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VALO2 Work Stream 2 consolidated final report 2026: *towards a Nordic guide to efficient and secure access to health data for secondary use under the EHDS*

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Contents

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	Systematized 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, referred to in this report as EHDS2, requires Member States to develop the legal, organisational, technical and governance capabilities needed to make health data available for permitted secondary-use purposes in a secure, transparent and efficient manner.

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.

Over the period 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 trusted 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 TEHDAS2, 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.

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 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 EHDS requirements. The VALO2 work included mapping national catalogue properties to HealthDCAT-AP, piloting cancer registry descriptions, analysing the Nordic health data landscape under 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 proportionality assessment conducted by Health Data Access Bodies 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 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 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 when 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 jurisdictional conditions are met. Denmark applies ethical-review requirements more narrowly, while Finland generally does not require 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, reclassification 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 trusted 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 mappings, 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 ethical-review requirements, territorial scope, application-language requirements and the distinction between quality assurance and scientific research;
- develop common 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 issues concerning 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 EHDS secondary use. By mapping User Journey steps, actors, support functions and recommendations to 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 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 representatives 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/SPE, Legal including ethical[1], 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 framework[2], 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.

[1] 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.

[2] 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 VALO[3] 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.

[3] 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 CDM[4,5] 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 project[6].

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).

[4] Observational Medical Outcomes Partnership - Common Data Model
[5] Nordic EHDS2 Competence Forum – final report - Sitra. 2025 (First VALO Project)

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

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 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 Regulation[7]. 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 toward 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 TEHDAS[8] and TEHDAS2[9] 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 Journey[10], from the applicant's and secondary user's perspective (Figure 1 and Annex 2).

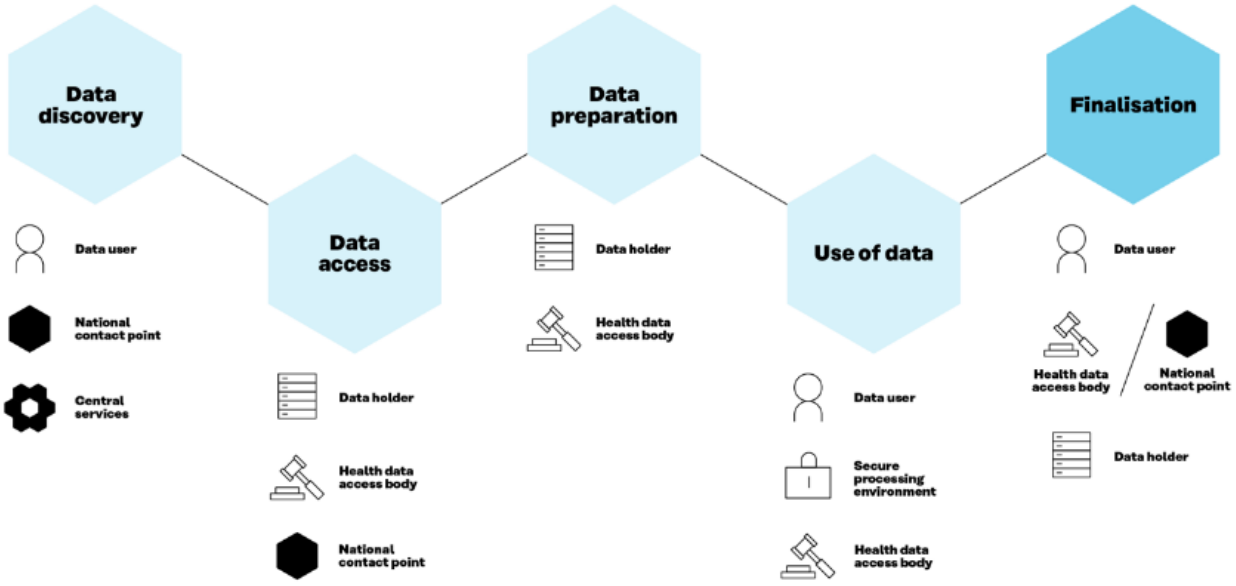

Figure 1. The User Journey of secondary use of health data, according to TEHDAS2 (M8.4 Draft guideline for data users on handling research outcomes), April 2026.

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.

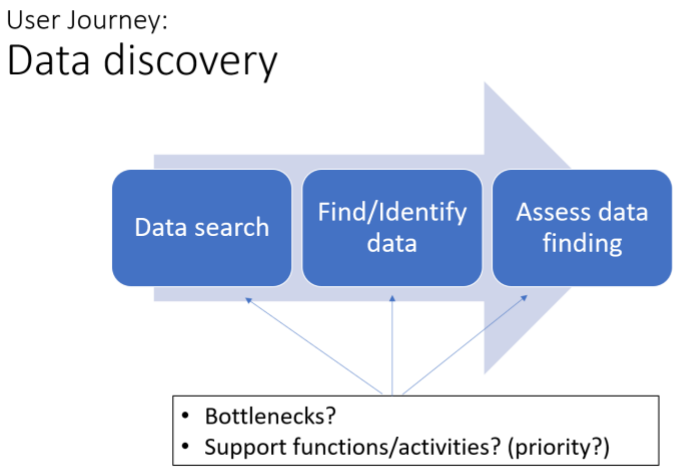

Figure 2. A draft model for a detailed mapping of the different sub-steps of the User Journey's main steps such as Data discovery, together with identification of bottlenecks and (priority) support functions and activities.

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]

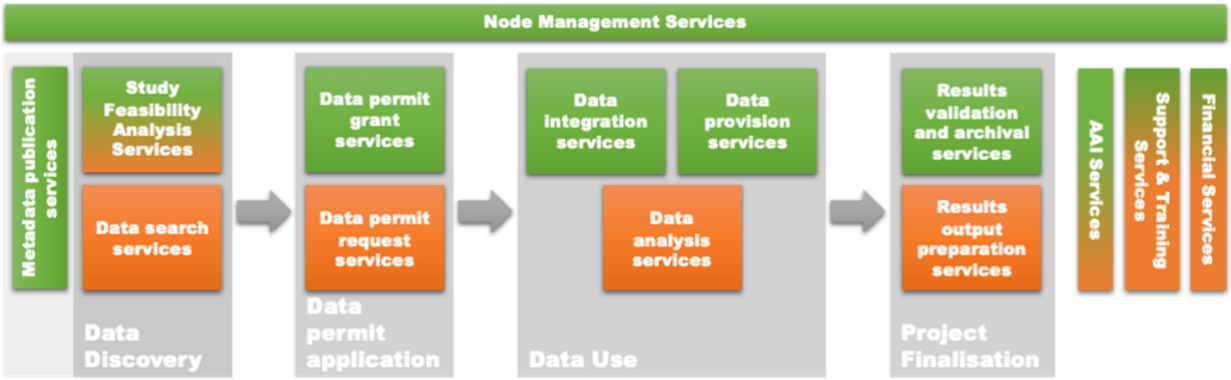

Figure 3. Revisited Users' Journey according to the first TEHDAS project: "...Green boxes represent those services that are related to the EHDS2 point-of-view, i.e., the services that are conceived to involve data controllers, data permit authorities and other actors than data users. The orange boxes 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 operationalization 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

Platform[13]. 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 specification[14].
2. Improve understanding of the Nordic health data landscape under EHDS Article 51[15].
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 since the VALO1 project, 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 countries regarding the interpretation of various dataset level mandatory properties, which was demonstrated through a practical exercise. These unresolved issues present a risk to harmonised implementation and could undermine cross-border data discoverability.

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

[14] https://healthdataeu.pages.code.europa.eu/healthdcat-ap/releases/release-7/
[15] Minimum categories of electronic health data for secondary use

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.
- 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*). 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 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) 2024/1689[16] 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 metrics[17] 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 and data quality reporting most likely can help AI developers to assess certain dataset quality related aspects, such as dataset provenance, data collection processes and original purpose of data collection. It can also help in assessing the availability, quantity and suitability of the datasets that are needed. In particular variable-level, up-to-date data quality reporting is likely to provide plenty of useful information to support the assessment.

However, current HealthDCAT-AP metadata and QUANTUM quality 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 is often required, for example in the examination of potential biases.

Lessons from Norway

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

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

4.3 Summary of recommendations

Following is a summary of recommendations for the Nordic countries:

1. 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.

2. Strive for improved guidance and definitions

- 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.

3. Develop 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.
- Strive for as harmonised dataset definitions as possible.
- Strive for common approaches to data quality and utility labelling and data quality reporting.

4. Strengthen understanding of the Nordic EHDS landscape

- Develop and publish a Nordic self-assessment tool 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.

5. Improve metadata quality and governance

- Invest in metadata quality, completeness, consistency, and long-term maintenance.
- Invest in data holder support and guidance especially related to the most used data.
- Establish sustainable metadata governance processes.

6. Strengthen AI readiness

- Pay attention to detailed and structured variable-level metadata.
- Pay attention to documentation of dataset provenance, collection processes, classifications used, and data quality characteristics.
- Support data holders in producing high-quality metadata in a resource-efficient manner.
- Establish mechanisms for collecting and using metadata quality and data quality-related user feedback.

7. Ensure adequate resources and technical support

- Allocate resources for metadata 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.

8. Continue and expand Nordic cooperation

- Maintain close collaboration on interpretation and implementation of EHDS metadata requirements.
- Share lessons learned, best practices, tools, and support models.
- Coordinate Nordic input into EU-level discussions and developments.
- Continue pursuing long-term harmonisation of metadata catalogues, data quality reporting, and metadata standards.

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 concluded that statistical bodies should, as a general rule, be considered as health data holders under Art. 2(2)(t). The assessment should therefore not depend solely on an organisation's formal sectoral position but also on its activities and the electronic health data it holds or processes.

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. The group

therefore considered this an issue that 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

HDABs will need workable procedures for protecting commercially sensitive information without creating unnecessary restrictions on secondary use. At the same time, differences in national fee policies, combined with the limited incentives for health data holders to invest in more efficient infrastructure, may affect the cost and attractiveness of accessing data in different countries. These issues illustrate why continued Nordic cooperation is important even where the

underlying EHDS rules are relatively clear. Different implementation choices may still create practical barriers to a smooth and comparable Nordic User Journey.

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(1)(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 Legislation 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**, I**P 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.

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.

For 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 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 VALO1 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 subject 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 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;
- 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; 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

[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

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 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 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 and 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 and ethical 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.

To clarify such legal aspects prior to application submission, legal advice should be available to the health data user.

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 legal requirements or obstacles, as well as on 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.

7.1.3.2 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.

7.1.3.3 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.

7.1.3.4 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.

7.1.3.5 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 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 and SPE onboarding

This step comprises 1) loading the permitted health data into the SPE, and 2) providing access for the authorised health data user(s) to the SPE, according to the HDAB decision. Both aspects are briefly discussed here:

- **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.
- **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 function the SPE operator should ensure prompt and secure health data provision as well as access and onboarding 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 requesting 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 API[20] where appropriate.

Federated analysis: 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.

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 principles[21]. 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

[20] Application Programming Interface
[21] Wilkinson, M., Dumontier, M., Aalbersberg, I. et al. The FAIR Guiding Principles for scientific data and stewardship. Sci Data 3, 160018 (2016)

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;
- 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 to 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 organized 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.

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 (including a Nordic support portal?).
- 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 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, HealthDCAT-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 VALO2 WS2 Final Report could be used as a similar supporting validation and readiness layer for national and Nordic preparations for EHDS. 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.

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

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. Closer cooperation 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.

ANNEXES