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Value from Nordic health data – the VALO project

Nordic EHDS2 Competence Forum – final report

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Document info

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Contents

Executive Summary	4
Tiivistelmä	5
Sammanfattning	6
1 Abbreviations	7
2 Introduction	9
3 Preparing for the Nordic EHDS2 Competence Forum	10
3.1 Mobilising Participation: Inviting Authorities to the Forum.....	11
3.2 National Progress Report Survey – template.....	11
4 Realising the Nordic EHDS2 Competence Forum	12
4.1 National progress reports – results	14
4.1.1 Denmark.....	14
4.1.2 Finland	14
4.1.3 Iceland.....	15
4.1.4 Norway	15
4.1.5 Sweden	15
4.1.6 Lithuania.....	16
4.2 Breakout sessions.....	16
4.2.1 HDAB breakout sessions – outcomes.....	17
HDAB: mandate, structure, and coordination.....	17
SPE: models, capacity and interoperability.....	17
Application process: bottlenecks and quality	18
Fees and financing.....	18
Data rights, ethics, and legal issues.....	18
4.2.2 Legal breakout session	19
National Legislation and EHDS alignment	19
Interpretation of permitted and prohibited purposes	19
Fees and financing.....	19
Opt-out and citizen rights	20
Trusted data holders and simplified processes.....	20
Combining health data and social data	20
IP rights and trade secrets	21
Data discovery and data quality	21
4.2.3 Metadata breakout session	21
4.3 Evaluation of Competence Forums.....	22
4.4 Future Nordic EHDS2 Competence Forums.....	22
5 Conclusions and way forward	23
6 External communication.....	24
Annex 1: List of VALO partner organisations and invitees.....	25
Annex 2: National progress report (survey template).....	29

Executive Summary

The VALO project, funded by the Nordic Council of Ministers, aims to strengthen Nordic cooperation in the secondary use of health data and support the implementation of the European Health Data Space (EHDS). Active participants in VALO were Finland, Iceland and Sweden, as well as Denmark and Norway. For the second half, the Baltic countries Estonia and Lithuania joined as observers.

Work Stream 2 (WS2) focused on establishing the Nordic EHDS2 Competence Forum, coordinating national progress reporting, and fostering collaboration on metadata, legal frameworks, and technical infrastructure. From September 2024 to September 2025, four Competence Forums were held across Nordic countries, with a fifth planned for October 2025. These forums brought together representatives from ministries and authorities across the Nordic and Baltic regions to share experiences, identify challenges, and explore harmonisation opportunities in implementation of EHDS2, i.e. the dimension of EHDS specifically concerning secondary use of health data.

Key outcomes include:

- **National Progress Reports:** A harmonised survey template enabled tracking of EHDS2 readiness across countries. Reports revealed varying levels of legal, organisational, and technical preparedness, with common challenges around Health Data Access Body (HDAB) appointment, metadata catalogues, and Secure Processing Environment (SPE) interoperability.
- **Breakout Sessions:** Themed discussions on HDAB/SPE, metadata, and legal aspects highlighted fragmentation in national approaches and the need for Nordic alignment. Topics such as fee structures, ethical review, opt-out models, and metadata standards were explored in depth.
- **Legal Harmonisation:** Countries are adapting national laws to EHDS, but timelines and interpretations vary. Joint Nordic efforts are recommended to align on permitted purposes, fee principles, opt-out mechanisms, and Intellectual Property (IP) rights handling.
- **Recommendations for VALO2:** The approved extension of the project into 2026 will in WS2 focus on identifying and mitigating bottlenecks in health data access. Continued Competence Forums, expanded breakout sessions, and deeper integration of metadata and legal workstreams are planned.

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

Tiivistelmä

VALO – Arvoa pohjoismaisesta terveystiedosta on Pohjoismaisen ministerineuvoston rahoittama hanke, joka pyrkii vahvistamaan pohjoismaista yhteistyötä terveystiedon toissijaisessa käytössä ja tukemaan Eurooppalaisen terveystietoalueen (European Health Data Space, EHDS) toimeenpanoa. Aktiivisia osallistujia VALO-hankkeessa olivat Suomi, Islanti ja Ruotsi sekä Tanska ja Norja. Hankkeen toisella puoliskolla Baltian maat Viro ja Liettua liittyivät tarkkailijoiksi.

Työpaketti 2 (WS2) keskittyi Pohjoismaisen EHDS2-osaamisfoorumin perustamiseen, kansallisen edistymisraportoinnin koordinointiin sekä yhteistyön edistämiseen metadatan, oikeudellisten viitekehysten ja teknisen infrastruktuurin osalta. Syyskuun 2024 ja syyskuun 2025 välillä järjestettiin neljä osaamisfoorumiä eri Pohjoismaissa, ja viides on suunniteltu lokakuulle 2025. Näissä foorumeissa ministeriöiden ja viranomaisien edustajat Pohjoismaista ja Baltian alueelta kokoontuivat jakamaan kokemuksia, tunnistamaan haasteita ja tutkimaan harmonisointimahdollisuuksia EHDS2:n toimeenpanossa eli EHDS:n ulottuvuudessa, joka koskee erityisesti terveystiedon toissijaisesta käytöstä.

Keskeiset tulokset ovat:

- **Kansalliset edistymisraportit:** Yhtenäistetty kyselypohja mahdollisti EHDS2-valmiuden seurannan eri maissa. Raportit paljastivat vaihtelevia oikeudellisia, organisatorisia ja teknisiä valmiuksia sekä yhteisiä haasteita liittyen esimerkiksi lupaviranomaisen (Health Data Access Body, HDAB) nimeämiseen, metadataluetteloihin ja tietoturvallisten käyttöympäristöjen (Secure Processing Environment, SPE) yhteentoimivuuteen.
- **Ryhmätyöistunnot:** Teemakohtaiset keskustelut lupaviranomaisesta, tietoturvalisistä käyttöympäristöistä, metadatasta ja oikeudellisista näkökohdista toivat esiin kansallisten lähestymistapojen pirstaleisuuden ja pohjoismaisen linjauksen tarpeen. Aiheita, kuten maksukäytännöt, eettinen arviointi, opt-out-mallit ja metadastandardit, käsiteltiin syvällisesti.
- **Oikeudellinen harmonisointi:** Maat mukauttavat kansallisia lakejaan EHDS:n mukaisiksi, mutta aikataulut ja tulkinnat vaihtelevat. Yhteisiä pohjoismaisia toimia suositellaan sallittujen käyttötarkoitusten, maksuperiaatteiden, opt-out-mekanismien ja immateriaalioikeuksien käsittelyn yhdenmukaistamiseksi.
- **Suosituksset VALO2-hankkeelle:** Hyväksytyt hankkeen jatko vuoteen 2026 keskittyvät toisessa työpaketissa (WS2) terveystiedon saatavuuden pullonkaulojen tunnistamiseen ja lieventämiseen. Suunnitelmassa ovat osaamisfoorumien jatko, laajennetut ryhmätyöistunnot sekä metadatan ja oikeudellisten työpakettien syvämpi integrointi.

Kaiken kaikkiaan VALO ja WS2 ovat luoneet vahvan perustan pohjoismais-baltialaiselle yhteistyölle EHDS2:n toimeenpanossa. Hanke osoittaa, kuinka arvokasta on strukturoitu vuoropuhelu, yhteiset työkalut ja koordinoitujen strategioiden monimutkaisessa sääntely- ja teknisessä toimintaympäristössä. VALO2 rakentaa näiden saavutusten varaan vahvistaakseen alueellista johtajuutta terveystiedon toissijaisessa käytössä.

Sammanfattning

VALO-projektet, finansierat av Nordiska ministerrådet, syftar till att stärka det nordiska samarbetet kring sekundäranvändning av hälsodata och stödja implementeringen av det europeiska hälsodataområdet, (European Health Data Space, EHDS). Aktiva deltagare i VALO var Finland, Island och Sverige samt Danmark och Norge. Under den andra halvan anslöt de baltiska länderna Estland och Litauen som observatörer.

Arbetsström 2 (WS2) fokuserade på att etablera det nordiska kompetensforumet för EHDS2, samordna nationell rapportering och främja samarbete kring metadata, rättsliga ramverk och teknisk infrastruktur. Mellan september 2024 och september 2025 hölls fyra kompetensforum i olika nordiska länder, och ett femte är planerat till oktober 2025. Dessa forum samlade representanter från ministerier och myndigheter i Norden och Baltikum för att dela erfarenheter, identifiera utmaningar och utforska harmoniseringsmöjligheter vid implementeringen av EHDS2, det vill säga den dimension av EHDS som specifikt rör sekundäranvändning av hälsodata.

Viktiga resultat inkluderar:

- **Nationella framstegsrapporter:** En harmoniserad enkätmall möjliggjorde uppföljning av EHDS2-beredskap i olika länder. Rapporterna visade varierande nivåer av juridisk, organisatorisk och teknisk beredskap, med gemensamma utmaningar kring utnämning av organ för tillgång till hälsodata (Health Data Access Body, HDAB), metadatakataloger och interoperabilitet med säker behandlingsmiljö (Secure Processing Environment, SPE).
- **Gruppdiskussioner:** Tematiska diskussioner om HDAB/SPE, metadata och juridiska aspekter belyste fragmentering i nationella tillvägagångssätt och behovet av nordisk samordning. Ämnen som avgiftsstrukturer, etikprövning, modeller för att motsätta sig tillgång till hälsodata (opt-out) och metadatastandarder diskuterades ingående.
- **Rättslig harmonisering:** Länderna anpassar nationella lagar till EHDS, men tidslinjer och tolkningar varierar. Gemensamma nordiska insatser rekommenderas för att samordna tillåtna ändamål, avgiftsprinciper, opt-out-mekanismer och hantering av immateriella rättigheter (Intellectual Property, IP).
- **Rekommendationer för VALO2:** Den godkända förlängningen av projektet för 2026 kommer i WS2 att fokusera på att identifiera och minska flaskhalsar i tillgången till hälsodata. Fortsatta kompetensforum, utökade gruppdiskussioner och djupare integration av metadata- och juridiska arbetsströmmar planeras.

Sammanfattningsvis har VALO och WS2 lagt en stark grund för nordiskt-baltiskt samarbete vid implementeringen av EHDS2. Projektet visar värdet av strukturerad dialog, gemensamma verktyg och koordinerade strategier för att navigera i komplexa regulatoriska och tekniska landskap. VALO2 kommer att bygga vidare på dessa framgångar för att ytterligare stärka regionens ledarskap inom sekundäranvändning av hälsodata.

1 Abbreviations

AI	Artificial Intelligence
CIOMS	Council for International Organizations of Medical Sciences
CoP	Community of Practice
CSVW	Comma-Separated Values - Web
DG SANTE	Directorate General for Health & Food Safety
EC	European Commission
ECDC	European Centre for Disease Control
EHDS	European Health Data Space
EHDS2	European Health Data Space – Secondary use
EOSC-ENTRUST	European Open Science Cloud – European Network of TRUSTed Research Environments
EU4Health	EU for Health projects funding programme
FAQ	Frequently asked questions
GDPR	General Data Protection Regulation
HDAB	Health Data Access Body
HUNT Cloud	Helseundersøkelsen i Nord-Trøndelag Cloud
DCAT-AP	Data Catalog Vocabulary – Application Profile
HL7 FHIR	Health Level 7 – Fast Healthcare Interoperability Resources
IP	Intellectual Property
JA	Joint Action
JACARDI	Joint Action on Cardiovascular Diseases and Diabetes
MS	Member State
NCP	National Contact Point
OMOP CDM (OHDSI)	Observational Medical Outcomes Partnership Common Data Model (Observational Health Data Sciences and Informatics)

OpenEHR	Open Electronic Health Record
Quantum	Healthdata quality and utility label
SAFE	Secure Accessible Federated Environment
SENASH	Sweden National services for Access to Swedish Health data for secondary use
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms
SPE	Secure Processing Environment
SPUHiN	Secure Procurement and Use of Health data in Norway
TEHDAS	Towards the European Health Data Space
THL	Finnish Institute for Health and Welfare
TSD	Tjenester for Sensitive Data
UNESCO	United Nations Educational Scientific and Cultural Organization
VALO	Value from Nordic Health Data
WS	Work Stream
Xt-EHR (JA)	Extended Electronic Health Records (Joint Action)

2 Introduction

This is the final report on the Nordic EHDS2 Competence Forum, the regular event promoted by Work Stream 2 (WS2) of the VALO project (Value from Nordic Health Data), which serves as a gateway to dialogues on the implementation of the European Health Data Space (EHDS). As a central component of WS2, this forum will be carried forward into the second phase of the project, VALO2.

Funded by the Nordic Council of Ministers, the VALO project had a two-fold aim: to determine common Nordic principles for implementing the Regulation on EHDS, and to explore how Nordic cooperation can be leveraged for promoting research, development and innovation related to secondary use of health data (hence the use of the term EHDS2). The overarching goal was to strengthen the Nordic countries' position as forerunners and their competitiveness, with regards to secondary use of health data.

To that end, the initial partners launching the project were Finland, Iceland and Sweden, while Denmark and Norway participated as observers. Following the successful launch of the VALO project and seeing the benefit of concrete collaboration through e.g. Competence Forums, Norway and Denmark joined the planning of VALO2 project as full partners. Continued efforts to expand the initiative yielded broader participation, with Estonia and Lithuania subsequently accepting the invitation to join the project as observers.

The VALO project has **four main goals**:

1. to **strengthen Nordic cooperation** and the use of health data in research, development and innovation.
2. to **prepare together for the EHDS**, to start implementing the changes and reforms required by EU legislation and to share best practices.
3. to **test and show in practice** the effectiveness of cross-border Nordic cooperation when it comes to the use of health data.
4. to **promote** the Nordic countries' leading position in the secondary use of health data.

In order to achieve these goals, the VALO project was structured around **three work streams** (WS), each addressing a strategic dimension of this collaboration:

WS1: Create a common value proposition and develop a Nordic model for collaboration on secondary use of health data.

WS2: Establish and organise an EHDS2 Competence Forum, where the Nordic countries meet to exchange information related to, and coordinate preparations for, the implementation of the EHDS, and try to find a common way to implement the EHDS HealthDCAT-AP metadata model into national health data catalogues and to ensure a shared Nordic view on metadata solutions for secondary use of health data.

WS3: Run pilot projects in research based on decentralised analysis and increased knowledge of how to work technically and semantically with distributed health data in the Nordic countries.

The overall objectives of WS2 were:

The Nordic countries get **better prepared** for the implementation of EHDS.

Relevant Nordic EHDS **stakeholders are aware of** what EHDS-related EU-funded projects that are ongoing, who are involved in them and what projects are in the pipeline.

Authorities who are responsible for EHDS2 implementation know each other, **peer support is active** and seamless, and there is harmonised implementation exemplified through collaboration on metadata catalogues.

By the time this report was finalised, four Nordic EHDS2 Competence Forums had been arranged, one in Finland, one in Denmark, one in Sweden and one in Iceland. A fifth and final Competence Forum is organised again in Finland by the very end of the VALO project.

It is evident that the Competence Forums have played a significant role in translating WS2 objectives into tangible outcomes. The following section will explore how the Forum came to fruition and evolved within the framework of WS2, highlighting both the challenges encountered and the opportunities leveraged through the process.

3 Preparing for the Nordic EHDS2 Competence Forum

The table below outlines the six tasks assigned to Work Stream 2. The first three are pivotal in shaping the Competence Forum: Task 2.1 involves the development of a reporting template used by authorities across the Nordic countries to monitor progress, which is subsequently presented within the Forum. Task 2.2 focuses on identifying relevant authorities whose participation in the Forum is considered strategically valuable for advancing the project’s goals and fostering cross-border collaboration. Task 2.3 addresses the administrative groundwork required to operationalise the Forum and ensure its smooth functioning.

Table 1. Tasks of Work Stream 2 of the VALO Project, with task number, title and brief description.

T2.1	Progress report template	Create a template which authorities in each Nordic country use to report on their progress in the EHDS2 competence forum
T2.2	Identify authorities and schedule meetings	Identify authorities which participate in EHDS2 Competence Forum and schedule quarterly meetings (Q3, Q4 2024, Q1, Q2 and Q3 2025)
T2.3	Nordic EHDS2 competence forum	Prepare and organise EHDS2 Competence Forums, collect and share country progress reports and make them available for the participants.
T2.4*	Nordic contributions to EU projects for EHDS	Mapping and compilation of Nordic participation and representatives in EHDS-related EU projects, including concrete clinical or research objectives.
T2.5*	Horizon scanning on future projects	Keep track of EHDS2 related upcoming calls and analyse Nordic priorities and collaboration opportunities.
T2.6*	Tracking progress on and supporting national metadata catalogues	Engage with the informal Nordic Health Metadata Network, focus on metadata data models vs. DCAT-AP Health Extension. Contribute updates on metadata catalogues related work and projects to T2.1 and T2.5 and respective outputs (2.1 -2.4)

The remaining tasks (2.4, 2.5, and 2.6) constitute separate deliverables under WS2. Tasks 2.4 and 2.5 refer, respectively, to the mapping and compilation of Nordic participation in EHDS-related projects, and the systematic tracking of EHDS2-relevant calls.

Task 2.6 monitors progress on the development of metadata catalogues and is documented in a separate report¹.

3.1 Mobilising Participation: Inviting Authorities to the Forum

The Nordic EHDS2 Competence Forum was held by invitation only. An initial objective was therefore to identify relevant authorities to participate in the Competence Forum and schedule quarterly EHDS2 Competence Forum meetings.

During the early phase of the work stream planning, project partners, as well as observers, from all the Nordic countries contributed to identifying the relevant participants in each country, on ministerial and authority level. Invitations were successfully sent out for the first Competence Forum (by invitation only meeting), which gathered 40 representatives from all the Nordic countries in Helsinki, in September 2024. In addition, a limited number of participants joined the meeting online.

For the following Competence Forums, invitations were sent out to the identified contacts as well as the participants in the previous meeting(s) with encouragement to forward the invitation to any relevant colleagues.

The list of identified potential participants grew throughout the project, partly due to Estonia and Lithuania joining as observers. A list of organisations invited for the Competence Forum is presented in Annex 1.

3.2 National Progress Report Survey – template

A harmonised survey template was developed, for ministries and authorities in the Nordic countries to report on their national progress on the preparations for the implementation of EHDS, specifically with regards to secondary use of health data. The results of these quarterly surveys were presented and discussed at the Nordic EHDS2 Competence Forum.

An initial template for the national progress reports was developed for the first EHDS2 Competence Forum in September 2024. The template consisted of a survey for the countries to fill in. The proposed template was shared with DG SANTE of the European Commission (EC). The EC expressed appreciation for the initiative to jointly prepare for the implementation of EHDS, as well as for the progress report template *per se*. In addition to this feedback EC constructively proposed a number of changes to the template, mainly in the form of additional relevant questions. Given the limited timeframe, it was not possible however to incorporate the proposed changes into the progress report template ahead of the first Competence Forum. Instead, the progress report template was slightly revised prior to the second Competence Forum in February 2025, in order to optimise the survey by combining and including questions and aspects as proposed by the EC. At the same time, an important aspect of the progress report template was to retain the questions in a way that

¹ Final metadata catalogues report. VALO Project. 2025

enabled longitudinal comparison of responses, thereby supporting the tracking of EHDS2 progress implementation across the Nordic countries.

The revised version of the progress report template is attached to this report (Annex 2).

In this context it should be added that during Summer 2025 EC distributed two surveys to all national member organisations of the Community of Practice for secondary use Direct Grants: i) *the HDAB SURVEY - HDAB Maturity Model*, specifically concerning the HDAB role with the digital abilities expected for EHDS, and ii) *the MS SURVEY - HDAB Maturity Model*, concerning more overarching strategic decisions and directions or plans on the national Member State level. During VALO2, it may prove valuable to analyse and compare the EC surveys and their results for the Nordic-Baltic countries with the national progress report survey conducted by the VALO project.

4 Realising the Nordic EHDS2 Competence Forum

By the time this report is finalised, a total of four Competence Forums have been organised during the VALO project – in Helsinki, Gothenburg, Copenhagen, and Reykjavik – and a fifth and final edition is currently being prepared again in Helsinki. This fulfils the ambition of convening national authorities on a quarterly basis to discuss the implementation of EHDS. Another ambition was to realise the Forum in each Nordic country – an objective that was only partially met, since Norway did not have the chance to host any of the editions. It is hoped that Norway will host a Competence Forum during the upcoming VALO2, potentially alongside one of the Baltic countries.

Each Competence Forum gathered approximately 40 participants from public authorities across all Nordic countries, with Lithuania and Estonia also represented in the later meetings. While in-person participation was encouraged, online attendance was made available for all editions. The forums were initially held as single-day meetings, later expanding to a two-day format at the Reykjavik edition.

Prior to each edition of the Forum, country progress reports were collected and made available to participants as preparatory material for discussion and collaborative work. The presentation of these results facilitated joint reflection on progress made, remaining challenges, areas of ambiguity, and opportunities for Nordic collaboration and harmonisation. A detailed account of the findings from the national progress reports is provided in section *4.1 National progress reports – results*.

At each Forum, the host country presented an update on the current status of the implementation of EHDS in their country, and/or other relevant topics. The Reykjavik Competence Forum, held over two days, included a study visit to the company *deCODE genetics* prior to the official start of the Forum. During the same Forum, a workshop was held on the draft for a Nordic model developed within WS1 of the VALO project, contributing to a stronger integration and alignment across the work streams.

The Forum also aimed to engage participants in in-depth discussions on three key topics: (i) HDAB/SPE², (ii) metadata and metadata catalogues, and (iii) legal and regulatory aspects.

² HDAB – Health Data Access Body; NCP2 – National Contact Point for secondary use of health data; SPE – Secure Processing Environment. This breakout session also handled a plethora of related issues, e.g. application process and support functions.

These themes were explored in dedicated breakout sessions, where participants worked in smaller groups to examine each area more closely and exchange national perspectives. A detailed account of the breakout sessions is presented in section 4.2 *Breakout sessions*.

In an effort to enhance the participant experience, a web-based evaluation was introduced following the second Competence Forum and continued thereafter. Valuable feedback gathered through these evaluations is presented in more detail in section 4.3 *Evaluation of Competence Forums*.

Below is a summary of each Competence Forum, highlighting location and notable activities:

First Competence Forum in Helsinki, Finland, September 2024:

The first Nordic EHDS2 Competence Forum brought together 40 participants from all the Nordic countries for a full-day, in-person meeting, complemented by eight online participants. A national update from the hosting country was presented by Findata, sharing their experiences: “Lessons learnt and the way forward”.

Second Competence Forum in Copenhagen, Denmark, February 2025:

The second Nordic EHDS2 Competence Forum took place in Nordens Hus in Copenhagen, gathering 28 participants from all Nordic countries for a full-day, in-person meeting. In addition, nine participants joined online. A national update from the hosting country was presented by the Danish Health Data Authority, and by Healthcare Denmark: “The Danish Strategy for Life Science towards 2030”.

Third Competence Forum in Gothenburg, Sweden, May 2025:

The third Nordic EHDS2 Competence Forum took place in Gothenburg, in conjunction with the Vitalis conference. It gathered 35 participants from all Nordic countries and Lithuania for a full-day, in-person meeting. In addition, five participants joined online. A national update from the hosting country was presented by the Ministry of Health and Social Affairs: “Swedish update on the implementation of EHDS”, and by the EU Direct Grant project SENASH: “Sweden - National services for Access to Swedish Health data for secondary use”.

Fourth Competence Forum in Reykjavik, Iceland, September 2025:

The fourth Nordic EHDS2 Competence Forum gathered 35 participants from all Nordic countries and Lithuania for a two-day meeting in Reykjavik. In addition, ten participants joined online. Prior to the official start of the Forum, a study visit to the company deCODE was organised, offering the opportunity for information exchange and dialogue in light of EHDS requirements on data access. A national update from the hosting country was presented by the Ministry of Health: “Healthcare Data for Better Care: Implications of the HIMSS Continuity of Care Assessment in Iceland”.

Fifth Competence Forum in Helsinki, Finland, October 2025:

At the time of writing this final report (Sept/Oct), the fifth Nordic EHDS2 Competence Forum was still in the planning stage, to be held late October.

4.1 National progress reports – results

An overview of the results and conclusions drawn from the responses to the National Progress Report on the preparations for EHDS implementation has been presented in different formats at each Competence Forum. Survey results, based on the progress report template, reflect national progress as reported between September 2024 and September 2025. The summary below offers a brief overview and should not be seen as a definitive or exhaustive.

4.1.1 Denmark

Strategy & Legislation: Denmark does not have a dedicated strategy for secondary use of health data but includes it in broader national strategies. A legal gap analysis was initiated in August 2025 to align national laws with EHDS requirements. Significant regulatory updates are needed, especially in data protection and interoperability. These are being scoped in connection with the 2024 Health Reform.

Organisational readiness: No formal HDAB or National Contact Point (NCP2) have been appointed. Responsibilities remain distributed across existing authorities.

Cost & Impact assessment: A general cost estimate was made earlier (1.2–7.5 billion DKK). A new cost analysis was launched in August 2025 to refine this.

Technical readiness: Denmark has a functioning Secure Processing Environment (SPE) managed by the Danish Health Data Authority. Metadata catalogue development is underway via an EC direct grant.

Communication & Engagement: Denmark has actively engaged stakeholders through workshops and panel discussions. A national communication strategy is in place, and public information is available via *Forskervservice*.

International collaboration: Denmark has participated in HealthData@EU Pilot, TEHDAS2, Xt-EHR, xSHARE, and other EU initiatives, though no formal strategy for EU project participation exists.

4.1.2 Finland

Strategy & Legislation: The Act on Secondary Use of Health and Social Data exists. Legislative review to align with EHDS starts in September 2025.

Organisational readiness: HDAB has not yet been formally appointed - roles will probably be distributed across **existing** authorities. NCP2 preparation underway.

Technical readiness: Ten audited SPEs exist. National health metadata catalogue is in place. Planning on how to transit to HealthDCAT-AP in spring 2026.

Communication & Collaboration: Active stakeholder engagement. Steering groups for 2025–2027 being appointed, and communication campaigns are ongoing.

International collaboration: Strong participation in EU projects (TEHDAS2, HealthData@EU, Quantum, VALO, JACARDI JA, EOSC-ENTRUST).

4.1.3 Iceland

Strategy & Legislation: Multiple laws support secondary use of health data. Legislative review is needed to align with EHDS. HDAB or NCP2 have not been appointed yet.

Organisational readiness: Ethics committees manage data access – coordination structures exist but are fragmented.

Technical Readiness: No health-specific SPE yet, although Statistics Iceland has an SPE. Metadata work is ongoing, however no national health data catalogue exists yet.

Communication & Collaboration: Permanent forums exist (e.g., EHDS IS group, VALO group). Public information available but not centralised.

International collaboration: Active in VALO, TEHDAS2, EU4Health, CIOMS, UNESCO, and ECDC.

4.1.4 Norway

Strategy & Legislation: A national strategy for secondary use of health data was finalised for 2025–2027, focusing on data availability, quality, reduced burden of clinicians, cooperation, and public trust. Existing national laws (Health Registry Act, Health Research Act) are in place but require updates, especially around genomics, consent, opt-out provisions, and commercial use. Norway plans to adopt national derogations under EHDS Article 71(4).

Organisational readiness: The Norwegian Institute of Public Health (NIPH) was formally appointed as the Coordinating HDAB in August 2025.

Gap analysis: Phase 1 completed in March 2025; Phase 2 (including cost estimates and implementation measures) is underway, due by November 2025.

Technical readiness: SPEs are identified (e.g., HUNT Cloud, SAFE, TSD). The SPUHiN³ project (national Direct Grant for secondary use) is developing minimum requirements and metadata integration.

Data Protection: Challenges persist around anonymisation and pseudonymisation. Federated solutions are being explored to mitigate re-identification risks.

Communication & Collaboration: Ongoing stakeholder engagement through advisory boards, webinars, and a national communication strategy. Norway actively participates in EU initiatives like SPUHiN (national level), QUANTUM, TEHDAS2, and United4Surveillance.

4.1.5 Sweden

Strategy & Legislation: There is no comprehensive national strategy yet, instead multiple sectoral strategies exist. Legal updates are underway via government inquiries (e.g., SOU 2024:57).

³ FAIR Secure Procurement and Use of Health data in Norway

Organisational readiness: HDAB is not formally appointed, but roles proposed for National Board of Health and Welfare (NBHW; coordinator role), Statistics Sweden SCB (SPE), and the Health and Care Inspectorate (IVO; supervision). NCP2 role is under evaluation.

Technical readiness: No national SPE yet, but candidates identified (MONA⁴, BIANCA⁵, SUNET⁶). Metadata catalogues exist; HealthDCAT-AP piloting is ongoing.

Communication & Collaboration: Active stakeholder engagement through councils, webinars, and national conferences. Longterm project forums like SENASH (Direct Grant for secondary use) and DIGIfor1healthSE are in place.

International Collaboration: Strong involvement in EU and Nordic projects (TEHDAS2, VALO, Horizon Europe, EU4Health).

4.1.6 Lithuania

Although Lithuania joined VALO as observer, it has nonetheless submitted a national progress report since February 2025, briefly summarised as follows:

Legal readiness: Lithuania has a foundational law (Law No. XIV-789) but acknowledges the need for updates, especially around opt-out procedures and interoperability.

Organisational readiness: The State Data Agency is confirmed as the HDAB, but finer details of application processes and supervision are evolving.

Technical readiness: A specific commercially available digital platform designed for integrating, modelling, and analysing data is used as SPE, and metadata catalogues are partially in place.

Communication & Collaboration: While initial reports lacked a formal strategy, later updates hint at increased stakeholder engagement and international collaboration (e.g., VALO, TEHDAS2).

4.2 Breakout sessions

The breakout sessions constitute a central component of the Nordic EHDS2 Competence Forum, providing an opportunity for expert representatives from ministries and government agencies from the Nordic-Baltic countries to have informal in-depth discussions in a trusting environment on these complex matters. As mentioned above, the breakout sessions have been structured around three broadly defined topics: i) HDAB/SPE⁷, ii) Metadata and metadata catalogues, iii) Legal and regulatory aspects.

⁴ Microdata Online Access (SCB)

⁵ Bianca is a research system dedicated to analysing sensitive personal data (NAISS).

⁶ Swedish University Computer Network

⁷ HDAB – Health Data Access Body ; NCP2 – National Contact Point for secondary use of health data ; SPE – Secure Processing Environment. This breakout session also handled a plethora of related issues, e.g. application processes and support functions.

The general objectives of the breakout sessions were to:

Compare national and Nordic (Nordic-Baltic) aspects, identifying needs for adjustments.

Discuss ambiguities and question marks in EHDS proposal.

Discuss possibilities for Nordic (Nordic-Baltic) collaboration (and harmonisation).

Throughout a series of meetings, the Nordic EHDS2 Competence Forum has mapped national and cross-border challenges, opportunities, and progress related to the implementation of the EHDS2. This chapter synthesises key findings from the breakout sessions held across four Competence Forums, with a focus on identifying areas where Nordic (Nordic-Baltic) collaboration and harmonisation are both necessary and feasible.

4.2.1 HDAB breakout sessions – outcomes

In the breakout sessions dedicated to discussions on HDAB-related issues, participants raised a range of questions related to the application process, support functions, SPEs, technical infrastructure, fees etc. The following is a brief summary of the discussion points, with indications of conclusions or consensus as well as potential for Nordic harmonisation and suggested ways forward.

4.2.1.1 Potential key areas for Nordic collaboration

HDAB: mandate, structure, and coordination

- **Uncertainty and fragmentation:** Most Nordic countries have not formally appointed their HDABs, potentially leading to unclear mandates, budgets, and responsibilities.
- **One or several HDABs per country?** Government decisions largely still pending.
- **Coordination challenges:** Fragmented national organisational landscapes and unclear division of roles between HDABs (candidate authorities) and data holders.
- **Potential for harmonisation:**
 - With regard to stakeholder communication, coordinate strategies for informing citizens, researchers, and data holders about EHDS2 and their rights.
 - Develop a common methodology for assessing costs and benefits of EHDS2 implementation.

SPE: models, capacity and interoperability

- **Multiple versus single SPEs?** All countries have SPE-like resources. Consensus is emerging that several specialised SPEs (depending on type of health data) are preferred over a single national one.
- **Technical and legal challenges:** Data transfer between SPEs, cross-border interoperability, and responsibility for anonymisation / pseudonymisation remain unresolved.
- **Capacity issues:** Increasing demand for data access and volumes, especially from AI projects, is straining existing infrastructure.
- **SPE landscape mapping:** As part of VALO2, mapping existing SPEs and identifying best practices (potential overlap with task of WS3 should first be investigated).

- **Potential for harmonisation:** Shared technical SPE standards and components to enable cross-border data use and cost savings. As part of this, define minimum requirements and shared components for SPEs, including secure data transfer protocols (aligned with EHDS requirements and specifications). Also moving from manual to API-based data transfer.

Application process: bottlenecks and quality

- **Major bottlenecks:** Lack of helpdesk and support functions, delays in data sampling and cost estimation, frequent data delivery errors.
- **Metadata and data discovery:** Researchers often lack information about available data, leading to inefficient applications.
- **Communication gaps:** Need for better tools and structured dialogue between applicants, HDABs, and data holders.
- **Potential for harmonisation:**
 - Formalising the Nordic Metadata Group to develop a shared metadata catalogue and data discovery platform (see also Metadata breakout).
 - Harmonised front-end with application forms, harmonised ethical review, traffic-light models for (common) variable selection, structured pre-application support and double-checks, to reduce errors and backlogs.

Fees and financing

- **Diverse fee structures:** There is significant variation between countries; Harmonised invoicing is seen as desirable but practically difficult.
- **Balancing costs and access:** Ensuring affordability for researchers, especially small and medium-sized enterprises (SMEs), as well as students, while covering operational costs.
- **Potential for harmonisation:** Common principles for fee principles and structures, even if full harmonisation does not seem feasible.

Data rights, ethics, and legal issues

- **Shift to citizen data empowerment:** This shift raises new challenges with regard to communication and consent.
- **Ethical review and GDPR⁸/EHDS alignment:** Differences in national practices, especially regarding private sector access and data minimisation.
- **Responsibility for anonymisation / pseudonymisation:** Varies between countries; some rely on researchers, others on HDABs.
- **Potential for harmonisation:** Develop joint guidelines for ethical review, data minimisation, anonymisation / pseudonymisation, GDPR and EHDS interpretation, and private sector access, thereby clarifying legal responsibilities (overlap with Legal breakout session).

⁸ General Data Protection Regulation

With regard to these issues, it is obvious that the discussions sometimes overlap with the topics of the Legal breakout session, and the Metadata breakout session (see below), although the observations and proposals are clearly derived from different expertise perspectives.

4.2.2 Legal breakout session

In the breakout sessions on legal issues the ongoing adaptation of national legislation to the EHDS Regulation was discussed, as well as interpretation of certain Articles of the EHDS Regulation. The latter allows for and potentially requires measures on national level to ensure legal certainty. Here follows a brief summary of the major topics that were discussed with indications of any conclusions or consensus as well as suggested ways forward.

4.2.2.1 Key Legal issues for Nordic collaboration

National Legislation and EHDS alignment

- All countries must adjust their national laws to meet EHDS requirements, but processes and timelines differ.
- **Potential for harmonisation:** Countries could explore ways to formalise or otherwise continue the collaboration established during the Legal breakout sessions, as part of VALO's Nordic model for collaboration, in order to address EHDS-related legal issues and promote harmonisation in the Nordics (see VALO final report on the Nordic model for collaboration⁹). For promotion of further practical collaboration shared folders and exchange of interpretations could be used, as well as Q&As¹⁰. For in-depth analysis of legislative needs countries have already initiated mapping out of required legal changes and started national inquiries.

Interpretation of permitted and prohibited purposes

- Articles 53¹¹ and 54¹² of EHDS are not comprehensive and can be interpreted differently, creating uncertainty about what is permitted or not when it comes to secondary use of health data.
- The HDAB's role in monitoring purposes of use is unclear and resource-intensive. Hence, continuous follow-up after a project is completed is difficult to implement.
- **Potential for harmonisation:** Joint Nordic guidelines for what is allowed or prohibited under EHDS.

Fees and financing

- There are different fee models across countries regarding who is allowed to charge fees and for what services.

⁹ VALO WS1 Final report: Nordic model for collaboration on the secondary use of health data - a proposal

¹⁰ Questions & Answers

¹¹ Article 53 in EHDS Regulation: Purposes for which electronic health data can be processed for secondary use

¹² Article 54 in EHDS Regulation: Prohibited secondary use

- There is a risk that multiple fees (for different steps of application process and data access) make secondary use expensive and hinder public benefit.
- There is a desire that fees should not be a barrier for Nordic solidarity and that the system should benefit research and innovation.
- Discussion about fees for guidance — some countries charge for support in data discovery, others do not. Suggestions include AI chat and Frequently Asked Questions (FAQs) to reduce the burden on data holders.
- **Potential for harmonisation:** Develop common principles for fees, especially for research and the public sector, as well as for guidance. There is a growing consensus on the importance of not letting fees hinder research, and on new ideas about guidance fees and digital support.

Opt-out and citizen rights

- Uncertainties exist about how opt-out should be implemented and which law – GDPR or EHDS? – takes precedence.
- How are citizens informed about their rights and the consequences of opting out? There is ongoing discussion about the possibility of “layered opt-out” (partial opt-out). The trust of the Nordic people needs to be cherished to ensure that we continue to receive plenty of high-quality health data.
- **Potential for harmonisation:** A harmonised opt-out model and joint information strategy for citizens to strengthen public trust. Several countries are discussing different models and information initiatives.

Trusted data holders and simplified processes

- It is unclear how responsibilities should be shared between HDAB and Trusted data holders, especially in simplified processes.
- There is a risk of duplication of work and expenses if both the Trusted data holder and the HDAB evaluate the application.
- **Potential for harmonisation:** Exploration of whether, and to what extent, a coordinated division of responsibilities between HDAB and the Trusted data holder can be achieved to support more effective collaboration. Initial group discussions indicate concrete examples of how HDAB and Trusted data holders can collaborate and avoid duplication of work.

Combining health data and social data

- Different national solutions exist: Finland already allows combination, but EHDS only covers health data - or is that an example of differing interpretation? There is a risk of fragmentation and divergent interpretations.

International and national collaboration

- Several countries have fragmented systems with independent biobanks and registries.
- According to the discussions, there is a need for a permanent structure for legal collaboration.

- Practical collaboration through shared folders, sharing of interpretations, Q&A, and coordination of Nordic positions ahead of EHDS committee work.
- **Potential for harmonisation:** EHDS2 HDABs Community of Practice and TEHDAS2 are used as platforms for international dialogue and joint development.

IP rights and trade secrets

- Who is responsible for determining if data contains trade secrets or IP¹³ rights — the HDAB or the data holder? (e.g. Researchers may access measurement data but not technical details about how a medical device works).
- There is a need for clear procedures and legal expertise.
- **Potential for harmonisation:** Joint guidelines for handling IP rights and trade secrets in data sharing. New discussions on the division of responsibilities and the need for legal expertise.

Data discovery and data quality

- Who is responsible for ensuring researchers get the right support in finding and understanding data? How much guidance should be free of charge?
- How to motivate researchers to share experiences about data quality after completing a study, without risking their credibility?
- **Potential for harmonisation:** Development of AI-based support tools and innovation labs (regulatory sandboxes?) for data discovery and quality exchange, to streamline guidance and experience sharing.

4.2.3 Metadata breakout session

The discussions in the Metadata breakout sessions have mainly focused on the work on metadata and national metadata catalogues, to a high degree emanating from the standard HealthDCAT-AP. This work is also connected to the metadata work conducted in Joint Action TEHDAS2, which is coordinated by Finnish Innovation Fund Sitra. Since Sitra is also coordinator of the VALO project this provides a potential for synergies.

Task T2.6 of VALO presents its work on metadata in a separate final report¹⁴, which includes also information and outcomes of the metadata breakout sessions of the Competence Forums. A summarising description of the metadata final report gives the following:

A main objective of this task was to engage with the informal Nordic Health Metadata Network, focusing on metadata data models vs. DCAT-AP Health Extension (HealthDCAT-AP). As a result, selected outcomes from the earlier Nordic Commons project were utilised for further work and development.

The themes and discussions of this task covered a concrete work plan, the status of national health metadata catalogues and preparations for EHDS, updates on national and EU projects related to metadata, discussions on EHDS requirements on metadata catalogues like the HealthDCAT-AP metadata model, different distributions in HealthDCAT-AP and dataset

¹³ Intellectual Property rights

¹⁴ Final metadata catalogues report. VALO Project. 2025

definition in EHDS. Through the integration of the Nordic Health Metadata Network into the VALO project the network's operation has also become more established.

To address these issues, Nordic countries are exploring a range of solutions. These include piloting the HealthDCAT-AP editor to improve usability, collaborating with DCAT-AP experts to align national catalogues, and using DatasetSeries to introduce hierarchical structuring. A pragmatic implementation approach aims to reduce the burden on data holders. Efforts are underway to develop a Nordic variable-level metadata specification, which has been shared with TEHDAS2 to influence the evolution of HealthDCAT-AP. Common principles for dataset definition are being established to ensure clarity and feasibility, and a proposal for a "HealthDCAT-AP Nordic extension" seeks to harmonise national adaptations. Continued collaboration through initiatives like the Nordic Health Metadata Network and the VALO2 project will support these *efforts*, alongside mapping Article 51¹⁵ data categories, exploring AI-related metadata needs, and coordinating feedback to shape EHDS Implementing Acts. In the long term, there is a vision to create a Nordic or Nordic-Baltic health data catalogue should EU-level solutions prove insufficient.

4.3 Evaluation of Competence Forums

Starting from the second Competence Forum, evaluations have been conducted by web surveys distributed to all participants. Despite reminders, the response rates have consistently remained below 50%. Below is a brief summary of the three evaluations conducted to date, following the Competence Forums held in Copenhagen, Gothenburg, and Reykjavik:

Progress over time:

- **Engagement:** Increased on-site participation and deeper networking across forums.
- **Satisfaction:** Consistently high, with growing appreciation for breakout sessions and peer exchange.
- **Challenges:** Hybrid format and technical issues persisted; need for more structured and outcome-driven discussions.
- **Evolution:**
 - From general exchange (Copenhagen) → deeper collaboration and structure (Gothenburg) → stronger community and strategic focus (Reykjavik).
 - Clear momentum toward operationalising shared models and harmonising Nordic efforts.

4.4 Future Nordic EHDS2 Competence Forums

The fifth Competence Forum will take place in Helsinki, Finland, on October 29th, 2025. On the following day – the VALO Project will also arrange its second Stakeholder Forum, which is an open event.

¹⁵ Article 51 of EHDS Regulation: Minimum categories of electronic health data for secondary use

Looking further ahead, meetings with the Competence Forum will continue to be organised as a part of VALO2, the now approved extension of the project. The ambition is to arrange a Competence Forum also in Norway, thereby covering all the Nordic countries. During VALO2, there may also be opportunities to organise Competence Forums in Lithuania and/or Estonia.

Breakout sessions are planned to continue in their current format to ensure continuity in discussions and ongoing work. An additional breakout session may be introduced, focusing initially on general aspects of data models to facilitate secondary use – OMOP CDM in relation to e.g. OpenEHR, SNOMED CT, HL7 FHIR.

A slightly new or clarified focus for WS2 and the Competence Forums in VALO2 is to further identify and describe the major bottlenecks of health data access for secondary use, as well as to present proposed recommendations and measures in order to mitigate or even avoid these bottlenecks. This will be presented in a final report of WS2 at the end of VALO2.

5 Conclusions and way forward

The Nordic countries share many challenges in implementing EHDS2 but also have a unique opportunity to jointly lead in harmonisation and collaboration. By focusing on the identified problem areas and following the recommendations above, the Nordic (Nordic-Baltic) region can create a more efficient, secure, and user-friendly health data ecosystem – benefiting research, innovation, and ultimately, public health. With the analysis and outcomes presented in this report, this potential will be further elaborated and concretised in the VALO2 extension of this project. A certain focus will be on bottlenecks for health data access and identified measures to mitigate or avoid these.

For VALO as a whole, the synergies of the different work streams (WS1-3) should be further developed and elaborated ahead, with the aim of concretising the proposed Nordic Model.

6 External communication

Information about VALO and the Nordic EHDS2 Competence Forum has been communicated, e.g. on the Sitra website as well as on other project partners websites, in professional social media posts and as part of a conference newsletter. Below some examples:

[Value from Nordic health data – VALO - Sitra](https://www.sitra.fi/en/projects/value-from-nordic-health-data-valo/)

<https://www.sitra.fi/en/projects/value-from-nordic-health-data-valo/>

[2nd VALO EHDS2 Competence Forum - Sitra](https://www.sitra.fi/en/events/2nd-valo-ehds2-competence-forum/)

<https://www.sitra.fi/en/events/2nd-valo-ehds2-competence-forum/>

[Cultivating a Nordic voice: second Competence Forum strengthens Nordic collaboration on health data - Sitra](https://www.sitra.fi/en/news/cultivating-a-nordic-voice-second-competence-forum-strengthens-nordic-collaboration-on-health-data) (2025-03-18)

<https://www.sitra.fi/en/news/cultivating-a-nordic-voice-second-competence-forum-strengthens-nordic-collaboration-on-health-data/>

[Vitalis hosts summit on Nordic health data - Vitalis – English](https://en.vitalis.nu/2025/02/vitalis-hosts-summit-on-nordic-health-data/)

<https://en.vitalis.nu/2025/02/vitalis-hosts-summit-on-nordic-health-data/>

[Presentation of VALO project – HIMSS](https://www.himss.org/sites/hde/files/markus-kalliola-value-from-nordic-health-data-valo.pdf)

<https://www.himss.org/sites/hde/files/markus-kalliola-value-from-nordic-health-data-valo.pdf>

[E-hälsomyndigheten – Förberedelser i Norden](https://www.ehalsomyndigheten.se/ehds/for-dig-som-forskare-och-innovator/forberedelser-i-norden/)

<https://www.ehalsomyndigheten.se/ehds/for-dig-som-forskare-och-innovator/forberedelser-i-norden/>

Annex 1: List of VALO partner organisations and invitees

National EHDS authorities – Key stakeholders in Nordic EHDS2 Competence Forum

Introduction

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

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

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

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

Finland

Finnish Ministry of Social Affairs and Health

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

The Finnish Innovation Fund, Sitra

Sitra is an independent future fund operating under the Finnish Parliament. It anticipates societal changes and develops solutions to Finland's challenges through foresight, experimentation, and collaboration. Its mission is to promote Finland's well-being and accelerate sustainable economic growth within the limits of nature's carrying capacity.

Finnish Institute for Health and Welfare (THL)

THL is an independent expert and research institute under the Finnish Ministry of Social Affairs and Health. It promotes the welfare, health, and safety of the population by producing research, statistics, and policy recommendations. THL also serves as a statistical authority and holds national registers in its field.

Findata – Finnish Social and Health Data Permit Authority

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

Iceland

Ministry of Health

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

Directorate of Health

The Directorate of Health supervises healthcare services in Iceland and promotes public health through prevention, licensing of professionals, and oversight of health data. It also manages health statistics and coordinates responses to communicable diseases.

Centre of Public Health Sciences, University of Iceland

This research center focuses on population-based studies and health promotion. It conducts large-scale epidemiological research using national health registers and trains graduate students in public health sciences.

University of Iceland, Faculty of Law

Supporting other authorities in legal matters.

Sweden

Swedish Ministry of Health and Social Affairs

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

Swedish eHealth Agency

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

The National Board of Health and Welfare

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

Statistics Sweden

Statistics Sweden SCB is the national statistical agency responsible for producing official statistics to support decision-making, research, and public debate. It collects, analyzes, and publishes data on areas such as population, labor market, economy, health, and education.

Norway

Norwegian Ministry of Health and Care Services

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

Norwegian Directorate of Health

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

Norwegian Institute of Public Health (NIPH)

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

Denmark

Danish Health Data Authority

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

Danish Regions

Danish Regions is the national interest organization representing Denmark's five regions. It safeguards regional interests in healthcare, education, environment, and finances, and negotiates with the national government on funding and employment conditions. The organization also promotes regional development and acts as a central employer for regional staff.

Region Zealand

Region Zealand is one of Denmark's five administrative regions. Its main responsibilities include operating hospitals, mental health services, and specialized social institutions. The region also works on transport planning, environmental protection, and regional development, with a strong focus on innovation and cross-sector collaboration.

Lithuania

Ministry of Health of the Republic of Lithuania

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

National Cancer Institute (NCI)

NCI is Lithuania's leading oncology center, accredited by the Organisation of European Cancer Institutes. It conducts advanced research in molecular biology, genetics, and immunotherapy, and provides specialized cancer care and prevention programs.

Vilnius University Hospital Santaros Klinikos

Santaros Klinikos is a major university hospital offering multidisciplinary care and advanced treatments, including robotic surgery and transplantations. It collaborates with Vilnius University to integrate clinical services with research and education.

Estonia

Ministry of Social Affairs of Estonia

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

Annex 2: National progress report (survey template)

National Progress Report EHDS2 (VALO Project)

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

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

Contact information to respondent(s)

Date of submitting answers

Topic	Question
1. Policy and regulatory readiness	
1.1 Existing Strategies, Laws, and Guidelines on Secondary Use of Health Data	
	<p>1.1.1 Are there existing national strategies, guidelines or recommendations specifically addressing the secondary use of health data? If yes, please provide details, including the main objectives and scope of these.</p> <p>1.1.2 Are there any existing laws or regulations in your country that govern the secondary use of health data? If yes, please provide details, including any relevant legal texts or guidelines. Is there an English or Scandinavian version of the text?</p>
1.2 Need for Regulatory Updates and Revisions	
	<p>1.2.1 Will legislation updates or new laws be necessary to fully implement and support the secondary use of health data under the EHDS framework? If yes, what are the key areas that need to be updated? (e.g., data protection, interoperability requirements). Is there a planned timeline?</p> <p>1.2.2 Are there risks of different interpretations of EHDS regarding the secondary use of health data? Please describe briefly any proposed solutions.</p>
1.3 Supervisory and Penalty Framework	
	<p>1.3.1 Is there already an appointed authority for overseeing the secondary use of health data within the EHDS framework? Please specify the name of the authority and its responsibilities.</p> <p>1.3.2 Have penalty and/or fee levels been decided for non-compliance with regulations governing the secondary use of health data? If yes, please provide details.</p> <p>1.3.3 Do you currently have national-level legislation or instructions on fees for the secondary use of health data? If yes, please provide details.</p>

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

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

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

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

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

1.4 Legislation Adjustments and Flexibility for Member States

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

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

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

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

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

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

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

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

2. Organisational readiness

2.1 Designation of Health Data Access Bodies (HDAB)

2.1.1 Has a Health Data Access Body (HDAB) been formally appointed in your country?

If yes, please provide details on whether it is a single national HDAB or if there are several HDABs with one coordinating entity.

2.1.2 Are the HDAB functions and responsibilities distributed between existing authorities? If yes, please explain how these responsibilities are shared.

2.1.3 Has a new HDAB authority or authorities been established specifically for the EHDS? If yes, please provide details on their roles and functions.

2.1.4 Has the health data access application process been decided and assigned to the HDAB? Please provide more information on how this process is managed.

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

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

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

2.3 Training and Capacity Building

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

2.4 Impact Assessment and Cost Estimates

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

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

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

3. Technical readiness

3.1 Secure Processing Environment (SPE)

(may also be known as Trusted Research Environment)

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

3.1.2 Is there currently any SPE in your country used for analysing health data? If yes, please provide more information.

3.1.3 Do national legislation or technical specifications exist for SPE (or similar)? If yes, please provide details on these specifications.

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

3.2 Metadata Management

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

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

If yes, please describe these catalogues.

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

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

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

3.3 Infrastructure and Systems

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

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

3.4 Data Protection and Security

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

Please describe these challenges and any planned solutions.

4. Strategic and budgetary considerations

4.1 Monitoring and Evaluation

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

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

4.2 Data Localization

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

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

5. Communication and collaboration

5.1 National Communication Strategy

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

5.2 Stakeholder Engagement

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

5.2.2 Have you planned communication campaigns on the EHDS?

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

5.3 Permanent Groups and Forums

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

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

5.4 Public Information

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

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

5.5 International Collaboration

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

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

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

6. Additional comments or feedback

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