2026.

3.2.1 Opt-out

The legal group's discussions on the implementation of the EHDS opt-out concluded that there were no major legal issues requiring further analysis at this stage. The group highlights however that the design of an opt-out mechanism should ensure that citizens are provided with sufficient information to understand their rights to opt-out and distinguish between the EHDS primary and secondary use opt-out, and GDPR rights.

The group discussed a model under which individuals would either opt out entirely or not opt out at all, as introducing more granular choices based on specific purposes, data categories, or data holders would increase implementation costs and administrative burden.

However, the group concluded that it is important to consider the implications of offering only a full opt-out or no opt-out at all. Such an approach may result in individuals opting out more extensively than they would do if there were a wider range of more specific options. For example, a citizen may wish to opt out only from the use of their data for training and evaluating AI systems and algorithms but would instead be required to opt out of all purposes and data categories, including those to which they have no objection. At the same time, a detailed granularity may challenge how user friendly the opt-out mechanism might be, taking into consideration that it must be crystal clear for the users what they actually opt-out against.

The group further noted that if the Nordic countries adopt different levels of granularity in their respective opt-out models, there is a risk that the resulting datasets will differ between countries. For example, where one country allows only a full opt-out while another permits more granular choices, citizens with similar preferences may opt out to different extents depending on the national implementation model. This could reduce the representativeness and comparability of Nordic datasets.

The group further observed that differing national approaches would reinforce an existing challenge already identified by researchers. Researchers have reported that differences in data minimisation principles and regulatory complexity already require them to "settle for less precise analysis because we need consistency across all participating countries, so we default to the lowest common denominator."⁽¹⁾ As a result, data made available by some countries may ultimately be excluded from a project because equivalent data cannot be accessed from another country. Further divergence in opt-out models could therefore make the lowest common denominator even more restrictive, further reducing

the comparability and usability of Nordic data and diminishing the attractiveness of applying for access to cross-border datasets.

As the issue was considered primarily operational and policy-related rather than legal in nature, the legal group recommended that the matter be discussed further within the HDAB group, if possible.

The issue of opt-out granularity also extends to the opt-out exception. Art. 71(4) provides that: “By way of exception from the right to opt out provided for in paragraph 1, a Member State may provide in its national law for a mechanism to make data for which a right to opt out has been exercised available, provided that all the following conditions are fulfilled...” This provision leaves considerable discretion to Member States regarding whether and how data, subject to an opt-out option, may still be made available for secondary use. As a result, national approaches may differ significantly. Such divergence could create challenges for the development of a common Nordic approach to the EHDS and may hinder cross-border data sharing and the establishment of harmonised health data infrastructures across the Nordic countries.

As a next step, the HDAB group could compare the planned national approaches to opt-out granularity and the exception under Art. 71(4) and assess their potential effects on the comparability and availability of Nordic datasets. The legal group could support this work where further legal interpretation is required.

3.2.2 Intellectual property rights and trade secrets

The EHDS places responsibility on HDABs for assessing and protecting the intellectual property rights and trade secrets (IPR&TS) of data holders when processing data access applications. This has raised concerns among private-sector stakeholders, who have expressed doubts as to whether HDABs, which may not possess detailed knowledge of the underlying datasets, will be able to adequately identify and protect commercially sensitive information.³⁴ While the topic has been addressed within the TEHDAS2 Joint Action (TEHDAS2), including through a dedicated workshop and guidance³⁵, no established solutions have yet emerged at the European level.

A project called FORTIFY was launched in May 2026 with the aim of developing practical legal, governance and technical solutions to support the secondary use of health data under the EHDS while safeguarding IPR&TS, commercially confidential information and regulatory protection. The legal and ethical analyses carried out in VALO2's Work Stream 2, together with the piloting activities in Work Stream 3, established a connection between the VALO2 project and PHASE IV AI, enabling the exchange of knowledge and experiences with experts working on complementary solutions. As a result, the chair of the VALO2 legal group presented the ethical challenges and potential solutions identified through the VALO2 project at the PHASE IV AI final conference. The conference also provided an opportunity to learn about emerging technical solutions for protecting IPR&TS within the EHDS framework.

³⁴ This can also of course be a question of resources.

³⁵ TEHDAS2 JA Guideline on a framework for collaboration.



FORTIFY and PHASE IV AI are aware of each other's work and remain connected through these activities. This cooperation helps ensure that the legal, ethical, and technical challenges identified during VALO2 will continue to be addressed in follow-up initiatives specifically designed to develop practical solutions for the implementation of the EHDS.

The legal group discussed the matter and acknowledged the importance of supporting data holders in identifying and protecting IPR&TS. At the same time, the group recognised that meaningful work in this area would require the involvement of specialised IPR&TS experts. Given the lack of dedicated funding and the limited time remaining within the VALO2 project, such an initiative was not considered feasible at this stage.

The group also explored whether Nordic-level guidance could be developed to support HDABs in their interactions with data holders. Such guidance could outline when discussions with data holders should take place and identify the minimum issues that should be addressed when assessing potential IPR&TS concerns. Discussing the matter at the Competence Forum in Gothenburg on 4 May 2026, the legal group concluded that the matter should be further considered by the HDAB group. In particular, the HDAB group may wish to assess whether a common Nordic declaration or commitment should be developed to signal to private-sector stakeholders that the Nordic countries are committed to protecting intellectual property rights and trade secrets in a proportionate and justified manner, ensuring both adequate protection and the avoidance of unnecessary restrictions on data use. The legal group informed the HDAB group that it is available to support the development of a more detailed Nordic guidance on the protection of IPR&TS, including possible legal means of protection. Moreover, the group noted that such an initiative could position the Nordic countries as forerunners in the implementation of the EHDS.

4 Interpretation and implementation of specific EHDS Articles

4.1 Art. 2(2)(t), definition of a data holder, statistical bodies

The definition of a health data holder under Art. 2(2)(t) EHDS has been the subject of discussion within the legal and metadata groups and among national authorities. In particular, Statistics Sweden has taken the position that it should not be regarded as a health data holder under the EHDS (3). This position was discussed at the Competence Forum in Gothenburg on 4 May 2026 and 22 September 2026. The legal group considered that statistical bodies should not, solely by virtue of being statistical bodies, be regarded as health data holders under the EHDS. Equally, they should not be excluded solely because they operate outside the healthcare or care sectors. Their status must instead be assessed on the basis of their specific activities, their role in relation to the electronic health data concerned and the conditions laid down in Art. 2(2)(t). The assessment should take account of the definition as a whole, including both the activity-based categories of entities covered by the provision and the way in which statistical bodies and their roles are organised at the national level.



The legal group interprets Art. 2(2)(t) as containing three alternative categories of entities that may qualify as health data holders:

Firstly, "any natural or legal person, public authority, agency or other body *in the* healthcare or the care sectors, including reimbursement services where necessary";

Secondly, "any natural or legal person developing products or services *intended for the* health, healthcare or care sectors, developing or manufacturing wellness applications, performing research in relation to the healthcare or care sectors, or acting as a mortality registry";

Thirdly, "any Union institution, body, office or agency" that fulfils the conditions set out in Art. 2(2)(t).

The legal group noted that the first category identifies entities by their position within the healthcare or care sectors, whereas the second category identifies entities by the activities they perform. Unlike the first category, the second does not expressly require that the entity itself belongs to the healthcare or care sectors. Instead, it focuses on whether the entity develops products or services intended for those sectors, develops or manufactures wellness applications, performs research relating to the healthcare or care sectors, or acts as a mortality registry.

Under this interpretation, an entity does not need to belong to the healthcare or care sector to qualify as a health data holder. For example, a statistical authority producing health statistics may fall within the second category where those statistics constitute products or services intended for the health, healthcare or care sectors, despite the authority itself not belonging to those sectors. The assessment should take account of the intended purpose and users of the statistical products or services, as well as whether the authority fulfils Art. 2(2)(t)(i) or (ii). Accordingly, an entity may qualify as a health data holder either because of its institutional role or because of the nature and intended purpose of the activities it carries out. Any resulting obligations would concern the authority's relevant electronic health data and activities, rather than its unrelated statistical activities.

Several textual, systematic, and practical considerations support statistical bodies to be data holders under the EHDS.

First, the objectives of the EHDS support a broader understanding of the concept of a health data holder. Recital 1 expressly recognises official statistics as one of the societal purposes that the Regulation is intended to support, stating that the EHDS aims to improve the use of electronic health data for purposes including "research, innovation, policymaking, health threats preparedness and response, ... official statistics or regulatory activities". This demonstrates that official statistics are not peripheral to the EHDS framework but form part of its core objectives.

Second, this interpretation is reinforced by Recital 6, which explicitly states that electronic health data include data that were initially collected for "research, statistical, health threat assessment, policymaking or regulatory purposes" and that such data should be made available in accordance with the rules laid down in the Regulation. The recital therefore

recognises that electronic health data may originate and continue to exist outside traditional healthcare delivery settings.

Third, the systematic structure of the Regulation points in the same direction. Art. 51 covers numerous categories of electronic health data that are frequently held by statistical authorities, including data relating to determinants of health, socioeconomic factors, population-level information, and linked datasets used for research and policymaking. An interpretation under which a statistical body is not considered a health data holder should therefore be assessed carefully, as it may create a gap between the categories of data covered by Article 51 and the entities responsible for making those data available.

This interpretation is also reflected in TEHDAS2 Joint Action Guideline 6.1(4), which states that a health data holder is any natural or legal person, or entity, that processes electronic health data for primary or secondary use. Although the TEHDAS2 guidance is not legally binding, it constitutes relevant interpretative material in the context of EHDS implementation. It supports a functional understanding of the concept of a health data holder by focusing on the processing and holding of electronic health data rather than on the formal institutional sector of the organisation. Nevertheless, the guidance must be read together with all the elements of the definition in Art. 2(2)(t).

A restrictive interpretation, on the other hand, could lead to inconsistent outcomes between Member States based solely on institutional organisation. In practice, comparable datasets may be held by different public authorities depending on national administrative arrangements. Whether a dataset falls within the operational scope of the EHDS should not depend solely on whether the responsible authority reports to a Ministry of Health, a Ministry of Finance, or another governmental body. This concern is further reinforced by the fact that Member States may define the concept of the "healthcare sector" differently. Consequently, the practical scope of the EHDS could vary considerably between Member States for reasons unrelated to the nature of the data themselves.

From a functional perspective, national statistical authorities may fulfil the characteristics associated with health data holders under the EHDS framework. They collect, maintain, process, link, and provide access to electronic health data and health-related datasets for research, policymaking, and statistical purposes. An interpretation under which such an authority is not considered a health data holder should therefore be assessed carefully, as it may affect the availability of relevant data through the EHDS secondary-use framework.

This interpretation is also consistent with existing national practice. For example, Statistics Finland already participates in the Finnish secondary-use framework established under the Act on the Secondary Use of Health and Social Welfare Data. A similar approach exists in Norway under the Personal Health Data Filing System Act. These examples demonstrate that statistical authorities can operate as data-holding organisations within a regulated health data access ecosystem.

Taken together, the textual, systematic and functional considerations discussed above provide strong grounds for considering statistical bodies that hold and process electronic

health data for health-related official statistics to be health data holders under the EHDS. This is particularly relevant where their statistical products or services are intended for the health, healthcare or care sectors and they fulfil Art. 2(2)(t)(i) or (ii). Nevertheless, their status is not automatic and must be assessed individually in light of all the relevant circumstances and considerations set out above.

For these reasons, the legal group considers that whether an entity qualifies as a health data holder under the EHDS should not be assessed solely on the basis of its institutional placement or sectoral affiliation. However, for the sake of clarity, it would be beneficial to have a clear definition on what constitutes as “developing products or services intended for the health, healthcare or care sectors”, in context of the second category of entities that may qualify as health data holders. Nevertheless, the assessment should focus on the activities carried out by the entity, the electronic health data it holds or processes, and whether the entity fulfils the conditions laid down in Art. 2(2)(t)(i) or (ii).

Sweden is currently developing a decision tree and assessment criteria to support organisations to determine whether they qualify as health data holders under the EHDS. During the discussions, it was noted that this initiative could benefit from a Nordic approach. A shared tool or interface used across the Nordic countries could enable benchmarking between data holders and provide greater consistency in the assessment process. Such an approach could also support organisations in understanding their role and obligations under the EHDS.

So far, the other Nordics and Baltics have not made any official decisions regarding the matter. A favoured next step for the legal group would be to examine how “healthcare or care sectors” should be interpreted for the purposes of Art. 2(2)(t), including whether sectoral affiliation should be assessed primarily on an institutional or functional basis. Developing a shared interpretation could support more consistent assessments of statistical bodies and other entities operating outside traditional healthcare and care structures. A more practical approach would be to work together with the metadata group and assess individual organisations whether they are to be considered as data holders or not under the EHDS.

4.2 Art. 50(3), possibilities of Health Data Intermediation Entities (HDIE)

4.2.1 Meaning of “certain categories of data holders”

The legal group discussed the wording of Art. 50(3), which provides that “Member States may provide in their national law that the duties of certain categories of health data holders are to be fulfilled by health data intermediation entities.” In particular, the group considered the meaning of the phrase “certain categories of data holders” and how narrowly such categories may be defined in practice.

The discussion focused on the level of granularity that may be applied when defining categories of data holders, including whether categories could be defined by combining characteristics such as the type of data holder and the type of data held. The group concluded that categories of data holders may be defined based on different attributes. Consequently, a HDIE would not necessarily need to assume the duties of all data

holders within a broad category, such as all small and medium-sized enterprises or all registries but could instead assume the duties of only certain data holders belonging to the same category.

4.2.2 Organisation and role of HDIE

The legal group also agreed that an HDIE may be either a public or a private legal entity. The conditions defining an HDIE should stem from the EHDS itself, thereby ensuring a common regulatory framework that promotes fair competition, legal certainty, and organisational flexibility across the Member States.

The EHDS provides only limited requirements regarding the organisational form of an HDIE. Recital 59 states that an HDIE should be a legal person, while Recital 76 states that HDIEs should not be designated as Trusted Health Data Holders (THDHs). However, the operative provisions of the EHDS do not expressly prohibit the same legal entity from performing both functions. The legal group therefore considered that Recital 76 should primarily be understood as requiring a functional separation of the HDIE and THDH roles with respect to the same datasets, rather than necessarily requiring that they always be separate legal entities. Consequently, the same organisation could, in principle, perform both functions in relation to different datasets or organisational responsibilities, provided that the respective roles, responsibilities, and datasets remain clearly separated.

The legal group further discussed whether Member States should be able to designate an HDIE in relation to specific datasets or groups of datasets, rather than only for predefined categories of health data holders. Such an interpretation would be consistent with the objective underlying the introduction of HDIEs, namely, to reduce the administrative burden on health data holders that may lack the capacity to fulfil all EHDS obligations themselves, such as smaller healthcare providers. Allowing HDIEs to be designated in relation to specific datasets would provide Member States with greater flexibility to organise their governance structures while preserving the functional separation envisaged by the EHDS.

The Finnish Government Proposal supplementing the implementation of the EHDS Regulation (Hallituksen esitys eduskunnalle eurooppalaista terveystietoaletta koskevan Euroopan parlamentin ja neuvoston asetuksen sähköisten terveystietojen toissijaista käyttöä ja asetuksen seuraamuksia täydentäväksi sääntelyksi) proposes allowing the use of HDIEs (5). In Norway, the possibility of using HDIEs has been considered, e.g., in relation to municipalities that hold health data. However, discussions have not yet addressed whether an intermediation entity would assume the responsibilities of all municipalities or only certain municipalities or datasets. The topic has not yet been raised in discussions in Denmark. Moreover, in Sweden the matter will be examined further by the Swedish government inquiry at a later stage.

4.2.3 HDIEs and fees

The legal group considers that an HDIE may charge applicants the same fees that would otherwise be charged by the health data holder in accordance with the EHDS. The involvement of an HDIE should not result in higher statutory fees for applicants seeking



access to health data. On the contrary, it should rather result in lower statutory fees, as the HDIE already have the necessary tools and resources to make data available, while some health data holders have not and will need to build an EHDS-compliant framework themselves, which will be both time- and money consuming

The legal group further considers that the EHDS does not regulate the commercial arrangements between the health data holder and the HDIE beyond the provisions governing the fees payable by applicants. Accordingly, the financial arrangements between the health data holder and the HDIE, including the remuneration of the HDIE for the services it provides, should be determined by the parties.

The legal group considers that these arrangements should remain a matter for the parties to negotiate rather than being prescribed in legislation. This would allow flexibility for different organisational models and encourage competition between HDIEs based on factors such as cost, efficiency and quality of service, while remaining consistent with the objective of Art. 50(3) EHDS to reduce the administrative burden of health data holders and provide organisational flexibility.

Any remuneration payable to the HDIE, including compensation for operational and administrative costs and any commercial return agreed between the parties, should therefore be covered through the financial arrangements between the health data holder and the HDIE rather than through increased fees charged to applicants.

4.2.4 HDIE's legal responsibility and controllership

TEHDAS2 Guideline 6.1 states that, while HDIEs may carry out operational tasks, the legal responsibility for compliance with the EHDS remains with the health data holder *unless national law explicitly provides otherwise*. This statement raised concern among some members of the legal group. In their view, an HDIE acts as a data processor on behalf of the health data holder, as also reflected in the example provided on page 82 of the same guideline. As a processor does not bear the legal responsibility of the controller for compliance with the GDPR or the EHDS, they questioned whether such responsibility could be transferred to an HDIE by national law.

Other members of the legal group took a different view. They considered that the allocation of responsibilities under the EHDS should be distinguished from the determination of controllership under the GDPR. Regardless of how responsibilities are allocated nationally, the EHDS provides that the data are nevertheless considered to be made available by the health data holders. From this perspective, whether an HDIE acts as a controller, joint controller or processor is determined separately under the GDPR and any applicable national legislation and does not, in itself, determine the allocation of duties or responsibilities under the EHDS.

The legal group did not have enough time to reach a common interpretation on this question. Thus, as a next step, the legal group should revisit the relationship between the allocation of duties under the EHDS and controllership under the GDPR as national implementation models develop. Further guidance from the European Commission or the European Data Protection Board would also be valuable.



4.2.5 Designation of HDIEs and allocation of duties

The legal group agrees with the interpretation adopted in Finnish Government Proposal (5). The group considers that Art. 50(3) EHDS should be interpreted in a manner that fulfils the objective of the Regulation, namely, to reduce the administrative burden of health data holders while allowing Member States flexibility in organising the fulfilment of the duties of HDIEs.

Where a Member State has exercised the national discretion provided by Art. 50(3) EHDS and has established in national law the possibility for health data holders to use HDIEs, each health data holder should remain responsible for deciding whether to make use of an HDIE and for selecting the HDIE with which it wishes to cooperate. The relationship between the health data holder and the HDIE should be based on a contractual arrangement that clearly specifies which of the health data holder's EHDS duties are carried out by the HDIE on its behalf. The allocation of duties should therefore occur through the contractual relationship between the health data holder and the HDIE, rather than through legislation identifying individual HDIEs. Thus, it would be possible for the HDIE to only take some of the duties of the health data holder instead of all of the duties. Moreover, allowing the health data holder to use several HDIEs if considered necessary. This contractual allocation of EHDS duties is conceptually similar to the possibility under the GDPR for a controller to entrust certain processing activities to a processor.

The legal group considers that this interpretation is consistent with both the objective of Art. 50(3) and the intentions expressed during the EHDS negotiations. During the negotiations, the purpose of the provision was understood to be to provide Member States with organisational flexibility and to reduce the administrative burden of health data holders, rather than to require national legislation to designate individual HDIEs or exhaustively define every possible organisational arrangement. Requiring legislative designation of each HDIE would unnecessarily reduce flexibility, require frequent legislative amendments, and limit the development of innovative service providers and market-based solutions.

To ensure legal certainty, transparency and effective supervision, the health data holder should notify the HDAB of the identity of the HDIE and specify which EHDS duties have been entrusted to that HDIE. This enables the HDAB to identify the entity performing the relevant operational tasks while maintaining transparency regarding the allocation of responsibilities.

The legal group considers that this approach provides an appropriate balance between legal certainty, operational flexibility and the objective of reducing the administrative burden of health data holders while remaining consistent with the wording and objectives of Art. 50(3) EHDS.

4.3 Art. 58(3) and 61(5) significant findings

Art. 58(3) Obligations of health data access bodies towards natural persons

Where a health data access body is informed by a health data user of a significant finding related to the health of a natural person, as referred to in Art. 61(5), the HDAB shall inform the health data holder about that finding. The health data holder shall, under the conditions laid down by national law, inform the natural person or health professional treating the natural person concerned. Natural persons shall have the right to request not to be informed of such findings.

Art. 61(5) Duties of health data users

Without prejudice to paragraph 2, health data users shall inform the HDAB of any significant finding related to the health of the natural person whose data are included in the dataset.

The provisions of EHDS pose new and remarkable legal requirements. Art. 61(5) imposes the health data users to inform the HDAB of “any *significant finding related to health*”. This is a huge issue from many points of view. No mention of actionable (ie. treatable or preventative) which is against the clinical, ethical and legal consensus of not reporting non-actionable findings. Where and how to draw an objective line when assessing what is significant?

EHDS will provide access to and merging large amounts of data, such as genomic data, biomarkers, lab values, image data, data from wearables, thus leading to unprecedented possibilities of “any” significant findings in the era of AI. Data sources are manifold varying from clinical data to biobank and research data resulting from biological sample analyses. Use of data in clinical context usually requires validation of the finding with a new sample due to some possible errors in the research context. Some scenarios: a significant finding related to health is a gene variant known to predispose to a disease that is treatable or preventable. What if there is no cure, i.e., the finding is not (yet) actionable at the time of data user’s finding? On the other hand, interpretation of image data with new tools may reveal previously undiagnosed cancer and the information would be critical for the person.

Art. 58(3) sets the information obligation to the data holders, who are diverse, many of them lacking clinical context, such as universities, statistics or research institutes. The information may be provided either to the natural person or to the healthcare professional treating the natural person. Thus, the Member States must enact new legislations for this matter, as Art. 58(3) refers to the process “*under the conditions laid down by national law*”.

In Finland, however, the Act on the secondary use of social and welfare data Section 55 sets the procedure for handling clinically significant and actionable findings in register-based research. In brief, the researcher in that case contacts the Data Permit Authority (Findata) which can reidentify the person, if needed.

The finding must be assessed by a special group in the Finnish Institute of Health and Welfare in terms of its significance, relevance etc. The individuals concerned are never contacted directly but via his or her local health care system. The ethical principle right-not-to-know applies, so the persons can opt-out for receiving this information in advance by registering to Findata’s register or when being contacted for potential health related

information later. To our knowledge, not many significant findings have so far been reported through this process. However, this does not preclude the possibility that significant findings have been reported through alternative channels, such as biobank-specific procedures in Finland.

Norway has national acts relating to health personnel (§10) and patients' rights (§3-2) that give individuals, including patients and research participants, the right to be informed of significant findings concerning their health and, where appropriate, to receive healthcare (7, 8). However, in its public consultation on the implementation of the EHDS (9), the Ministry of Health acknowledged that more detailed national guidance will be needed to implement the requirements of Art. 58(3).

In Denmark, the criteria for when a data subject *can* be informed vary based on the type of project (10, 11, 12, 13).³⁶ For instance, for notifiable health science research projects, the data subject must either suffer from or be certain or highly likely to be at risk of developing, a life-threatening or clearly serious illness, which can be treated, prevented or alleviated. By contrast, for health-related statistical and scientific studies carried out pursuant to § 10 of the Danish Data Protection Act, the data subject must suffer from a life-threatening or clearly serious illness, which is also infectious, and which can be treated.

In Iceland, the Act on Scientific Research in the Health Sector no. 44/2014 (14) grants the Minister of Health the authority to issue Regulations concerning *inter alia* the circumstances in which, and in the manner in which, a participant in a scientific research study shall be informed of important findings that emerge during the conduct of the research and that concern the participants' health, c.f. Art. 34. At the time of the writing of this report, there is no such Regulation in effect.

One must remember also the provisions of the Council of Europe Biomedicine Convention that apply for genetic information. People are entitled for pre- and post-test counselling. Thus, if the significant finding relates to previous unknown condition, the person must be offered access to clinical counselling first.

Overall, this kind of information is complicated to handle. It has potential to both increase the costs of the health care system in an uncontrollable manner but also help people's lives and save the costs. The legal group recommends establishing a European multidisciplinary special task force to guide the legislation. It is essential to have a clear procedure and roles to reap the benefits but avoid the chaos.

Sweden does not currently have legislation nor system that would enable reporting significant findings as described in Arts. 58(3) and 61(5).

³⁶ The Danish regulation on the reporting of significant health findings (BEK nr 736 af 24/05/2022) applies only in relation to notifiable health science and health data science research projects. The Danish Committee Act (LBK nr 1268 af 28/11/2024), notifiable clinical trials of medical devices and performance studies of in vitro diagnostic medical devices. The Danish Clinical Trials Act (LOV nr 1853 af 09/12/2020), as well as health-related statistical and scientific studies carried out pursuant to § 10 of the Danish Data Protection Act (LBK nr 289 af 08/03/2024), which include only personal data from national and regional health registers.

4.4 Art. 62, fees

The legal group agrees that Art. 62 applies from the point at which a data applicant submits an application as described in Arts. 67–69. Any costs incurred before that stage, such as guidance provided by data holders regarding available datasets or support provided by the HDAB on how to complete an application, may be charged in accordance with national rules and practices.

Based on this, the legal group also discussed whether reduced fees for application guidance, provided by HDABs, could be aligned across the Nordic countries to encourage more applicants to conduct research and other projects using Nordic data. As the matter did not raise any legal concerns, the group suggested that it could be discussed further by the HDAB group if considered relevant and feasible given the limited time within VALO2.

The group also concluded that the EHDS does not provide sufficient financial incentives for data holders to invest in improving their systems and infrastructure to make data extraction and other data provision processes more efficient. Such investments cannot generally be recovered through the fees charged to applicants under the EHDS framework.

The group considered that one possible way to address this issue could be the use of a third-party software solution, platform, or similar service that would perform data extraction and other technical tasks required to fulfil the obligations of data holders under the EHDS. The costs of such a solution could be covered through user-based fees or another transparent financing model. A similar lack of incentives was identified in relation to the development of dynamic ready-made datasets.

The group noted, however, that this is ultimately a structural issue within the EHDS framework itself. As such, it should be raised in future discussions between Member States and at the European Union level, with the aim of promoting transparent and equitable fee policies and ensuring that data holders have appropriate incentives to develop efficient data access infrastructures. Within the current framework, there is a risk that datasets from higher-cost countries may be less attractive to applicants due to high costs, potentially leading to situations where research and other activities rely primarily on data from lower-cost countries.

The national implementation proposals currently under consideration further illustrate this concern. In Norway, the public consultation on the implementation of the EHDS (9) proposes that the fees permitted under Art. 62(1) third sub-section should cover the full, and not just part of the actual costs of making the data available, as practice is today. As for the possibility to offer reduced fees in accordance with Art. 62(1) fourth sub-section, the current Norwegian legislation does not allow such a differentiation, but Norway is now considering it under the EHDS for certain categories of health data users such as universities, college sector or public authorities, as well as when data is to be used for legally mandated tasks such as research, quality improvement, and patient safety, or when requesting data that the user has reported themselves to a health register. No final decisions have yet been made.

The Finnish Government Proposal (5) proposes making use of the flexibility provided in Art. 62(1) fourth sub-section by enabling reduced fees for certain categories of health data users, including public health authorities, university and university researchers, and microenterprises, as well as the possibility of waiving fees in exceptional circumstances. The Government is to adopt more detailed provisions by decree regarding the conditions under which reduced fees or fee waivers may be granted. However, no final decisions have yet been made.

These examples demonstrate that Member States are already considering different approaches to the implementation of Art. 62, highlighting the importance of continued dialogue at both the Nordic and European levels regarding the practical implications of divergent national fee policies.

As a next step, the legal group could prepare a joint expert opinion when the draft implementing act on fees is opened for public consultation. The opinion could address the limited incentives for health data holders to invest in efficient data-access infrastructure and the potential effects of different fee levels on cross-border access to Nordic data.

4.5 Consideration of ethical aspects under Art. 68(1)(b)

Art. 54(e) prohibits the use of electronic health data where the intended activity conflicts with ethical provisions laid down in national law. However, it does not necessarily mean that, in the absence of such provisions, ethical considerations are entirely excluded from the HDAB's assessment.

Under Art. 68(1), the HDAB is required to assess whether all conditions for granting a data permit are fulfilled. In particular, Art. 68(1)(b) requires the HDAB to verify that "the requested data are necessary, adequate and proportionate for the purposes described in the health data access application, taking into account the data minimisation and purpose limitation requirements provided for in Art. 66."

The legal group supports an interpretation that this assessment cannot always be carried out solely as a technical or administrative exercise. Evaluating whether the data requested in the data permit application is genuinely necessary, adequate and proportionate for the proposed purpose may, in certain cases, require the HDAB to assess whether the proposed project is scientifically appropriate. This does not amount to a separate ethics review but rather forms part of the HDAB's obligation under Art. 68(1)(b) to assess whether the requested data are justified in relation to the stated purpose. Where appropriate, this assessment may also require the HDAB to consider whether the proposed use raises fundamental ethical concerns that are relevant to determining whether the requested data is necessary, adequate and proportionate for the stated purpose.

For scientific research projects, this may require the HDAB to consider whether the research plan demonstrates that the requested data is necessary to answer the proposed research question. Depending on the study design, this may include internationally recognised elements of scientific quality, such as an appropriate study design, a justification for the requested dataset, and, where applicable, a statistical power

calculation or other equivalent methodological justification. At the same time, the legal group recognises that the assessment must remain proportionate to the nature of the project. For example, exploratory or hypothesis-generating studies may legitimately require broader datasets, making traditional data minimisation assessments less straightforward. In such cases, the appropriateness of the requested data should be assessed in light of the chosen study design and methodology rather than by applying rigid criteria.

The legal group further notes that an applicant should be able to provide concise scientific justification for why the requested data is necessary for the proposed purpose. An inability to explain the methodological basis of the project may indicate that the requirements of Art. 68(1)(b) are not fulfilled. It may also be relevant to the assessment under Art. 68(1)(d), which requires the HDAB to verify that the health data user possesses the expertise necessary to carry out the proposed secondary use in accordance with recognised scientific and professional standards. The legal group therefore considers that Art. 68 does not require the HDAB to grant access to any applicant requesting health data. Rather, it permits the HDAB to assess whether both the proposed secondary use and the applicant demonstrate the scientific and professional competence necessary to justify access to the requested data.

This interpretation is particularly important for applications involving the development or training of artificial intelligence and other algorithmic systems. If Art. 68 were interpreted as preventing any consideration of ethical concerns in the absence of national ethical provisions, an HDAB in such a Member State could be obliged to grant a data permit despite serious ethical concerns, provided that all other formal legal requirements were met. This would leave no mechanism within the EHDS permit procedure to prevent ethically problematic uses of health data, including AI training activities that may raise significant societal or fundamental rights concerns.

The legal group therefore considers that Art. 68(1)(b) should be interpreted as permitting the HDAB to take basic ethical considerations into account, where relevant, as part of its assessment of whether the requested data are necessary, adequate and proportionate for the stated purpose. Such an interpretation does not create a separate ethics review within the EHDS permit procedure but ensures that the HDAB's assessment is sufficiently substantive to support the objectives of the EHDS and to promote the trustworthy and responsible secondary use of health data across Member States.

As a next step, the legal and HDAB groups could consider whether the interpretation developed in this chapter should form the basis of a common Nordic approach to assessments under Art. 68(1)(b). If supported by the participating countries, this approach could then be presented in discussions with the European Commission and other Member States with the aim of promoting a shared interpretation at Union level.

References

1. VALO: [Final report: Nordic model for collaboration on the secondary use of health data - a proposal](#). November 2025
2. Wenkai Li: [Broken Promises? The Ethical Challenge of Making Pre-Existing Datasets Collected on the Basis of Consent Available under the EHDS Regulation](#). 7 July 2026.
3. Statistiska centralbyrån, *Rättsligt utlåtande – Hälsoadatainnehavare*, dnr SCB2025/460. 27.11.2025.
4. TEHDAS2 JA: [Guideline for data holders on making personal and non-personal electronic health data available for reuse](#). 26.2.2026.
5. [Draft governmental proposal regarding the national implementation of the EHDS in Finland](#) August 2026.
6. [The Act on the secondary use of social and welfare data](#).
7. The Act of 2 July 1999 No. 64 relating to Health Personnel.
8. The Act of 2 July 1999 No. 63 relating to patients' rights.
9. [Gjennomføring av forordning \(EU\) 2025/327 om det europeiske Gjennomføring av forordning \(EU\) 2025/327 om det europeiske helsedataområdet og om endring av direktiv 2011/24/EU og forordning \(EU\) 2024/2847 i norsk rett - Forslag til lov om det europeiske helsedataområdet](#)
10. BEK nr 736 af 24/05/2022 [Bekendtgørelse om tilbagemelding om væsentlige helbredsmaessige fund fra anmeldelsespligtige sundhedsvidenskabelige og sundhedsdatavidenskabelige forskningsprojekter, kliniske afprøvninger af medicinsk udstyr, undersøgelse af ydeevne af medicinsk udstyr til in vitro-diagnostik samt visse registerforskningsprojekter](#)
11. LBK nr 1268 af 28/11/2024 the Danish Committee Act.
12. LOV nr 1853 af 09/12/2020 the Danish Clinical Trials Act.
13. Danish Data Protection Act LBK nr 289 af 08/03/2024 Bekendtgørelse af lov om supplerende bestemmelser til forordning om beskyttelse af fysiske personer i forbindelse med behandling af personoplysninger og om fri udveksling af sådanne oplysninger [Databeskyttelsesloven](#)
14. The Act on Scientific Research in the Health Sector no. 44/2014

Annex 6. Full report on ethical aspects

Ethical review requirements for the secondary use of health data in the Nordic countries

*Challenges, comparisons and future collaboration
under the EHDS*

Report 1.0

Value from Nordic health data – VALO2 project

1 October 2026

Document info

0.5 Authors

Author	Partner
Jenina Soimala	The Finnish Institute for Health and Welfare
Ingvild Haaland	REC West, University of Bergen, Norway
Margit Ramberg	REC North, University of Tromsø, Norway
Védís Helga Eiríksdóttir	Directorate of Health, Iceland
Editors	
Christina Møllebro	The Norwegian Institute for Public Health (NIPH)
Susanne Pihl Jakobsen	National Research Ethic Committee (NREC), Denmark
Anne Savolainen	National Board of Health and Welfare, Sweden
Hrefna Dögg Gunnarsdóttir	University of Iceland, Faculty of Law

0.6 Keywords

Keywords

Health data, Nordic, EHDS, ethics review

Disclaimer

The content of this report represents the views of the author(s) and do not necessarily reflect the views of the experts interviewed.

Copyright Notice

Copyright © 2026 The contributing VALO2 Parties and authors identified in this report.

Contents

Executive summary	201
1 Introduction	202
2 National triggers for ethical review in the Nordic countries	204
2.1 Finland	204
2.2 Sweden.....	205
2.3 Norway.....	206
2.4 Denmark	207
2.5 Iceland	209
2.6 Comparison of the Nordic approaches	209
3 Application language.....	211
4 Territorial applicability of national ethical review legislation.....	212
5 Quality assurance versus scientific research	213
5.1 Finland	214
5.2 Sweden.....	214
5.3 Norway.....	214
5.4 Denmark	215
5.5 Iceland	215
5.6 Comparison of quality assurance and scientific research in the Nordic countries.....	216
5.7 Scientific research in the EHDS and GDPR framework.....	217
5.7.1 Scientific research under Art. 53(1)(e) EHDS and TEHDAS2 JA Guideline 5.2.....	218
5.7.2 Scientific research under the GDPR and EDPB Guidelines 1/2026	219
5.7.3 Implications for the Nordic interpretation	220
6 Practical lessons learned from the Work Stream 3 pilots	221
7 Continued Nordic collaboration on ethical review and broader ethical aspects	223
References	227
Annex 6a. Responsible ethical committees and institutions for the national mappings	228
Annex 6b. Action suggestions.....	229

Executive summary

The European Health Data Space will create a common European framework for the secondary use of electronic health data for research, innovation, policymaking and other permitted purposes. However, while the EHDS harmonises access to health data at the European level, decisions on whether a project requires ethical review remain governed by national legislation. This report compares the ethical review frameworks of the Nordic countries, identifies practical differences that may affect cross-border projects and highlights areas where continued Nordic cooperation could support the successful implementation of the EHDS.

The comparison shows that all Nordic countries have well-established systems for research ethics, but they apply different legal triggers for ethical review of secondary use activities. Sweden, Norway and Iceland generally require ethical review for scientific research using health data, while Denmark applies ethical review only to specific categories of research involving sensitive bioinformatic data. Finland differs because secondary use of health data generally does not require statutory ethical review under national legislation. At the same time, Finland has a mature research ethics governance system based on legislation governing other types of research, institutional ethics committees and the principles of good scientific practice promoted by the Finnish National Board on Research Integrity. The comparison shows that the national approaches have overlapping practical features, although their legal triggers, definitions and procedures differ.

One of the report's main findings is that the distinction between quality assurance and scientific research remains one of the most important practical sources of uncertainty for applicants. In all Nordic countries except Finland, classifying an activity as quality assurance or research forms the starting point for determining whether ethical review may be required. Although the national approaches have overlapping practical features, the countries do not apply a uniform legal definition or a single common test. Differences in the applicable legal frameworks, classification criteria and their interpretation may therefore result in similar projects being classified differently across countries, reducing predictability and increasing the administrative burden for multinational research projects.

The experiences from VALO and VALO2 pilots illustrate how these differences can affect cross-border projects in practice. During the VALO2 pilot, the classification of the project as scientific research in Norway resulted in a different regulatory pathway and additional procedural requirements, than in the previous VALO pilot, demonstrating how national ethical review requirements and related procedures can influence project planning and timelines. At the same time, the pilot confirmed that ethical review and related national requirements are one important component of the broader operational framework needed for successful cross-border secondary use of health data under the EHDS.

The report concludes that continued Nordic collaboration and shared interpretation will be essential to support successful EHDS implementation and improve predictability for cross-border projects. It also emphasises that ethics committees and ethical expertise should be actively involved in EHDS implementation now, rather than only once the first secondary-use applications are submitted. Early involvement will help identify practical

challenges, promote consistent interpretation of national requirements and strengthen cooperation between ethics committees, Health Data Access Bodies and other stakeholders before the EHDS becomes fully operational.

1 Introduction

The European Health Data Space (EHDS) establishes a common legal framework for the secondary use of electronic health data across the European Union. While much of the discussion surrounding the EHDS has focused on Health Data Access Bodies (HDABs), secure processing environments (SPE), interoperability and data quality, one provision of the Regulation became the spark for the ethical work carried out within the VALO2 project.

Art. 54(e) of the EHDS provides that access to and processing of electronic health data shall not take place where such processing would conflict with ethical provisions laid down in national law. Although the EHDS creates a harmonised European framework for secondary use of health data, ethical requirements remain governed by national legislation.

At first glance, this may appear straightforward. However, the provision immediately raises several practical questions. What does this mean for an applicant seeking access to health data from several countries? Could the same project require ethical review in one country but not in another? Could different national ethical requirements delay or even prevent cross-border access to health data under the EHDS? If so, where are the biggest differences and can any of these bottlenecks be addressed before the EHDS becomes fully operational?

During the stakeholder interviews conducted within Work Stream 1 of VALO, it also became evident that although Nordic health data are internationally recognised as a valuable resource for research and innovation, accessing these data remains burdensome (1). Considerable attention has been devoted to legal, technical and organisational barriers, while the potential impact of national ethical requirements has received much less discussion. At the same time, ethics committees have so far been only marginally involved in broader EHDS implementation activities, despite the fact that they will continue to play an important role wherever national legislation requires ethical review and may also support HDABs under the EHDS framework. Consequently, an ethical expert group was established within VALO2 to map the current national ethical review landscapes across the Nordic countries, identify similarities and differences, assess what future applicants under the EHDS may need to navigate, and contribute ethical expertise to the broader implementation of the EHDS.

The objective of the work was not to evaluate national ethical systems. Instead, the aim was to understand how national ethical requirements may influence cross-border secondary use of health data, identify potential implementation bottlenecks, and explore where greater transparency, cooperation and harmonisation among the Nordic countries could facilitate the implementation of the EHDS and further strengthen the attractiveness of Nordic health data.

The VALO2 ethical expert group consisted of experts from different ethical committees, with varying capacity, from all Nordic countries. The work focused on mapping the national legislation governing ethical review requirements relevant to the secondary use of health data. The ethical expert group was established in March 2026.³⁷ As the experts had not previously participated in the VALO2 project, part of the work involved familiarising the group with VALO, the EHDS, its objectives and the specific questions relevant to secondary use of health data. Due to the limited timeframe available, it was unfortunately not possible to involve ethical experts from the observer countries, Estonia and Lithuania, in the mapping exercise. Their perspectives would be a valuable addition to any future continuation of this work.

The mapping demonstrated that notable differences exist between the Nordic countries. In particular, Finland and Denmark differ from the other Nordic countries in that register-based research generally does not require ethical review under national legislation or it is required only in specific cases, whereas Sweden, Norway, and Iceland currently do require ethical review, although the legal triggers differ between countries.

The findings demonstrate that an applicant seeking access to health data from several Nordic countries may encounter different ethical requirements depending on the country, the type of data requested, the purpose of the project and, in some cases,³⁸ [OBJ]. Some of these differences, such as application language requirements or administrative procedures, may be relatively straightforward to address through administrative changes. Others, including the distinction between quality assurance (QA) and scientific research, national ethical review triggers and broader legislative differences, are more deeply rooted in national legal systems and will require continued dialogue and, potentially, legislative reform.

For this reason, the expert group devoted particular attention to the distinction between QA and scientific research. This issue emerged as one of the most significant practical challenges identified during the mapping and represents an area where continued Nordic collaboration could contribute to greater transparency, predictability and mutual understanding in the implementation of the EHDS.

This report summarises the findings of this Nordic mapping exercise, discusses the principal ethical bottlenecks identified by the expert group and outlines considerations for future Nordic cooperation on ethical review in support of the successful implementation of the EHDS. In particular, it highlights the importance of involving ethics committees and ethical expertise in EHDS implementation at an early stage so that national ethical review systems, HDABs and other actors can develop coherent practices before the EHDS becomes fully operational.

³⁷ The national mapping exercise within the VALO2 project was conducted between March and May 2026 by bioethics and ethics committees or their representatives in the Nordic countries. See Annex 1.

³⁸ That is, whether the project's activities are sufficiently connected to a particular country for that country's ethical review legislation to apply.

2 National triggers for ethical review in the Nordic countries

The following chapters provide country-specific summaries based on the national mapping exercises carried out within the VALO2 project. Information on the institutions and experts responsible for each national mapping is provided in Annex 6a. The country summaries are followed by a comparative analysis of the key findings.

2.1 Finland

Finland differs from the other Nordic countries because there is no binding national legislation that requires an ethical review solely on the basis that health data are used for secondary purposes. Register-based research and other studies relying on secondary use of health data do not require a separate ethical review under Finnish law.

This does not mean that ethical review does not exist in Finland. Rather, ethical review is linked to other types of research. Medical research involving interventions on human participants is regulated by the Medical Research Act (488/1999) (2), while non-medical research involving human participants is assessed under the ethical guidelines of the Finnish National Board on Research Integrity (TENK) (3). These frameworks are outside the scope of EHDS secondary use and therefore do not generally apply to register-based research using existing health data.

Finland nevertheless has a well-established system of research ethics governance. In addition to the statutory ethics review system established under the Medical Research Act, universities, research organisations and many healthcare organisations maintain ethics committees for research falling outside the scope of that Act, and the principles of good scientific practice promoted by TENK are widely followed (4). In practice, some data holders or organisations responsible for handling data access requests may, in individual cases, request applicants to obtain an ethics committee opinion where a project raises particularly sensitive ethical issues. Such practices reflect institutional governance and established research ethics practices rather than a general statutory requirement applicable to the secondary use of health data. According to TENK's guidelines, an ethics committee opinion may also be requested where this is required by a research funder, collaborative partner, the subject of the research or a scientific publisher, even where Finnish legislation does not otherwise require an ethical review of the project. Ethical review may therefore be requested for several non-statutory reasons, including funding or publication requirements and institutional policies. The existence of these established ethics review structures demonstrates that Finland already possesses a mature research ethics governance framework. Should future legislative developments related to the EHDS make statutory ethical review more widely applicable to the secondary use of health data, implementation could build upon these existing mechanisms rather than requiring the creation of an entirely new system.

Consequently, no specific purpose, data category, research method or territorial factor triggers a statutory ethical review under Finnish law for the secondary use of health data. Register-based research, research using pseudonymised data, research using anonymised data and other secondary use of health data do not require ethical approval solely because health data are processed.

Unlike the other Nordic countries, Finland therefore does not distinguish between QA and scientific research for the purpose of determining whether a statutory ethical review is required in the secondary use of health data. This topic is discussed further in Chapter 5

Thus, Finland is a clear outlier among the Nordic countries. While the other countries have statutory ethical review requirements for at least some categories of secondary use of health data, Finland generally relies on the data permit process and other legal safeguards rather than a mandatory ethical review.

2.2 Sweden

The legal basis for ethical review in Sweden is the Ethical Review Act (2003:460) concerning the Ethical Review of Research Involving Humans (5). For EHDS secondary use, this is the primary legislation determining whether ethical review is required, although other national legislation and EU legislation may also apply.

Sweden applies a mixed trigger, meaning that the purpose of the project, the type of data and where the research is conducted determine whether ethical review is required. The following two requirements are cumulative, meaning that an ethical review is required if both conditions are present.

Firstly, the scientific research involves special categories of personal data, according to Art. 9.1. GDPR or human biological material. This includes scientific research, development and innovation, training, testing and evaluation of algorithms, and education activities that constitute scientific research. As register-based research using Swedish health data will almost always involve special categories of personal data, this condition is generally applicable.

Secondly, according to the guidance published by the Swedish Ethical Review Authority (FAQ), ethical review is required in Sweden whenever any part of the so-called implementation phase of a research project is to be carried out in Sweden. The activities comprising the implementation phase include the recruitment of research participants, the collection of research data or other research material, the conduct of research procedures or interventions, and the analysis and processing of research data.

Where a foreign researcher intends to collect data in Sweden—for example, by collecting or obtaining data—for the purpose of conducting further research in another country, Swedish ethical approval is required for the data collection activities (6). The storage of research data constitutes part of the research. Consequently, even where a Swedish researcher collects data abroad, the research is considered to be conducted in Sweden once the data collection results in the storage of research data in Sweden.

If only one or none of these two cumulative conditions are met, ethical approval is not required in Sweden.

Furthermore, Sweden distinguishes between QA and scientific research. Projects classified as QA or quality development generally do not require ethical review, whereas projects classified as scientific research generally require ethical review where the research involves special categories of personal data or biological material. The

distinction between these two categories is not always straightforward and is discussed in more detail in Chapter 5

Ethical review is generally not required for:

- Art. 53(a) EHDS – public interest activities;
- Art. 53(b) EHDS – policymaking activities;
- Art. 53(c) EHDS – official statistics, including statistics within the meaning of Art. 3(1) of Regulation (EC) No 223/2009;
- certain activities under Art. 53(d) EHDS, where education or teaching is carried out solely for educational purposes and does not constitute scientific research; and
- projects where no personal data according to GDPR or special categories of personal data, according to art. 9.1. GDPR are processed.

Applications for ethical review must be submitted in Swedish, although the research plan and the principal investigator's CV may be submitted in English (7). Different language requirements apply to clinical trials, which fall outside the scope of this report.

Ethical approval must exist before data is requested or accessed. Ethical review is carried out by the Swedish Ethical Review Authority (*Etikprövningsmyndigheten*), with appeals handled by the Ethical Review Appeals Board (*Överklagandenämnden för etikprövning*).

2.3 Norway

The legal basis for ethical review in Norway is primarily the Health Research Act (Act of 20 June 2008 No. 44) (*Helseforskningsloven*) (8). Other relevant legislation includes the Health Personnel Act (*Helsepersonelloven*) and the Health Register Act (*Helseregisterloven*). For EHDS secondary use, the Health Research Act is the primary legislation determining when ethical review is required.

Ethical review is required where a project constitutes medical and health research, meaning research conducted using scientific methods to generate new knowledge about health and disease. The requirement applies to directly and indirectly identifiable personal health data. For the purposes of this report, the relevant EHDS data categories are Art. 51(a), (b), (d), (e), (f), (g), (h), (i), (k), (l), (m), (n), (o), (p) and (q).

The Health Research Act applies to all medical and health research conducted on Norwegian territory, or to research performed under the direction of a person or body established in Norway.³⁹ If those substantive conditions are met and the project falls

³⁹ For example, where a Swedish research institution is responsible for a project and the Norwegian health data are stored and processed in Sweden, the project may fall outside the territorial scope of the Norwegian REC, provided that no research is conducted in Norway and no research-responsible person or body established in Norway directs the project. Limited cooperation with Norwegian researchers does not, by itself, alter this conclusion. In that case the granting authorities, will require the project to present an ethical review from Sweden.

within the territorial scope of the Act, ethical review is required. Ethical approval must be obtained before access to the data is granted.

Norway distinguishes between QA and scientific research. Projects classified as QA generally do not require ethical review, whereas projects classified as medical and health research do. The distinction between these categories is not always straightforward and is discussed in more detail in Chapter 5

Ethical review is generally not required for:

- QA and educational purposes;
- research that is not medical and health research;
- projects using genuinely anonymous data; and
- projects using only data from Norwegian health registries once the adopted amendments to the Health Research Act enter into force (Art. 51(k), (l) and (o)).

Amendments to the Health Research Act have been adopted and are expected to enter into force during 2026. Once the amendments are in force, research using only data from Norwegian health registries will be exempt from ethical review. If registry data are combined with other types of data, such as medical records or questionnaire data, ethical review will still be required where the project otherwise falls within the scope of the Health Research Act.

⁴⁰ ~~only~~, an exemption from the duty of confidentiality may still be required under the Health Personnel Act or the Health Register Act. Depending on the type of data and the purpose of the project, the exemption may be granted by a Regional Committee for Medical and Health Research Ethics (REC), the Norwegian Health Data Service (HDS), the Norwegian Directorate of Health or the relevant institution.

Applications for ethical review are generally submitted in Norwegian, although another language may be accepted where properly justified. Ethical review is carried out by one of the Regional Committees for Medical and Health Research Ethics (9). The National Committee for Medical and Health Research Ethics acts as the appeal body.

2.4 Denmark

In Denmark, register research *solely* based on health data (e.g. from administrative or patients register) does not require ethical approval, unless it concerns certain sensitive data, which at present only includes genome- and image data and there is Danish research activity. Thus, making these two criteria cumulative. The legal basis for ethical review is the Committee Act (*Lov om videnskabetisk behandling af sundhedsvidenskabelige forskningsprojekter og sundhedsdatavidenskabelige forskningsprojekter*) (10).

⁴⁰ This applies for using data from medical records without consent or health registries that are not based on consent.

Ethical review is required for scientific research based on the secondary use of sensitive bioinformatic data originating from clinical care or from a previous research project, where the project involves extensive genomic mapping or diagnostic imaging, cf. § 21 b of the Committee Act. The relevant EHDS data categories include genomic data and imaging data corresponding to Art. 51(f) and, depending on the source of the data, Arts. 51(m), 51(n) and 51(q). Register-based research requires ethical review only where it involves these categories of sensitive bioinformatic data. However, if health data is also used as a part of a clinical medicine trial, a medical device trial, or a general health research intervention trial, the ethical rules governing those trials in Denmark will apply according to article 18 of the Committee Act (10, 11, 8).

Danish research activity means research activities carried out in Denmark by a researcher/investigator whose place of work is located in Denmark. Consequently, where a multinational consortium includes a Danish partner, Danish ethical review is required only if that partner performs a certain amount of research activities in Denmark. The mere inclusion of a Danish organisation in a consortium does not, in itself, trigger Danish ethical review. In practice, the research ethics committees may need to assess whether a project includes Danish research activity.

Denmark distinguishes between QA and scientific research. Projects classified as quality control or quality improvement generally do not require ethical review, whereas qualifying health data research projects may require ethical review where the conditions of the Committee Act are fulfilled. It may, however, be difficult in practice to determine whether a project constitutes research or quality control. This distinction is discussed further in Chapter 5

Ethical review is generally not required for:

- quality control and quality improvement;
- research using only data, such as register-based research based on administrative or clinical registers;
- health research involving only questionnaires or interviews; and
- health research using data from patient records only, although such projects require approval under the Health Act rather than ethical review under the Committee Act.

Applications concerning research on sensitive health data solely (genome- and imaging data) are submitted to the National Research Ethics Committee (NREC). Ethical approval must be obtained before access to the data. The assessment is substantive and considers, among other things, whether the project contributes valuable new knowledge, whether there are sufficient grounds for conducting the project, whether the conclusions are justified, whether participants' privacy and integrity are adequately protected, and whether appropriate procedures are in place for handling incidental findings.

2.5 Iceland

The legal basis for ethical review in Iceland is the Act on Scientific Research in the Health Sector No. 44/2014 (13). It governs the secondary use of existing health information, health registers and biobank data for scientific research.

Iceland applies a mixed trigger, meaning that ethical review depends on the purpose of the project, the type of data, and the project's territorial connection to Iceland. Ethical review is required where scientific methods are applied to health data in order to generate new knowledge about health or disease. The requirement applies to identifiable and pseudonymised health data across all EHDS data categories under Art. 51, including register-based research and research using biobank data.

Iceland distinguishes between QA and scientific research. QA, quality improvement, and administrative or statistical activities that do not aim to generate new scientific knowledge generally do not require ethical review. In practice, the distinction is based primarily on the purpose of the activity and whether the objective is to produce new, generalisable scientific knowledge or to improve local services or healthcare delivery. This distinction is discussed in more detail in Chapter 5

Ethical review is generally not required for:

- QA and quality improvement activities;
- administrative or statistical uses of health data that do not aim to generate new scientific knowledge.

The ethical review requirement is not linked to the nationality of the applicant. Instead, it is primarily connected to Icelandic data and participants. The Act applies where Icelandic health data are used, or the participants are located in Iceland. Applications are generally submitted in Icelandic, although English may be accepted in exceptional cases. The principal investigator may also need to demonstrate proficiency in Icelandic on a case-by-case basis.

Ethical approval must be obtained before data are accessed. Ethical review is primarily carried out by the Icelandic National Bioethics Committee, although studies conducted entirely within Landspítali University Hospital or Akureyri Hospital may instead be reviewed by the institutional review board of the respective hospital. The assessment is substantive and considers, among other things, whether the acquisition, use and disclosure of health data are proportionate to the research objectives, whether the requested data are adequate and relevant, and whether participants' dignity, rights and privacy are adequately protected.

2.6 Comparison of the Nordic approaches

Although all Nordic countries have established governance mechanisms for the secondary use of health data, their approaches to ethical review differ considerably. Consequently, an applicant seeking access to health data from several Nordic countries may encounter different legal requirements depending on the country from which the data are requested.

The most significant difference concerns the circumstances in which ethical review is required. Sweden and Iceland generally require ethical review for scientific research involving secondary use of health data. Norway currently follows a similar approach for medical and health research but is moving towards exempting certain register-based research. Denmark applies a more targeted approach, where ethical review is required only for specific categories of secondary-use research involving sensitive bioinformatic data and where the Danish legislation applies to the research activities concerned. Finland differs from the other Nordic countries in that secondary use of health data, including register-based research, does not generally require a statutory ethical review.

The comparison also demonstrated that the legal basis for ethical review varies considerably across the Nordic countries. Iceland primarily links ethical review to the purpose of the project and the project's connection to Icelandic data or participants. Norway and Denmark both apply a sequential assessment. In Norway, the project must first qualify as medical and health research within the scope of the Health Research Act and, secondly, fall within the territorial scope of that Act. In Denmark, the project must first fall within the substantive scope of the Committee Act and, secondly, involve research activities to which the Danish legislation applies. In Sweden, the scientific research must involve special categories of personal data or human biological material and, secondly, the research is conducted in Sweden. Consequently, projects with similar objectives may be subject to different ethical requirements depending on the applicable national legislation.

The comparison further showed that, although all Nordic countries recognise that secondary use of health data may be carried out for different purposes, the legal significance of these purposes varies. In Sweden, Norway, Denmark and Iceland, the distinction between scientific research and QA may determine whether ethical review is required. In Finland, by contrast, this distinction does not determine whether a statutory ethical review is required for the secondary use of health data.

At the same time, the comparison demonstrated that differences in statutory legislation do not necessarily reflect the broader research ethics landscape. All Nordic countries have established research ethics governance structures, although these are organised differently. In Finland, for example, universities, research organisations and other institutions maintain ethics review mechanisms and principles of good scientific practice are widely applied, despite the absence of a general statutory ethical review requirement for EHDS-type secondary use of health data. This suggests that the practical differences between the Nordic countries may be less pronounced than the legislative comparison alone would indicate and provides a strong foundation for continued Nordic cooperation in the implementation of the EHDS.

Based on this comparison, the ethical expert group identified several practical issues that may affect future EHDS applicants irrespective of the underlying legal model. These include:

- application language requirements;
- the territorial applicability of national ethical review legislation in cross-border projects; and

- the distinction between QA and scientific research.

These topics are discussed in the following chapters.

3 Application language

One practical difference identified during the comparison concerns the language in which ethical review applications may be submitted. While Finland does not have a statutory ethical review process for EHDS-type secondary use of health data, the other Nordic countries generally require ethical review applications to be submitted in their national language.

In Sweden, applications must be submitted in Swedish, although the research plan and the principal investigator's curriculum vitae may be submitted in English. In Norway and Iceland, applications are generally submitted in the respective national language, although another language may be accepted where justified. Denmark accepts applications with protocols in English as well as Danish (however material targeted trial subjects or laypersons must be in Danish). Guidance materials are likewise primarily available in the respective national languages.

The ethical expert group acknowledges that national language requirements may facilitate communication between applicants and ethical committees and may encourage collaboration with local partners who are familiar with the national legal and healthcare context. In some cases, requiring the national language may therefore be justified.

However, language requirements may also create an unnecessary administrative barrier for international applicants. Where local partners are involved primarily to prepare or submit ethical review applications rather than because of their scientific expertise, collaborations risk becoming driven by administrative necessity instead of scientific value. This may be particularly challenging for multinational projects seeking access to health data from several Nordic countries, where applications may need to be prepared in multiple languages.

The ethical expert group therefore considered that allowing ethical review applications and guidance materials to be submitted and accessed in English should be explored, while recognising that national authorities may still require parts of the process to be conducted in the national language where this is considered necessary. Lowering language barriers would enable researchers to engage more directly with the application process, facilitate cross-border collaboration and improve the accessibility of Nordic health data resources. At the same time, collaborations could increasingly be built around complementary scientific expertise rather than administrative requirements, thereby supporting the objectives of the European Health Data Space and strengthening the Nordic region's attractiveness as an international research environment.

4 Territorial applicability of national ethical review legislation

In addition to differences in the substantive legal triggers for ethical review, the comparison identified differences in the territorial applicability of national ethical review legislation. While the substantive trigger determines whether a project falls within the scope of a country's ethical review system, territorial rules determine whether that country's legislation applies to a particular project.

Among the Nordic countries, Denmark, Norway and Sweden apply explicit territorial conditions. In Sweden, ethical review is required where the research falls within the substantive scope of the Ethical Review Act and any part of the research project's implementation phase is carried out in Sweden. This phase includes recruiting research participants, collecting research data or other research material, conducting research procedures or interventions, and analysing, processing or storing research data. Accordingly, Swedish ethical approval is required where a foreign researcher collects or obtains data in Sweden for further research abroad. Research is also considered to be conducted in Sweden where data collected abroad are stored in Sweden. In Norway, the Health Research Act applies to all medical and health research conducted on Norwegian territory or to research performed under the direction of a person or body established in Norway. Similarly, in Denmark, the Committee Act applies to research activities carried out in Denmark, by a researcher/investigator, whose place of work is located in Denmark. In multinational research consortia, Danish ethical review is therefore required only where a Danish partner performs a certain amount of research activities in Denmark and the project otherwise falls within the substantive scope of the Committee Act. The mere inclusion of a Danish organisation in a consortium does not, by itself, make the Danish ethical review legislation applicable. Similar considerations concerning the applicability of national ethical review requirements in multinational research consortia also apply in Norway.

In Iceland, the applicability of the legislation is linked primarily to the use of Icelandic health data and participants rather than to the nationality or establishment of the applicant. Finland likewise does not apply comparable territorial conditions for statutory ethical review of EHDS-type secondary use of health data.

The expert group acknowledges that territorial rules are a natural feature of national legislation, ensuring that ethical committees exercise jurisdiction only over projects with a sufficient connection to the country concerned. However, from the perspective of international applicants, these rules are not always easy to identify or interpret, particularly in multinational research consortia where research tasks are shared between several organisations.

The expert group also notes that differences in the territorial applicability of national ethical review legislation may unintentionally influence the composition of multinational research consortia. Where the involvement of a partner from a particular country may result in additional ethical review or procedural requirements, there may be an incentive to allocate research activities to partners in other jurisdictions or to limit the involvement of organisations from countries where additional requirements apply. Such

considerations could reduce opportunities to involve the most appropriate scientific or clinical expertise and may undermine the objective of the EHDS to facilitate effective cross-border collaboration in the secondary use of health data. Greater transparency regarding the territorial applicability of national legislation, together with greater harmonisation where appropriate, could help ensure that consortium composition is driven primarily by scientific expertise and project needs rather than differences in national regulatory requirements.

The expert group therefore recommends that the territorial applicability of national ethical review legislation be described more clearly in national guidance materials. In addition, common Nordic guidance for multinational research projects could improve legal certainty by explaining when a country's ethical review legislation applies and how responsibilities should be allocated between consortium partners. Greater transparency would reduce unnecessary administrative uncertainty while supporting the objectives of the EHDS to facilitate cross-border secondary use of health data.

5 Quality assurance versus scientific research

One of the main findings of the ethical expert group concerns the distinction between QA and scientific research. In all Nordic countries, except Finland, this distinction is important because it influences whether ethical review needs to be considered. Projects classified as QA generally do not require ethical review. Whereas, if a project is classified as scientific research, ethical review may be required depending on the applicable national legislation and whether the relevant legal conditions are fulfilled.

As a result, the same multinational project, applying for the same or similar health data, may be classified as QA in one Nordic country and as scientific research in another. This reduces predictability for applicants, increases administrative burden and may discourage researchers from seeking access to health data from several Nordic countries.

Based on the work carried out by the ethical expert group, it became evident that drawing the line between QA and scientific research is challenging across the Nordic countries. Although similar principles exist, each country has developed its own interpretation and framework. The experts also noted that variation occurs not only between countries but, in some cases, also between individual ethical committees or other competent authorities within the same country.

The practical implications of these differences were also demonstrated during the Work Stream 3 pilot of the VALO2 project (remote access to secure processing environments), where the classification of a project as scientific research rather than QA affected the applicable legal requirements and the time needed to obtain access to health data. The pilot experiences are discussed further in Chapter 6

The following chapters describe how QA and scientific research are currently understood in the Nordic countries, how they differ and align. The scientific research definition is then reflected against the European Data Protection Board Guidelines 01/2026 on the processing of personal data for scientific research purposes (14) and the TEHDAS2 Joint

Action Guideline 5.2 for Health Data Access Bodies on minimum categories and limitations on the reuse of electronic health data (15).

5.1 Finland

Finland does not have written guidance distinguishing QA from scientific research when assessing applications for access to health data for secondary use.

5.2 Sweden

There are no legal definitions within the healthcare sector of the exact term “QA”. But there are references to QA requirements established in various laws, regulations, and related provisions. The purpose of QA is, inter alia, to ensure that patients receive safe and high-quality care. QA within healthcare is linked to the responsibility of the individual healthcare provider to ensure that the activities conducted comply with applicable legal requirements and maintain adequate standards of quality and patient safety.

In the Swedish context, QA in healthcare versus medical research are also conducted within separate areas of operation and serve fundamentally different purposes and objectives.

Scientific research, by contrast, is defined broadly as experimental, theoretical or observational work conducted to acquire new knowledge, including scientifically based development work. Activities carried out solely within Bachelor or Master education are excluded from the definition of research and are therefore exempt from ethical review.

5.3 Norway

QA is defined as projects, investigations and evaluations with the purpose of controlling that diagnostics and treatment actually give the intended results. The distinction between QA and medical and health-related scientific research is linked to the fact that national legislation obliges the health and care sector to work systematically on quality assurance and on patient and user safety.

To determine the difference between scientific research and QA, Regional Ethics Committees (REC) often uses the Council of Europe’s Guide for Research Ethics Committee Members: Research is about obtaining new knowledge; about finding out what is or will become best practice – e.g. ‘What is the most effective way of treating pressure sores?’. Quality assurance is about quality; about finding out if best practices are being followed – e.g. ‘How are we treating pressure sores and how does this compare with accepted best practice?’.

A proposed approach is to concentrate on three key issues:

- 1) Is the purpose of the proposed project to try to improve the quality of patient care in a local setting?
- 2) Will the project involve evaluating practice against standards?
- 3) Will the patients undergo something that is not otherwise part of the normal routine treatment?

If the answer to the first two questions is 'yes' and the answer to the third is 'no', the project is probably QA, otherwise it is probably research.

QA is exempt from ethical review under Norwegian legislation. Nevertheless, despite the available guidance, differing interpretations still occur between regions. If the project manager is unsure whether or not the project is considered to be research or QA, they can submit the question to the ethical review committee (REC) in Norway for an assessment, before proceeding with a formal application. A similar approach is used in Iceland.

Medical and health research is defined as activity conducted using scientific methods to generate new knowledge about health and disease.

5.4 Denmark

Quality control and quality development do not have to be reported to a research ethics committee.

The Danish research ethics committees assess whether the project falls under the definition of health research defined in the Committee Act. The term 'health research' in the Committee Act encompasses treatment, diagnosis, prevention and rehabilitation. 'Research' is defined as a planned activity aimed at systematically acquiring knowledge about the etiology of diseases, or about the prevention, diagnosis, treatment and rehabilitation of people, as well as about human biological, physiological or psychological processes and genetic predispositions.

There is no single general definition of scientific research. Instead, the assessment focuses on whether an activity constitutes a health research project rather than, for example, QA or patient care. In practice and by law, research is understood as projects that aim to generate or evaluate new knowledge within the field of health research, see above. Whether the results are published may be taken into account in the assessment, but this is not in itself decisive.

5.5 Iceland

Only health research studies are subject to approval by the National Bioethics Committee. Under Art. 3(1) of Act No. 44/2014, health research is defined as research involving human participants, biological samples, or health data, in which scientific methods are applied to increase knowledge about health and disease (13). If it is unclear whether a project constitutes health research falling within the Committee's remit, or another type of research, such as a quality assessment project that does not fall within the Committee's remit, an application must be submitted to the Committee for assessment. A similar approach is used in Norway.

In its assessment, the Committee seeks to evaluate the project, based on the information provided in the application. Factors considered may include, among other things, the background of the researchers, the study population (healthy individuals or patients), and the purpose and objectives of the project. The mere fact that questions are asked about physical or mental health do not make project health research. Quality improvement

projects have generally not been considered subject to approval by the Committee. Quality improvement projects are understood to be projects carried out entirely within an institution by its own staff, with the genuine purpose of improving practice, for example by enhancing procedures or workflows. Such projects have therefore not generally been regarded as falling within the Committee's approval requirements. Example: A project examining whether a change in the registration process for patients attending an out-of-hours primary care service resulted in shorter waiting times would typically be considered a quality improvement project rather than research requiring ethical approval.

5.6 Comparison of quality assurance and scientific research in the Nordic countries

Across the Nordic countries, QA and scientific research share certain common characteristics, but the terminology, legal definitions and criteria used to distinguish them differ. The purpose of the activity is an important consideration in all countries, but it is not the only or necessarily decisive criterion.

QA is understood as an activity that:

- aims to monitor, evaluate or improve the quality of healthcare or healthcare services;
- focuses on local practice or organisational development;
- supports patient safety, quality management and the continuous improvement of healthcare; and
- does not primarily seek to generate new, generalisable knowledge.

Scientific research, in turn, is generally understood as an activity that:

- uses scientific methods;
- aims to generate or evaluate new knowledge;
- is systematic and research-oriented rather than operational; and
- seeks results that extend beyond the immediate organisation or healthcare setting.

Despite these common principles, the comparison identified several important differences between the Nordic countries.

- Basis of the distinction
 - Norway and Iceland primarily distinguish QA from scientific research based on the purpose of the activity, focusing on whether the objective is to improve local healthcare or to generate new knowledge.
 - Sweden applies a broad statutory definition of research while recognising QA as a separate operational activity. There is no exact legal definition of QA within the healthcare sector. Instead, QA requirements are established in various laws, regulations and related provisions and are linked to the responsibility of healthcare providers to ensure the quality and safety of their activities.



- Denmark assesses whether an activity falls within the definition of a health research project under the Committee Act rather than constituting QA or patient care. The term “health research” encompasses treatment, diagnosis, prevention and rehabilitation. Research is understood as a planned activity aimed at systematically acquiring knowledge within these fields. Whether the results are intended for publication may be taken into account, but this is not in itself decisive.
- Finland does not have specific guidance distinguishing QA from scientific research when assessing applications for secondary use of health data.
- Interpretation in practice
 - Sweden, Norway, Denmark and Iceland all reported that distinguishing QA from scientific research may be challenging, particularly where existing health data are analysed using scientific methods.
 - The experts also noted that interpretations differ not only between countries but, in some cases, also between organisations and individual ethical committees or other competent authorities.
 - In Norway and Iceland, a project may be submitted to the competent ethics committee for an assessment if it is unclear whether the activity constitutes research or QA.
- Practical consequences
 - In all Nordic countries, except Finland, the classification of a project as QA or scientific research forms the starting point for assessing whether ethical review is required. Where a project is classified as scientific research, the applicable national legislation must then be assessed to determine whether the remaining legal conditions for ethical review are fulfilled. Classification as research does not therefore mean that ethical review is automatically required.

Overall, the comparison demonstrates that the Nordic countries have overlapping practical understandings of QA and scientific research, but they do not apply a uniform legal definition or a single common test for distinguishing them. The principal differences concern the legal frameworks, classification criteria and their application in practice. These differences may lead to similar projects being classified differently across countries, reducing predictability for applicants seeking access to health data from multiple Nordic countries.

5.7 Scientific research in the EHDS and GDPR framework

The previous sections demonstrated that, in the Nordic countries, except Finland, the distinction between QA and scientific research forms the starting point for assessing whether a project may be subject to ethical review. Although similarities exist between the national approaches, differences exist in how the boundary between QA and scientific research is interpreted and applied in practice.

These national approaches should also be considered in the broader European legal context. This chapter therefore reflects the Nordic approaches against the European Data Protection Board (EDPB) Guidelines 01/2026 on the processing of personal data for scientific research purposes (14) and the TEHDAS2 Joint Action Guideline 5.2 for Health Data Access Bodies on minimum categories and limitations on the reuse of health data (TEHDAS2 Guideline) (15). Particular attention is given to the EHDS secondary use purposes relating to scientific research, including development and innovation activities, and the training, testing and evaluation of algorithms, artificial intelligence (AI) systems, medical devices and digital health applications, which are expressly recognised under Art. 53(1)(e) EHDS.

When an applicant requests access to health data under the EHDS for the purpose of scientific research, both the HDAB and, where applicable, national ethics committees may assess the proposed activity. Although these bodies perform different legal functions, they may assess the same project from different perspectives. The HDAB determines whether the proposed use falls within one of the permitted secondary use purposes under Art. 53 EHDS, while the ethics committee assesses whether national ethical review requirements are fulfilled.

The EHDS preserves the application of national ethical requirements through Art. 54(e). However, while Member States remain competent to determine when ethical review is required under their national legislation, the concept of scientific research should be interpreted consistently with the broader European legal framework. Consequently, when assessing whether a project constitutes scientific research or QA, national approaches should be considered in light of the EHDS, the GDPR and the relevant European guidance. The following sections examine these European instruments and their relevance for interpreting the distinction between QA and scientific research.

5.7.1 Scientific research under Art. 53(1)(e) EHDS and TEHDAS2 JA Guideline 5.2

Art. 53(1)(e) EHDS identifies scientific research as an allowed purpose for the secondary use of electronic health data. The provision explicitly includes:

- development and innovation activities for products or services; and
- training, testing and evaluation of algorithms, including in medical devices, in vitro diagnostic medical devices, AI systems and digital health applications.

The TEHDAS2 Guideline (15) interprets scientific research broadly and explicitly links its interpretation to GDPR Recital 159 and EHDS Recital 61. According to the guideline, scientific research should be interpreted broadly enough to encompass activities such as:

- technological development and demonstration;
- fundamental research;
- applied research;
- privately funded research; and
- studies conducted in the public interest in the area of public health.

The guideline further states that scientific research:

- must have a clear scientific aim and methods;
- encompasses many research fields, including social sciences, humanities, biomedical sciences and others, when conducted according to recognised scientific methodology;
- should have a systematic approach, empirical grounding, transparency and ethical conduct;
- often begins with a clear research question or problem;
- aims to contribute to the existing body of knowledge; and
- has the goal of acquiring new knowledge.

Moreover, the Guideline examines why Art. 53(1)(e) explicitly refers to AI development and the training, testing and evaluation of algorithms. According to the Guideline, these examples are included to prevent an unduly narrow interpretation that might exclude applied or technology-driven research and to ensure alignment with the broad interpretation of "scientific research" established under GDPR Recital 159 and reflected in EHDS Recital 61. However, the Guideline also emphasises that the inclusion of AI-related activities does not create a separate purpose for processing under the EHDS. Rather, it clarifies that such activities may qualify as scientific research only when they are conducted according to recognised scientific methodology and pursue genuine scientific objectives.

The TEHDAS2 Guideline therefore supports a broad interpretation of scientific research, while making clear that the concept remains linked to recognised scientific methodology and scientific objectives. Consequently, the mere fact that a project involves the development, training, testing or evaluation of AI systems or algorithms does not automatically qualify it as scientific research under Art. 53(1)(e). Instead, the decisive question remains whether the activity is genuinely conducted as scientific research rather than for purely operational, commercial, quality assurance or service-development purposes.

For ethics committees, this interpretation is particularly relevant because many projects involving AI development or algorithm training may appear to resemble scientific research while serving different primary purposes. The assessment should therefore focus not on the technology being used, but on whether the project itself fulfils the characteristics of scientific research, including recognised scientific methodology, the pursuit of new knowledge and a genuine scientific objective.

5.7.2 Scientific research under the GDPR and EDPB Guidelines 1/2026

The EDPB Guidelines 1/2026 on the processing of personal data for scientific research purposes (14)⁴¹ take a similar approach. The Guidelines acknowledge that there is no single exhaustive or universally applicable definition of scientific research under EU law.

⁴¹ The Guidelines were subject to public consultation between 16 April and 25 June 2026.

Instead, the EDPB identifies six indicative factors that should be considered when assessing whether an activity can be regarded as scientific research:

1. a methodical and systematic approach;
2. adherence to recognised ethical standards;
3. verifiability and transparency;
4. autonomy and independence;
5. scientific objectives; and
6. the potential to contribute to existing scientific knowledge or to apply existing knowledge in novel ways.

Importantly, the EDPB emphasises that these factors must be assessed in light of the relevant scientific field. The way in which these indicators manifest themselves may differ between disciplines such as biomedical research, epidemiology, social sciences, humanities or technological research.

The EDPB does not present these factors as strict cumulative legal requirements. Rather, they are intended to assist controllers and supervisory authorities in assessing the nature of the activity. According to the Guidelines, where all indicators are present there will generally be a strong presumption that the activity constitutes scientific research. Where fewer indicators are present, additional justification may be necessary to demonstrate why the activity should nevertheless be regarded as scientific research.

5.7.3 Implications for the Nordic interpretation

The Nordic approaches identified in the mapping show several points of convergence with both the TEHDAS2 Guideline's interpretation of Art. 53(1)(e) EHDS and the EDPB Guidelines. In particular, the emphasis placed in several Nordic countries on scientific methods, systematic activity and the generation or acquisition of new knowledge is also reflected in the European sources. However, the Nordic countries do not apply a uniform legal definition or a single common test for identifying scientific research, and the degree of alignment therefore varies according to the applicable national framework.

At the same time, the European framework provides additional elements that may assist ethics committees when assessing difficult borderline cases. In particular, the EDPB places greater emphasis on transparency, scientific independence, ethical standards and the broader context in which the activity is conducted. The assessment is therefore not limited to asking whether a project seeks to generate new knowledge.

Thus, the EHDS and GDPR frameworks are broadly compatible with the national approaches identified in the Nordic mapping. They reflect similar core characteristics of scientific research while providing a broader and more structured set of indicators for assessing whether a project should be regarded as scientific research or as another type of activity, such as QA, quality improvement, service development or operational monitoring.

The most significant development concerns projects involving innovation activities, algorithm development, machine learning and AI. Art. 53(1)(e) EHDS expressly

recognises that such activities may fall within scientific research. However, neither the TEHDAS2 Guideline nor the EDPB Guidelines suggest that they automatically do so. Instead, they must be assessed against the broader characteristics of scientific research.

In conclusion, the EDPB's approach may even operate as a limiting factor. While Art. 53(1)(e) EHDS broadens the range of activities that may potentially qualify as scientific research, the EDPB's six indicative factors require a structured assessment of whether the activity genuinely possesses a scientific character. Consequently, the relevant question for ethics committees is not whether a project uses AI, develops an algorithm or creates an innovative product, but whether the project, viewed as a whole and within its relevant scientific field, displays the characteristics of scientific research recognised under both national law and the broader European framework.

6 Practical lessons learned from the Work Stream 3 pilots

The experiences gained during the Work Stream 3 pilots of the VALO and VALO2 projects illustrate how the distinction between QA and scientific research may influence both the regulatory pathway and the overall project timeline in cross-border research. In Norway, the regulatory planning and timetable for VALO2 were based on the experience gained during the first VALO pilot, which had been classified as QA. However, VALO2 pilot was instead assessed as scientific research and entered a different regulatory pathway, introducing additional procedural requirements that had not been foreseen during project planning and resulting in a longer overall timeline.

The first pilot (VALO) was classified as QA. Consequently, no ethical review was required in Norway. However, because the project involved the use of personal health data without obtaining consent from the participants, an exemption from the duty of confidentiality was still required under Norwegian law. The exemption was granted and the pilot proceeded as planned. The analyses were carried out locally in Finland, Denmark and Norway, and only aggregated results were shared with the researchers in Norway.

The second pilot (VALO2) was based on the same cohorts and pursued the same overall objective. The principal difference was methodological rather than scientific. Whereas the VALO pilot relied on a federated analysis model in which each participating organisation executed the analyses locally and only aggregated results were shared, the VALO2 pilot was designed to evaluate a model more closely reflecting the future EHDS framework. Researchers were granted remote access to secure processing environments, allowing them to work directly with pseudonymised individual-level data within the secure environments, refine the analysis script where necessary and execute the analyses without transferring the underlying data across national borders. This represented a substantially different operational model from the federated approach used earlier in VALO, despite the scientific objectives of the two pilots remaining largely unchanged.

The project was initially submitted to the same local hospital ethics committee in Norway, that had previously assessed the first VALO pilot as QA. During the assessment, however, the committee concluded that the VALO2 project should instead be regarded as scientific research. As a result, the project could no longer be handled through the

local institutional process but instead entered an entirely different regulatory pathway. Responsibility for the ethical assessment transferred to the Regional Committee for Medical and Health Research Ethics (REC), making the project subject to the REC's application procedures and submission timetable. Because the decision was communicated only after the submission deadline for the next REC meeting had passed, the project had to wait until the following application round before the ethical review process could begin.

Following the REC's assessment, ethical approval was granted. As in the VALO pilot, the project also required an exemption from the duty of confidentiality because personal health data were used without obtaining consent from the participants. Unlike in the first pilot, however, the exemption was granted subject to additional conditions. Before access to the data could be provided, all living participants in the cohort had to be informed about the project and given an opportunity to opt out, whereas the REC approved the use of data relating to deceased participants. This required additional administrative work to identify and contact the participants, organise the notification process and wait until the four-week opt-out period expired before access to the data could be granted.

The practical delay, in Norway, was therefore not caused solely by the requirement for ethical review. Rather, it resulted from the project being classified as scientific research which led to the application of a regulatory pathway that had not been anticipated when the project was designed.

This classification transferred responsibility for the assessment to the REC, introduced dependence on the REC's submission timetable and, following ethical approval, resulted in a conditional exemption from the duty of confidentiality that required participant notification and completion of the opt-out period before access to the data could be granted. The combined effect of these sequential procedural requirements resulted in a delay of approximately five months compared with the original project timetable. The timetable for VALO2 had been prepared based on the experience gained during the VALO pilot, where the applicable legal pathway had been considerably less procedurally demanding and complex. Although the overall objective, study population and scientific aims of the project remained essentially unchanged, a different assessment of the project's nature resulted in a substantially different regulatory pathway and several additional procedural requirements that could not reasonably have been anticipated at the outset of the project.

The purpose of presenting this example is not to question the individual decisions taken by the competent authorities. Rather, it illustrates how relatively small methodological changes in a cross-border project may lead to a different legal assessment and, consequently, substantially different procedural requirements. From the perspective of applicants, such outcomes may be difficult to predict in advance and may significantly affect project planning, resource allocation and implementation timelines.

The experiences from the VALO and VALO2 pilots demonstrate that the distinction between QA and scientific research is not merely a theoretical legal question. It may determine the entire regulatory pathway applicable to a project, including the competent authority, the procedural steps required before access to data can be granted and,

ultimately, the overall project timeline. In the VALO2 pilot, the conditions attached to the exemption from the duty of confidentiality, not the ethical review itself, became the most time-consuming element of the approval process.

The pilots also highlighted three broader implementation issues that extend beyond the individual project. First, differences in the practical interpretation of QA and scientific research may reduce predictability for applicants seeking access to health data from several Nordic countries. Secondly, the Norwegian requirement for an exemption from the duty of confidentiality demonstrates how national procedural requirements may continue to influence access to health data under the EHDS despite the introduction of a harmonised European framework. Thirdly, discussions within the consortium suggested that the transition from federated analyses to remote researcher access within secure processing environments may affect how projects are interpreted in practice. Although the VALO2 experience does not permit conclusions about the reasons for the Norwegian assessment, the pilots illustrate the importance of monitoring how this operational model, which is central to the EHDS, is interpreted during implementation. These observations suggest that, in addition to legislative implementation, there is a need for continued practical cooperation and dialogue on ethical review requirements and related procedures within the Nordic countries. The VALO2 pilot also demonstrated that ethical review and related national requirements form only one part of the broader operational ecosystem required for successful cross-border secondary use of health data, alongside secure processing environments, researcher onboarding, data provisioning, operational support and output release processes.⁴² The experiences gained through VALO2 provide a valuable foundation for such future work, which is discussed further in the following chapter.

7 Continued Nordic collaboration on ethical review and broader ethical aspects

The work carried out within VALO2 demonstrates that ethical review and related national requirements remain important components of the future EHDS ecosystem. While the EHDS establishes a common European framework for the secondary use of electronic health data, national ethical requirements continue to play a significant role whenever national legislation requires ethical review. The comparison of the Nordic countries and the experiences gained during the Work Stream 3 pilots showed that, although many similarities exist, practical differences remain that may affect the predictability and efficiency of cross-border access to health data.

The ethical expert group established within VALO2 has provided a valuable forum for discussing these issues across the Nordic countries. As the project comes to an end, the work should not conclude with the publication of this report. Rather, it should continue through a more structured and long-term Nordic collaboration on ethical review and broader ethical aspects of secondary use.

⁴² This matter is thoroughly discussed in the VALO2 Data Governance Workstream lessons learned report.

The Nordic Model developed within Work Stream 1 provides a natural starting point for such cooperation. At present, the Nordic countries do not have a formal established community of practice⁴³ for ethical committees comparable to those that already exist in several other areas of health data governance⁴⁴. Building upon the network created through VALO2 would therefore provide an opportunity to establish a regular forum where ethical experts can exchange experiences, discuss emerging issues and learn from one another in preparation for the EHDS. The future composition of such a forum should be further assessed. While the VALO2 ethical expert group provided an excellent starting point, broader representation from each Nordic country would strengthen the continuity of the work and ensure that relevant expertise from different ethical committees and organisations is represented.

As an initial priority, continued collaboration could focus on the practical distinction between QA and scientific research. Although the Nordic countries have overlapping practical understandings of QA and scientific research, the work carried out during VALO2 demonstrated that differences remain in how borderline cases are interpreted in practice. Continuing the dialogue through the discussion of practical examples and difficult cases could gradually improve consistency and predictability without requiring changes to national legislation or limiting the independence of ethical committees.

The work could also build directly upon the findings of this report by identifying additional areas where greater Nordic alignment may be beneficial. One example is the Norwegian requirement for an exemption from the duty of confidentiality, which represents a procedural requirement not found in the other Nordic countries. Continued dialogue could help identify whether similar national procedural issues exist elsewhere and whether practical approaches could be developed to improve predictability for applicants while maintaining the safeguards established under national legislation. It may also be valuable to examine whether such a requirement can continue to be maintained under the EHDS and, if so, how it can be implemented in a sustainable manner, particularly if it results in large numbers of information notices being sent to Norwegian citizens.

The work undertaken during VALO2 also demonstrated that the topics examined in this report represent only a first step. During the comparison, several additional ethical questions emerged that could not be analysed in greater detail within the timeframe of the project. One example concerns the use of national quality registers, which illustrates particularly well how difficult the practical distinction between QA and scientific research can become.

Finland and Norway maintain extensive national quality-register infrastructures whose primary purpose is to support quality improvement within healthcare. At the same time, these registers are frequently used for scientific research. In Finland, research based on quality registers often aims to improve the quality of the registers themselves by identifying best practices and improving patient care. Such projects may simultaneously

⁴³ At present, the Nordic countries do not have a formally established and continuous community of practice for ethics committees, although informal meetings between the secretariats of Nordic research ethics committees have taken place.

⁴⁴ e.g. Nordic eHealth group, Nordic Standardisation group, Nordic Baltic Mortality Group, Nordic Data Protection Authorities (Nordic DPA).

generate new scientific knowledge while directly supporting quality improvement, making it difficult to classify them exclusively as either QA or scientific research. Norway faces similar challenges. Although the primary purpose of the national quality registers is quality improvement, the same registers are regularly used for medical and health research, and the applicable approval pathway depends on how the activity is classified and whether additional data sources are involved. Sweden likewise emphasises that its quality registries primarily exist to improve healthcare while simultaneously serving as an important resource for research.

These examples demonstrate that the distinction between QA and scientific research extends well beyond the examples discussed in this report. They also illustrate that many practical questions remain unresolved and would benefit from continued Nordic dialogue and the exchange of experiences between ethical experts.

Another issue concerns the governance of AI and algorithm development under the EHDS. None of the national mappings identified AI development or the training, testing and evaluation of algorithms as an independent statutory trigger for ethical review. At the same time, Art. 53(1)(e) EHDS expressly recognises these activities as examples of scientific research when carried out for scientific purposes. The ethical exercises conducted within VALO2 also gave rise to a broader legal discussion on the interpretation of Art. 68(1)(b) EHDS, which is examined in the report prepared by the VALO2 legal expert group.⁴⁵ If national legislation does not provide for ethical review of AI-related secondary use and Art. 68(1)(b) EHDS is interpreted as not permitting HDABs to take even basic ethical considerations into account, Member States may consider introducing additional national legislative provisions to address this perceived gap. Divergent national legislative responses could create new barriers to cross-border research, reduce predictability and lead to unnecessary differences between the Nordic countries. Continued Nordic dialogue would enable the identification of such issues before national implementation decisions are finalised, exchange experiences and jointly explore possible solutions. This would help ensure that national decisions are made on the basis of shared knowledge and a common understanding of the legal issues, thereby reducing the risk of unnecessary divergence while fully respecting each country's legislative autonomy.

Although this report has focused primarily on national ethical-review requirements, future Nordic collaboration could also consider the broader ethical aspects of secondary use under the EHDS. These may include patient rights, transparency and information provided to individuals, and the design and operation of opt-out mechanisms. Such questions should be kept conceptually distinct from formal ethical review, but they form part of the wider ethical context in which EHDS secondary use will be implemented.

Finally, the ethical expert group should be regarded as an important stakeholder in the broader implementation of the EHDS. To date, much of the implementation work has focused on legislation, HDABs and technical infrastructure. However, wherever national legislation requires ethical review, ethics committees will continue to play an essential role in enabling access to health data. Their practical experience will also be valuable to

⁴⁵ See Annex 5 of the VALO2 Work Stream 2 consolidated final report 2026; Nordic Interpretation of specific EHDS Articles.

the other collaborative groups established under the Nordic Model (see final report from WS1 of VALO2), in the same way that legal and technical expertise is already shared across work streams. It is therefore important that ethical experts become actively involved in national and Nordic EHDS implementation already during the implementation phase, rather than only once the first EHDS secondary-use applications are expected in 2029. This would provide an opportunity to identify practical bottlenecks, develop common understanding and improve preparedness before the EHDS becomes fully operational.

Continued Nordic cooperation should not seek to replace national decision-making or undermine the independence of national ethical committees. Rather, its purpose should be to provide a permanent Nordic community of practice where ethical experts can exchange experiences, discuss difficult cases and contribute to the practical implementation of the EHDS. The Nordic Model developed through VALO2 provides a natural foundation for such cooperation. Building on the existing network would allow the work to continue beyond the lifetime of the project, although the future composition of the group should be further assessed to ensure broad representation from all Nordic countries.

The forum could initially focus on the themes identified in this report, including the practical distinction between QA and scientific research, the interaction between ethical review and national procedural requirements such as the Norwegian exemption from the duty of confidentiality, and the broader ethical aspects identified above. Beyond serving as a platform for exchanging experiences, the forum could also identify areas where greater Nordic harmonisation would be beneficial, assess whether differences arise from legislation or practice, and develop proposals for how these could be addressed. This would allow the Nordic countries to distinguish between areas where legislative harmonisation is desirable, areas where greater practical alignment is sufficient, and areas where national differences should remain. In this way, the collaboration could support both practical implementation and, where considered appropriate by the Nordic countries themselves, future legislative or policy development while fully respecting national competence and the independence of ethical review bodies.

By building upon the collaboration established during VALO2, the Nordic countries have an opportunity to strengthen both the predictability and the attractiveness of their health data ecosystems. A permanent Nordic forum for cooperation on ethical review and broader ethical aspects would support mutual learning, facilitate EHDS implementation, provide evidence-based recommendations for future development and help ensure that the Nordic countries continue to be recognised as international leaders in the responsible secondary use of health data.

References

1. VALO: Final report: Nordic model for collaboration on the secondary use of health data - a proposal. November 2025.
2. Laki lääketieteellisestä tutkimuksesta | 488/1999 | Lainsäädäntö | Finlex
3. Finnish National Board on Research Integrity (TENK): The ethical principles of research with human participants and ethical review in the human sciences in Finland. Finnish National Board on Research Integrity TENK guidelines 2019 . March 2019
4. Finnish National Board on Research Integrity (TENK): Organisations committed to ethical review in human sciences | Finnish National Board on Research Integrity TENK. 12 January 2026.
5. Lag (2003:460) om etikprövning av forskning som avser människor
6. Forskning i Sverige och utomlands: När krävs etikprövning i Sverige? - Etikprövningsmyndigheten.
7. Initial application (grundansökan) - Etikprövningsmyndigheten. 4 September 2026.
8. The Norwegian Health Research Act: <https://lovdata.no/dokument/NL/lov/2008-06-20-44>.
9. About REC - Rekportalen.
10. Danish Committee Act Bekendtgørelse af lov om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter og sundhedsdatavidenskabelige forskningsprojekter.
11. Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC.
12. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices.
13. Icelandic Act on Scientific Research in the Health Sector No 44/2014.
14. European Data Protection Board: Guidelines 1/2026 on processing of personal data for scientific research purposes | European Data Protection Board. 15 April 2026.
15. TEHDAS2 Joint Action: Guideline for Health Data Access Bodies on minimum categories and limitations on the reuse of health data. 24 March 2026.



Annex 6a. Responsible ethical committees and institutions for the national mappings

Country	Committee/Institute	Name
Finland	The Finnish Institute for Health and Welfare	Pieta Näsänen-Gilmore Jenina Soimala Sirpa Soini Sampo Viiri
Sweden	National Board of Health and Welfare	Johanna Holm Michal Korek
Norway	The National Committee for Medical and Health Research Ethics (NREC) and Regional Committees for Medical and Health Research Ethics (REC)	Camilla Bø Iversen Ingvild Haaland Margit Ramberg
Denmark	National Research Ethic Committee (NREC)	Susanne Pihl Jakobsen
Iceland	The National Bioethics Committee / Directorate of Health	Aslaug Einarsdottir Védís Helga Eiríksdóttir

These are the people and organisations that have given their written contribution to the sections concerning their respective country's current national landscape on the matter.



Annex 6b. Action suggestions

Need to incorporate the ethical committees into the EHDS implementation work sooner rather than later

Ethics committees should be actively involved in EHDS implementation at an early stage.

Applicants seeking access to health data under the EHDS will continue to be subject to national requirements concerning ethical review where such requirements apply. In addition, the EHDS foresees a role for ethics expertise within the secondary-use governance framework, including the possibility for ethics committees to support HDABs or to participate directly in their activities. Ethics committees are therefore important stakeholders in the implementation of the EHDS.

Based on discussions conducted within the VALO2 project, awareness of the EHDS and its implications for ethical review processes currently appears limited among some ethics committees. Delaying their involvement in national implementation efforts may create challenges related to legal certainty, consistency of interpretation, operational readiness, and alignment between existing national frameworks and the requirements of the EHDS.

Early engagement would allow ethics committees to assess how their current practices, procedures, and mandates interact with the EHDS framework and to identify any areas where legislative, procedural, or organisational adjustments may be needed. It would also support more consistent decision-making and facilitate smoother cooperation between ethics committees, HDABs, and other actors involved in secondary use governance.

For these reasons, ethics committees should be included in EHDS implementation activities as early as possible to ensure that they are adequately prepared for their future role, and that national implementation is both effective and legally coherent.

Enhance and prioritise continued collaboration between ethical committees by focusing first on the distinction between quality assurance and scientific research

The work carried out within VALO2 demonstrates the value of bringing together ethical experts from across the Nordic countries. At present, however, there is no formal Nordic community of practice through which ethics committees can exchange experiences, discuss emerging questions related to the EHDS or develop a common understanding of its practical implementation.

One of the first priorities for such collaboration should be the practical distinction between quality assurance and scientific research. Although the national legal frameworks are broadly similar, the mapping and discussions demonstrated that this distinction remains challenging in several countries and that interpretations may differ not only between countries but, in some cases, also between ethics committees or other competent authorities within the same country. Continued dialogue on practical examples and

borderline cases would improve transparency, predictability and mutual understanding while fully respecting the independence of national ethical review bodies.

As the network becomes established, its work could gradually expand to other practical questions identified in this report. These include the interpretation of new EHDS scientific research purposes, such as the development, training, testing and evaluation of AI systems and algorithms; the interaction between ethics committees and HDABs; national procedural requirements that affect access to health data; and the exchange of experiences on emerging borderline cases during EHDS implementation. A structured community of practice would provide an effective forum for developing a shared understanding of these issues while respecting differences in national legislation.

The ethical expert network established through VALO2 and the Nordic Model provides a natural foundation for this cooperation. A permanent forum would enable ethics committees to maintain direct links with the legal, technical and policy experts involved in EHDS implementation, allowing experiences and practical challenges to be shared across disciplines instead of being addressed in isolation.

Future collaboration should also be expanded to include the Baltic countries. As Estonia and Lithuania were not able to participate in the mapping exercise within the timeframe of VALO2, their perspectives are currently missing. Including them in future work would strengthen regional cooperation and support more consistent implementation of the EHDS across the Nordic-Baltic region.

The future composition of such a forum should be carefully considered. While the VALO2 ethical expert group provided an excellent starting point, broader representation from each Nordic country would strengthen the continuity of the work and ensure that relevant expertise from different ethical committees and organisations is represented. Experience from VALO2 demonstrates that successful Nordic collaboration depends not only on the participation of all countries, but also on ensuring that each country is able to dedicate sufficient expertise and resources throughout the work. The preparation of this report also highlighted the importance of allocating sufficient resources for participation in Nordic collaboration. Differences in the availability of experts and the time they could dedicate to the work inevitably influenced the depth of discussions and the extent to which national perspectives could be reflected in the report. Future collaboration would therefore benefit from ensuring that all participating countries are represented by experts with both the mandate and the resources to contribute actively throughout the process. This would help ensure that future work benefits from balanced representation, a broader exchange of national experiences and a stronger common understanding of emerging ethical questions under the EHDS.

Application language barriers should be considered and removed when possible

The ethical expert group acknowledges that requiring ethical review applications to be submitted only in the national language may encourage the involvement of local partners. However, such involvement may often be driven by administrative necessity

rather than scientific need. Language requirements can therefore create an unnecessary barrier for international applicants and reduce the attractiveness of Nordic health data resources for cross-border research.

Allowing ethical review applications and guidance materials to be submitted and accessed in English would lower these barriers and enable researchers to engage directly with the application process. This would likely increase international interest in Nordic health data and create more opportunities for meaningful scientific collaboration. Rather than promoting partnerships primarily for administrative purposes, an English-language process would encourage collaborations based on scientific expertise and added value, supporting the objectives of the EHDS and strengthening the Nordic region's competitiveness as a research environment.

Territorial ethical review requirements may influence consortium composition

The comparison identified that the territorial applicability of national ethical review legislation differs between the Nordic countries. Denmark, Norway and Sweden apply explicit territorial conditions, although the relevant national connection is defined differently in each country. Applicability may depend not only on the characteristics of the project itself but also on where research activities are conducted, where data are collected, analysed, processed or stored, and whether a person or institution established in the country has scientific responsibility for the project. In multinational consortia, the mere inclusion of a Danish or Norwegian organisation does not, by itself, make the respective national legislation applicable. Nevertheless, the allocation of research activities and scientific responsibilities may determine which national ethical review frameworks apply. These differences may create uncertainty for international research collaborations and multinational consortia.

International consortia may therefore need to assess carefully which national ethical review systems apply to different parts of a project. Without clear guidance, this may increase administrative complexity, create uncertainty regarding regulatory obligations and influence how research activities and responsibilities are allocated within a consortium. In practice, there is a risk that research tasks are assigned in a way that avoids additional ethical review requirements rather than making the best use of the scientific expertise available within the consortium. This may reduce opportunities for experts from some Nordic countries to participate fully in international collaborations.

To support equitable cross-border collaboration and strengthen the Nordic region's competitiveness in health research and innovation, the expert group considers that the territorial applicability of national ethical review legislation should be communicated as clearly as possible. Common guidance for multinational research projects should explain which research activities and institutional connections establish territorial applicability, including how the collection, analysis, processing and storage of data are treated. It should also distinguish the territorial jurisdiction of an ethics committee from any separate documentation that a data-granting authority may require when a project is conducted and ethically reviewed in another country. Greater transparency would



improve legal certainty for applicants while supporting the objectives of the European Health Data Space.

Annex 7a. Data from the Nordics: Draft for a joint Nordic overview for data users

This annex presents a visualisation of what a *Data from the Nordics web guide* could look like, for secondary use of health data. Please notice that the information given below is preliminary, and provided here only as example of the information structure.

Picture 1. Condense overall view for the basic information.

Data from the Nordics

A practical overview of health data registries and access pathways in Nordic countries.

The Nordic countries offer good opportunities for research based on population-wide registries. These datasets cover entire populations over long periods and can be linked using unique personal identifiers.

Data categories available from the Nordics

From this page you'll find a summary of each countries' relevant authorities and data access processes, and links that guide you for more detailed information.

Denmark

- Access model: Centralised
- Application route: Single coordinated application process
- Main entry point: Danish Health Data Authority
- Support services: Health Data Access guidance, Research Services support, email, phone

How to apply

Read more

Finland

- Access model: Centralised
- Application route: Single application possible
- Main entry point: Findata
- Support services: Personal consultation via booking, email, website assistants

How to apply

Read more



Iceland

- Access model: Hybrid
- Application route: Depends on data holder
- Main entry point: Directorate of Health
- Support services: Directorate of Health guidance, email

How to apply



Read more



Norway

- Access model: Centralised
- Application route: Single application route
- Main entry point: Helsedata.no
- Support services: Helsedataservice, application support

How to apply



Read more



Sweden

- Access model: Decentralised
- Application route: Multiple applications may be required
- Main entry point: National Board of Health and Welfare (Socialstyrelsen)
- Support services: Dataguiden + relevant authorities and data holders

How to apply



Read more



Reports from *Value from Nordic Health Data* projects (VALO & VALO2)

- [VALO Metadata catalogues – final report \(sitra.fi\)](#)
- [Lessons learned from multi-site federated analysis in VALO NSCLC pilot study \(sitra.fi\)](#)
- [VALO NSCLC pilot study \(sitra.fi\)](#)
- [Nordic EHDS2 Competence Forum – final report \(sitra.fi\)](#)
- [Nordic model for collaboration on the secondary use of health data – a proposal \(sitra.fi\)](#)
- [The Nordic model for collaboration on health data: insights from an evolving process \(sitra.fi\)](#)
- [Secondary use of health data in Nordic co-operation \(sitra.fi\)](#)

Have questions? Get in touch with us

Book a time for personal consultation





Picture 2. Further information visible in expandable sections.

Data from the Nordics

A practical overview of health data registries and access pathways in Nordic countries.

The Nordic countries offer good opportunities for research based on population-wide registries. These datasets cover entire populations over long periods and can be linked using unique personal identifiers.

Data categories available from the Nordics

- Population data
- Healthcare data
- Medication data
- Laboratory data
- Mortality data
- Vaccination data
- Social care data
- Socioeconomic data
- Quality registries
- Research cohorts
- Biobanks and genomic data

Common strengths

- Nationwide coverage
- Longitudinal follow-up
- Personal identity code based linkage
- Secure processing environments
- High-quality public registers

From this page you'll find a summary of each countries' relevant authorities and data access processes, and links that guide you for more detailed information.

Denmark

- Access model: Centralised
- Application route: Single coordinated application process
- Main entry point: Danish Health Data Authority
- Support services: Health Data Access guidance, Research Services support, email, phone

How to apply



Finland

- Access model: Centralised
- Application route: Single application possible
- Main entry point: Findata
- Support services: Personal consultation via booking, email, website assistants

How to apply



Picture 3. Structured content / headings for country-specific information, links for detailed information.

Iceland

- Access model: Hybrid
- Application route: Depends on data holder
- Main entry point: Directorate of Health
- Support services: Directorate of Health guidance, email

How to apply

- Identify the relevant data holder and submit an application to the responsible authority or organisation.
- Depending on the requested data and study design, additional approvals, including ethical review, may be required before access can be granted.

Read more

Data available

- [Statistics, health registers and research](#) 

Access authority

- [Directorate of Health](#) 

Application guidance

- [Statistics, health registers and research](#) 

Norway

- Access model: Centralised
- Application route: Single application route
- Main entry point: Helsedata.no
- Support services: Helsedataservice, application support

How to apply

- Search available datasets and variables through Helsedata.no and submit an application through the national application system.
- Helsedataservice provides support during the application process. Approved datasets are prepared and delivered by the responsible data holders.

Read more

Data available

- [Helsedata.no](#) 

Access authority

- [Helsedata.no](#) 
- [The Norwegian Institute of Public Health \(fhi.no\)](#) 

Application guidance

- [Access to data – The Norwegian Institute of Public Health \(fhi.no\)](#) 
- [Helsedata.no](#) 

Sweden

- Access model: Decentralised
- Application route: Multiple applications may be required
- Main entry point: Relevant data holders
- Support services: Dataguiden + relevant authorities and data holders

How to apply

Read more

Reports from *Value from Nordic Health Data* projects (VALO & VALO2)

- [VALO Metadata catalogues – final report \(sitra.fi\)](#) 
- [Lessons learned from multi-site federated analysis in VALO NSCLC pilot study \(sitra.fi\)](#) 
- [VALO NSCLC pilot study \(sitra.fi\)](#) 
- [Nordic EHDS2 Competence Forum – final report \(sitra.fi\)](#) 
- [Nordic model for collaboration on the secondary use of health data – a proposal \(sitra.fi\)](#) 
- [The Nordic model for collaboration on health data: insights from an](#)

Annex 7b. Matrix of VALO outputs as a validation layer for EHDS implementation

Purpose. This annex provides **portfolio-level traceability** between the main VALO and VALO2 outputs, the consolidated findings of this VALO2 WS2 Final Report and the EHDS secondary-use framework. It shows how the earlier thematic and pilot outputs contribute evidence, practical experience and implementation lessons to the final WS2 consolidated report (this Nordic guide...), and identifies where these results are relevant to forthcoming EU implementing acts and common specifications. It complements **Annex 2**, which translates the extended User Journey into an **operational matrix** of actors, bottlenecks, support needs and recommended preventive measures.

Reading note. The last column to the right identifies the principal implementing-act or common-specification topics linked to the cited articles. It should not be read as stating that every instrument has already been adopted or that the wording shown is its final official title.

VALO / VALO2 output	Principal EHDS Articles	Distinct evidence contribution and role in the consolidated report	Main implementation instruments and linked articles
VALO Metadata catalogues – final report (2025)	Arts. 57(1)(j), 60(3)–(4), 77–80	Metadata publication, national and EU dataset catalogues, dataset descriptions, data quality and utility labelling, and discoverability. Provides the foundation for the pre-discovery and discovery parts of the User Journey and for recommendations on HealthDCAT-AP implementation, validation and sustainable metadata governance.	Dataset description and national/EU catalogue specifications under Arts. 77 and 79; data quality and utility label specifications under Art. 78; identification and labelling of high-impact datasets under Art. 80.
Nordic model for collaboration on the secondary use of health data (2025)	Arts. 55–57, 62, 67–70, 72, 75	Nordic governance and cooperation, HDAB functions, access pathways, applications, permits, health data requests, fees, trusted health data holders and cross-border coordination. Provides the governance baseline for the report's analysis of common services, applicant support and Nordic alignment.	Common templates for applications, data permits and health data requests under Art. 70; HealthData@EU infrastructure, services and cross-border exchange under Art. 75; fee-policy principles under Art. 62.
Lessons learned from multi-site federated analysis in the VALO NSCLC pilot study (2025)	Arts. 51, 57(1)(b), 60–61, 66–68, 73, 75	Practical multi-country evidence on dataset discovery and fitness, permissions, data preparation and harmonisation, secure processing, federated analysis, output control and reproducibility. Grounds the report's identification of cumulative legal, organisational and technical bottlenecks.	SPE technical, information-security and interoperability requirements under Art. 73; HealthData@EU architecture and cross-border services under Art. 75; application and permit templates under Art. 70; metadata and DQUL instruments under Arts. 77–78 where relevant to discovery and fitness assessment.
VALO2 WS2 Consolidated Final Report 2026 "Towards a Nordic guide..."	Arts. 2(2)(t), 51–62, 66–80	End-to-end synthesis of Nordic readiness for EHDS secondary use: identification of health data holders and datasets; metadata and discovery; feasibility; legal and ethical prerequisites; applicant-side and grant-side services; data preparation; SPE use; cross-border and federated analysis; output release; publication, findings, reproducibility and project closure. Converts the combined evidence into the extended User Journey, bottlenecks and implementation recommendations.	Cross-cutting relevance to the secondary-use implementation package, particularly: fee principles (Art. 62); common access templates (Art. 70); SPE requirements (Art. 73); HealthData@EU (Art. 75); dataset catalogue and description specifications (Arts. 77 and 79); DQUL (Art. 78); and high-impact datasets (Art. 80).

Interpretive value for the report. The matrix should remain concise and traceability-oriented. Its principal value is to demonstrate the progression from earlier thematic and pilot outputs to the consolidated findings and recommendations, and to make their relevance to the EHDS implementation framework explicit.

Source and status note. Article references are based on Regulation (EU) 2025/327. The precise scope, titles and timing of implementing acts and common specifications should be updated when final instruments are adopted.