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

Report 1.0
Value from health data – VALO project

November 2025

Document info

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0.2 Keywords

Keywords	Health data, Nordic, EHDS, Nordic Model

0.3 Document history (to be removed from the published version)

Date	Version	Editor	Change	Status
2025-09-24	0.1	Rebekka Björg Guðmundsdóttir, Védís Helga Eiríksdóttir,	First draft	Draft
2025-09-30	0.2	All authors	Provided feedback and comments	Draft
2025-10-21	0.3	Rebekka Björg Guðmundsdóttir, Védís Helga	Final version	draft
2025-10-22	0.4	Persephone Doupi and Markus Kalliola	Provided feedback and comments	draft

2025-11-10	0.5	Rebekka Björg Guðmundsdóttir, Védís Helga	Final revisions	Final version

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Contents

Table of Tables

Table of Figures

List of abbreviations

Abbreviation	**Full Term**
ATC	Anatomical Therapeutic Chemical Classification System
EHDS	European Health Data Space
EU	European Union
FDA	Food and Drug Administration (United States)
GDPR	General Data Protection Regulation
HDAB	Health Data Access Body
ICD	International Classification of Diseases
MR-S	Health and Social Affairs (Nordic Council of Ministers policy area)
MR-U	Education and Research (Nordic Council of Ministers policy area)
MR-VÆKST	Business Policy (Nordic Council of Ministers policy area)
NCP	National Contact Point
NCM	Nordic Council of Ministers
NeRN	Nordic eHealth Research Network
REC	Research Ethics Committee
SPE	Secure Processing Environment
VALO	Value from Nordic Health Data (project name)

Executive summary

The Nordic countries exhibit exceptional health data capabilities, shared values, and complementary expertise that together create valuable opportunities for research, innovation and policymaking. As the European Health Data Space (EHDS) reshapes health data use across Europe, coordinated action becomes essential to preserve and enhance these regional strengths.

Extensive stakeholder interviews across all Nordic countries reveal a consistent paradox. Researchers and industry representatives universally recognise Nordic data superiority, yet systematic barriers prevent effective collaboration. Researchers describe long access timelines, varying General Data Protection Regulation (GDPR) interpretations across countries, and administrative complexities that force suboptimal single-country strategies. Industry stakeholders identify data access delays as their primary competitive challenge, leading them to avoid cross-border integration entirely. Previous Nordic initiatives have been hindered largely due to reliance on individual enthusiasm rather than institutional commitment. Both groups emphasise the urgency of coordinated action to preserve regional advantages within the emerging EHDS framework.

This report proposes a practical framework for transforming individual national capabilities into coordinated regional strength. The Nordic Model for collaboration on the secondary use of health data consists of three specialised components unified through central coordination. Knowledge Sharing on Systems and Structures coordinates policy and governance functions, building on emerging EHDS infrastructure. The Nordic EHDS2 Competence Forum provides a foundation that could be formalised and expanded. Research Collaboration and Statistics facilitates cross-border coordination through improved information sharing. Innovation and Industry could structure engagement channels through knowledge exchange and partnership opportunities while maintaining clear boundaries with regulatory functions. The Driver component ensures strategic alignment across all components, optimises resources, and maintains the ethical standards essential for public trust. Rather than creating new institutions, the model emphasises the consolidation and coordination of existing Nordic structures, particularly the Nordic Council of Ministers, Nordic Welfare Centre, and NordForsk.

This approach advances a unified value proposition of a Nordic environment empowering stakeholders to collaborate in advancing the utilisation of health data for research, development, innovation, and policymaking to benefit health, wellbeing, and economic prosperity. The vision delivers EHDS leadership through coordinated implementation, research excellence through pooled expertise, evidence-based policymaking through shared insights, and economic value through reduced complexity and enhanced competitiveness.

Development of the Nordic model follows a phased approach. Comprehensive mapping of existing Nordic institutions, working groups and committees that could take on responsibilities or be included in the model. Pilot coordination through specific EHDS implementation challenges demonstrates value and refines mechanisms based on practical experience. Systematic integration builds stronger institutional connections based on success. This pragmatic pathway builds trust before requiring significant commitments from participating countries. Success requires expanded stakeholder engagement, coordinated EHDS implementation with Baltic observer participation in VALO2, clear metrics tracking collaboration outcomes, shared Nordic values, and sustainable operations through enhanced coordination of existing institutions.

The convergence of EHDS requirements, growing global competition, and stakeholder consensus creates both urgency and opportunity. Without coordinated action, Nordic countries risk underutilising their exceptional health data assets. With unified effort, they can transform individual national strengths into an integrated regional powerhouse that establishes global leadership in responsible health data innovation while advancing health outcomes, scientific knowledge, and economic prosperity for all Nordic citizens. VALO2 will advance this agenda, but ultimate success depends fundamentally on sustained political commitment and broad stakeholder engagement across the region.

Tiivistelmä

Pohjoismailla on poikkeuksellisen vahvat terveysdatan hyödyntämismahdollisuudet, yhteiset arvot ja toisiaan täydentävä asiantuntemus, jotka yhdessä luovat arvokkaita mahdollisuuksia tutkimukselle, innovaatiolle ja päätöksenteolle. Kun eurooppalainen terveystietoalue (EHDS) muuttaa terveysdatan käyttöä koko Euroopassa, koordinoitu toiminta on välttämätöntä näiden alueellisten vahvuuksien säilyttämiseksi ja kehittämiseksi.

Laajat sidosryhmähaastattelut kaikissa Pohjoismaissa paljastavat johdonmukaisen paradoksin. Tutkijat ja teollisuuden edustajat tunnistavat yksimielisesti pohjoismaisen datan ylivoimaisuuden, mutta järjestelmälliset esteet estävät tehokkaan yhteistyön. Tutkijat kuvailevat pitkiä odotusaikoja käyttölupien saamisessa, vaihtelevia GDPR-tulkintoja eri maissa sekä hallinnollisia monimutkaisuuksia, jotka pakottavat epäoptimaalisiin maakohtaisiin strategioihin. Teollisuuden sidosryhmät pitävät viiveitä datan käyttöoikeuden saamisessa ensisijaisena haasteenaan, mikä johtaa siihen, että rajat ylittävä integraatio vältetään kokonaan. Aiemmat pohjoismaiset aloitteet ovat olleet riippuvaisia lähinnä yksittäisten henkilöiden innostuksesta, ei institutionaalisesta sitoutumisesta. Molemmat ryhmät korostavat koordinoidun toiminnan kiireellisyyttä alueellisten etujen säilyttämiseksi kehittyvässä EHDS-kehyksessä.

Tämä raportti ehdottaa käytännön mallia, jolla yksittäiset kansalliset kyvykkyydet muutetaan koordinoiduksi alueelliseksi voimaksi. Pohjoismainen malli terveysdatan toissijaisen käytön yhteistyölle koostuu kolmesta erikoistuneesta osasta, joita yhdistää keskitetty koordinointi. **Tietojärjestelmien ja rakenteiden tiedonvaihto** koordinoi politiikkaa ja hallintoa hyödyntäen kehittyvää EHDS-infrastruktuuria. **Pohjoismainen EHDS2-osaamisfoorumi** tarjoaa perustan, jota voidaan virallistaa ja laajentaa. **Tutkimusyhteistyö ja tilastot** edistävät rajat ylittävää koordinointia parannetun tiedonvaihdon avulla. **Innovaatiot ja teollisuus** voivat rakentaa osallistumiskanavia tiedonvaihdon ja kumppanuusmahdollisuuksien kautta säilyttäen selkeät rajat sääntelytoimintoihin. **Ajurikomponentti** varmistaa strategisen linjauksen kaikissa osissa, optimoi resurssit ja ylläpitää eettisiä standardeja, jotka ovat olennaisia julkisen luottamuksen kannalta. Uusien instituutioiden luomisen sijaan malli korostaa olemassa olevien pohjoismaisten rakenteiden, erityisesti Pohjoismaiden ministerineuvoston, Nordic Welfare Centren ja NordForskin, konsolidointia ja koordinointia.

Tämä lähestymistapa edistää yhtenäistä arvolupausta pohjoismaisesta ympäristöstä, joka mahdollistaa sidosryhmien yhteistyön terveysdatan hyödyntämisessä tutkimuksen, kehityksen, innovaation ja päätöksenteon edistämiseksi terveyden, hyvinvoinnin ja taloudellisen vaurauden hyväksi. Visio tarjoaa EHDS-johtajuutta koordinoidun toimeenpanon kautta, tutkimuksen huippuosaamista yhdistetyn asiantuntemuksen avulla, näyttöön perustuvaa päätöksentekoa ja taloudellista arvoa vähentämällä monimutkaisuutta ja parantamalla kilpailukykyä.

Pohjoismaisen mallin kehittäminen etenee vaiheittain. Ensimmäiseksi kartoitetaan kattavasti olemassa olevat pohjoismaiset instituutiot, työryhmät ja komiteat, jotka voivat ottaa vastuuta tai sisällyttää malliin. Pilotointi EHDS:n toimeenpanon erityishaasteiden kautta osoittaa arvon ja hienosäätää mekanismeja käytännön kokemusten perusteella. Järjestelmällinen integrointi rakentaa vahvempia institutionaalisia yhteyksiä onnistumisten pohjalta. Tämä pragmaattinen polku rakentaa luottamusta ennen merkittävien sitoumusten vaatimista osallistuvilta mailta. Onnistuminen edellyttää laajennettua sidosryhmäosallistumista, koordinoitua EHDS-toimeenpanoa Baltian maiden tarkkailijaosallistumisella VALO2:ssa, selkeitä mittareita yhteistyön tulosten seuraamiseksi, yhteisiä pohjoismaisia arvoja ja kestävää toimintaa olemassa olevien instituutioiden tehostetun koordinoinnin kautta.

EHDS-vaatimusten, kasvavan globaalin kilpailun ja sidosryhmien yksimielisyyden yhdistyminen luo sekä kiireellisyyttä että mahdollisuuksia. Ilman koordinoitua toimintaa Pohjoismaat eivät saa täyttä

hyötyä poikkeuksellisista terveysdataresursseistaan. Yhdistetyllä panostuksella ne voivat muuttaa kansalliset vahvuudet integroiduksi alueelliseksi voimaksi, joka luo maailmanlaajuista johtajuutta vastuullisessa terveysdatainnovaatiossa ja edistää terveyttä, tieteellistä tietoa ja taloudellista vaurautta kaikille Pohjoismaiden kansalaisille. VALO2-hanke edistää tätä tavoitetta, mutta lopullinen menestys riippuu olennaisesti kestävästä poliittisesta sitoutumisesta ja laajasta sidosryhmäosallistumisesta koko alueella.

Sammanfattning

De nordiska länderna har exceptionellt starka förutsättningar att nyttja hälsodata, samt gemensamma värderingar och kompletterande expertis. Tillsammans skapar detta värdefulla möjligheter för forskning, innovation och beslutsfattande. I samband med att det europeiska hälsodataområdet (EHDS) omformar användningen av hälsodata i hela Europa blir samordnade insatser avgörande för att Norden ska kunna bevara och stärka dessa regionala styrkor.

Omfattande intervjuer med intressenter i alla nordiska länder avslöjar samma paradox. Forskare och representanter för industri är eniga om att nordiskt data är av hög kvalitet. Effektivt samarbete förhindras ändå av systematiska hinder. Forskare beskriver långa handläggningstider för att få tillstånd att använda data, olika länders varierande tolkningar av GDPR och administrativa svårigheter som leder till att varje land utvecklar sina egna strategier, vilket inte är optimalt. Industrin anger att största problemet för deras konkurrenskraft är förseningar i att få tillgång till data, vilket leder till att integration över landsgränserna helt undviks. Tidigare nordiska initiativ har i stor utsträckning hindrats av att de varit beroende av individuellt engagemang snarare än förankrat institutionellt stöd. Båda grupperna betonar behovet av samordnade insatser för att bevara nordiska regionala fördelar inom det framväxande EHDS-ramverket.

Denna rapport gör ett förslag på en praktisk modell vars syfte är att omvandla enskilda nationella färdigheter till samordnad regional styrka. Den nordiska modellen för samarbete kring sekundär användning av hälsodata består av tre specialiserade komponenter som förenas genom centraliserad koordination. **Kunskapsutbyte om system och strukturer** samordnar politik- och styrningsfunktioner och bygger vidare på den framväxande EHDS-infrastrukturen. **Det nordiska kompetensforumet för EHDS** utgör en bas som kan ges en mer formell struktur och vidareutvecklas. **Forskningssamarbete och statistik** förbättrar informationsutbyte, vilket underlättar koordinering över landsgränser. **Innovations- och industriverksamhet** kan utveckla former för samarbete och engagemang genom kunskapsutbyte och partnerskap, samtidigt som man bibehåller tydliga gränser mot regleringsfunktioner. **Pådrivaren** säkerställer att alla komponenter samordnas strategiskt, att resurser används optimalt och att etiska standarder hålls högt för att bibehålla allmänhetens förtriende. I stället för att skapa nya institutioner betonar modellen integrering och samordning av befintliga nordiska strukturer, särskilt Nordiska ministerrådet, Nordic Welfare Centre och NordForsk.

Denna strategi skapar ett enhetligt nordiskt värdeerbjudande: en samarbetsmiljö som gör det möjligt för intressenter att främja användningen av hälsodata för forskning, utveckling, innovation och politikutveckling, med syftet att stärka hälsa, välbefinnande och ekonomiskt välstånd. Visionen innebär att Norden tar ledarskap inom EHDS genom samordnad implementering, uppnår framstående forskning genom samlad expertis, delar insikter för evidensbaserat beslutsfattande och skapar ekonomiskt värde genom minskad komplexitet och ökad konkurrenskraft.

Utvecklingen av den nordiska modellen följer ett stegvis tillvägagångssätt. Först genomförs en omfattande kartläggning av befintliga nordiska institutioner, arbetsgrupper och kommittéer som kan ta ansvar för, eller ingå i, modellen. Pilotprojekt som fokuserar på specifika utmaningar i EHDS-implementeringen visar på värdet av samarbete och ger möjlighet att förfina arbetssätt utifrån praktisk erfarenhet. Genom framgång och systematisk integrering av dessa erfarenheter byggs starkare band mellan institutioner. Denna pragmatiska process bygger förtroende redan innan deltagande länder behöver göra större åtaganden. Framgång förutsätter ett ökat engagemang från intressenter, samordnad EHDS-implementering med baltiskt observatörsdeltagande i VALO2, tydliga mätvärden för att följa upp och utvärdera samarbetsresultat, gemensamma nordiska värderingar och hållbar verksamhet genom förbättrad samordning av befintliga institutioner.

Kraven från EHDS, den växande globala konkurrensen och intressenternas enighet skapar tillsammans både en känsla av brådska och nya möjligheter. Utan samordnade insatser riskerar de nordiska länderna att underutnyttja sina exceptionella hälsodataresurser. Med gemensamma insatser kan varje lands styrkor förenas till en regional resurs som ger globalt ledarskap inom ansvarsfull hälsodatainnovation och samtidigt bidrar till bättre hälsa, starkare vetenskap och ökat välstånd för alla nordiska medborgare. VALO2 kommer att driva denna agenda framåt, men bestående framgång är beroende av långsiktigt politiskt engagemang och brett deltagande från intressenter i hela regionen.

1 Introduction

The five Nordic countries – Denmark, Finland, Iceland, Norway and Sweden – exhibit exceptional health data capabilities, shared values, and complementary expertise (1) that together create valuable opportunities for research, innovation and policymaking. The European Health Data Space (EHDS) Regulation (2) is reshaping the landscape for health data use across Europe. The region stands at a crossroads between amplifying these advantages into regional strengths and allowing them to be diminished through continued fragmentation.

The Nordic region's distinctive characteristics create strong foundations for collaborative health data initiatives. Extensive population-wide health registers, built over many decades, offer extraordinary longitudinal data. Unique personal identification numbers enable precise data linkage across different datasets. High public trust in research and institutional governance, alongside similar publicly-funded healthcare with minimal patient costs, (1,3) create a solid basis for joint efforts. However, these advantages remain underutilised due to regulatory fragmentation, administrative inefficiencies, and varying approaches to cross-border data sharing within the Nordic countries. (1) As a result, researchers and innovators face avoidable obstacles (e.g. data delivery and lack of interoperability) when conducting cross-border studies, and miss promising opportunities that instead flow to regions with different data protection regulations or more streamlined collaboration. (1,4)

Conversely, coordinated Nordic action can transform individual national strengths into shared competitive advantages that amplify each country's voice and create new opportunities. Nordic collaboration enables research power through combined datasets that make feasible studies, impossible to execute in single countries. It also accelerates innovation by creating shared regulatory approaches that reduce market barriers for health technology companies. In addition, it strengthens policy influence by ensuring a unified Nordic position which carries greater weight in European discussions. Coordinated EHDS implementation reduces duplication and costs while positioning joint Nordic initiatives to establish international best practices for responsible secondary use of health data use.

The convergence of EHDS requirements, (2) growing global demand for health data insights, and increasing competition from other regions creates urgency for coordinated Nordic action. A unified Nordic approach can preserve the trust, quality, and accessibility that define Nordic health systems while establishing the region as a leader in responsible health data innovation. This report presents a pathway for transforming Nordic health data capabilities from individual national assets into an integrated region advantage that benefits researchers, industry, policymakers, and ultimately, all Nordic citizens through better health outcomes and stronger international competitiveness.

While focused primarily on the Nordic countries' capabilities and collaborative opportunities, the Baltic countries – Estonia, Latvia and Lithuania – represent natural partners in this endeavour. Their geographic proximity, increasing health data infrastructure maturity and shared commitment to digital innovation create potential synergies that extend the Nordic model's reach and impact. The framework presented here is designed with sufficient flexibility to accommodate future Baltic participation where mutually beneficial, recognising that coordinated action across the region can amplify both Nordic and Baltic voices in European health data discussions.

1.1 Objectives

This report has three primary objectives:

1. **Define a unified Nordic value proposition** that articulates the region's competitive advantages in health data collaboration and secondary use of health data.
2. **Propose an operational Nordic model** that transforms individual national capabilities into coordinated regional strength through practical collaboration mechanisms.
3. **Provide implementation recommendations** for establishing the framework of the proposed Nordic model within the EHDS context.

Secondary use of health data encompasses the application of health information beyond direct patient care. This includes individual-level or aggregated datasets for research, innovation, policymaking, and regulatory activities. (5) This definition acknowledges both the scientific potential and ethical responsibilities inherent in health data utilisation.

The analysis draws from extensive interviews with research and industry leaders across all Nordic countries. It is complemented by an assessment of current cooperation mechanisms and identifies future opportunities within the EHDS context. The proposed Nordic model serves the diverse needs of citizens, patients, healthcare developers, researchers, industry, and policymakers. It maintains the transparency, quality, and ethical standards that define Nordic approaches to health data governance.

2 Nordic health data collaboration analysis results

We conducted stakeholder interviews to gain insights into experiences from Nordic researchers and innovators and identify strengths and challenges they face when collaborating in cross-border projects. This chapter outlines a short summary of our analysis of these interviews. This analysis draws from semi-structured qualitative interviews with two stakeholder groups conducted as part of the VALO project. Five research stakeholders (senior researchers and principal researchers from Nordic academic institutions and research organisations) and six industry representatives (from multinational pharmaceutical companies, technology providers, and consulting firms) participated in 45–90-minute interviews covering collaboration experiences, regulatory barriers, infrastructure needs and EHDS implementation perspectives.

Research participants were identified through systematic mapping of key institutions and VALO partner recommendations based on cross-border health data experience. Industry participants represented organisations with significant Nordic operations and established health data practices, including executives, epidemiologists, data scientists, and regulatory specialists. These interviews provide valuable insights into stakeholders´ experiences and priorities but should be seen as indicative rather than comprehensive sector coverage. The findings inform policy development while acknowledging the limited scope relative to the broader Nordic research and industry communities. Table 1 summarises key themes and alignment levels, with detailed methodology and complete findings available in Annex 1.

2.1 Stakeholder perspectives on Nordic health data collaboration

The interviews reveal both the significant potential and persistent challenges facing Nordic health data collaboration. Despite universal recognition of the region's advantages, stakeholders have adapted their practices in ways that limit cross-border integration, suggesting fundamental institutional and operational barriers that require systematic attention.

Strengths and barriers in Nordic health data collaboration

The analysis reveals a fundamental paradox undermining Nordic health data collaboration. The region possesses unparalleled advantages for health data research: a combined population of 27 million, comprehensive health registers, unique personal identification numbers enabling precise data linkage, and exceptionally high public trust. Yet these advantages consistently fail to translate into effective cross-border collaboration due to systematic institutional, regulatory, and operational barriers.

Both researchers and industry stakeholders recognise the value of Nordic collaboration: achieving statistical power through combined datasets that enables meaningful analysis of rare conditions and exposures impossible within individual countries. Researchers unanimously highlighted the superior quality of Nordic health registers compared to international alternatives, with comprehensive population coverage, long-term data collection, and high data quality standards. Industry stakeholders consistently acknowledged these same advantages, noting how Nordic data quality attracts international research partnerships and funding opportunities.

However, this recognised potential often conflicts with operational realities that force stakeholders to abandon or significantly compromise their collaborative ambitions.

Data access timelines as primary operational barrier

The most critical finding across all stakeholder groups is the impact of data access delays in Nordic collaboration. Research participants described “frustratingly long and unpredictable timelines” typically requiring 1-2 years from initial ethics committee application to actual data delivery, with additional time needed for analysis. These long delays often exceed the duration of research funding periods, creating significant practical challenges for project implementation.

Industry stakeholders identified access time as their “single biggest challenge” affecting competitive positioning, with representatives consistently reporting access times ranging from several months to over a year. One industry stakeholder noted that these delays force companies to choose between Nordic data quality and operational efficiency, often leading them to use lower quality but more accessible data from other regions.

The extent of these delays varies significantly across Nordic countries, creating additional complexity for cross-border collaborations. Denmark aims to provide individual-level data within 30 business days, while Finland’s Findata system has processed over 860 applications since 2019 and reduced timelines to 60 business days. However, Norway faces more extended timelines, with access potentially taking up to a year after permit delivery depending on request complexity. These disparities force researchers planning multinational studies to factor varying timelines into project planning, further emphasising the need for harmonised approval processes.

National variations in regulatory implementation

A particularly troubling finding is that GDPR implementation has counterintuitively increased rather than reduced regulatory complexity for Nordic collaboration. Despite the regulation’s intended harmonisation effect, researchers consistently reported different interpretations and implementation across Nordic countries, requiring legal expertise in multiple jurisdictions and creating uncertainty about data permit application approvals.

The varying mandates and roles of Research Ethics Committees (REC) across countries exemplify this fragmentation. Danish RECs only engage with research involving human subjects or certain bioinformatics projects, while Norwegian RECs have broader mandates covering research on humans, biological material, and health information. Iceland takes the most comprehensive approach with its National Bioethics Committee overseeing scientific health research generally, while Swedish and Finnish systems fall somewhere between these approaches.

Industry participants universally experienced complications from differing national interpretations of EU regulations, particularly GDPR. Beyond the EHDS and GDPR frameworks that are the primary focus of the VALO project, industry stakeholders identified additional regulatory complexity affecting the Nordic health data ecosystem. Technology providers particularly face challenges from multiple legislative instruments (e.g. Medical Device Regulation [MDR/IVDR], AI Act, Health technology assessment regulation [HTAR]) when expanding solutions across Nordic countries. While these broader regulatory challenges fall outside VALO’s core scope of EHDS implementation for secondary use of health data, they represent important contextual factors affecting industry participation in Nordic health data collaboration.

Stakeholder adaptation to cross-border complexities

Stakeholders have developed pragmatic responses to collaboration barriers that significantly limit cross-border data integration. All industry participants reported avoiding genuine cross-border data integration due to complexity and time costs, instead conducting studies in one Nordic country and applying insights to others. As one industry representative explained, "*It's very rare that we collect data in all Nordic countries and merge them together because it's too complicated.*"

Researchers similarly described a situation where data minimisation principles and regulatory complexity force them to "*settle for less precise analysis because we need consistency across all participating countries, so we default to the lowest common denominator.*" This adaptation represents a significant departure from optimal Nordic cooperation, where the potential advantages of combined Nordic datasets are constrained by practical barriers that necessitate suboptimal research designs.

The shift toward single-country strategies represents a missed opportunity, as it moves away from the benefits of pooling Nordic data while leaving the underlying institutional and regulatory complexities unresolved.

Formal mandates versus individual initiative in collaboration

A critical insight from research stakeholders is the importance of institutional commitment in Nordic health data collaboration. Researchers emphasised that successful Nordic collaboration requires formal institutional mandates and dedicated resources rather than voluntary or pro bono participation. Previous initiatives, including the Nordic Commons project and earlier Nordic model initiatives from NordMAN, faced challenges that researchers attributed to relying on individual enthusiasm rather than institutional commitment, with some noting these approaches "*did not work in practice*" despite similar legal frameworks.

Multiple participants highlighted coordination challenges both within and between countries, noting that effective Nordic collaboration requires proper coordination within national systems first. Without strong domestic coordination, cross-border initiatives face significant obstacles. This creates a coordination challenge where Nordic cooperation depends on national institutional capacity that may be insufficient.

The stakeholder interviews reveal a clear gap between the recognised potential of Nordic health data collaboration and current operational realities. While there is universal agreement on the region's unique advantages and the value of combined datasets, high consensus also exists around the barriers preventing effective cooperation.

Table 1. Key findings from stakeholder interviews.

Theme	Research stakeholders	Industry stakeholders	Level of alignment*
Nordic data quality	Superior register quality, comprehensive coverage	Acknowledge advantages despite operational constraints	High
Statistical power	Essential for rare diseases and rare events	Enables more opportunity together rather than individual countries	High
Data access delays	1–2-year delays major barrier	"*Single biggest challenge*" for competitiveness	High
Regulatory fragmentation	Different GDPR interpretations across countries	Complex compliance across Nordic jurisdictions	High
Single-country strategies	Forced to *"lowest common denominator"* approaches	Avoid cross-border integration *"to complicated"*	High
EHDS expectations	Potentially transformative but uncertain integration	Potentially transformative but worried about reduced data quality	High
Collaboration requirements	Need institutional mandates and resources	Require multiparty partnerships with vendors	Moderate
Solution preferences	Split between pooled vs federated approaches	Varies by sector and technical needs	Moderate
Implementation urgency	Accept longer development timelines	Want immediate streamlined processes	Moderate
Geographic scope	Prefer Nordic focus	Mixed: Nordic vs. broader European/global	Moderate
Value drivers	Clinical impact and research advancement	Commercial applications and efficiency	Low
Risk tolerance	Optimistic long-term	Concerned about regulatory changes	Low

**Level of alignment*

High alignment = strong consensus and shared priorities among stakeholder groups
Moderate alignment = some differences but overall consensus among stakeholder groups
Low alignment = significant divergence in perspectives among stakeholder groups

Most disconcerting is how stakeholders have systematically adapted to these challenges by limiting cross-border integration. The reliance on individual initiatives rather than institutional mandates has proven insufficient to overcome structural coordination challenges both within and between countries.

The findings suggest that realising Nordic health data collaboration potential requires addressing fundamental institutional capacity and regulatory harmonisation, particularly as the region prepares for EHDS implementation. Without systematic attention to these coordination challenges, the Nordic countries risk underutilising their collective health data assets despite possessing some of the world's most comprehensive and high-quality health registers and other data collections.

3 Nordic value proposition

Based on our comprehensive analysis of the Nordic landscape (1) and extensive stakeholder interviews (described before and in more detail in Annex 1), we propose the following value proposition for Nordic collaboration on secondary use of health data:

> **“A Nordic environment that empowers stakeholders to collaborate in advancing use of health data for research, development, innovation and policymaking - to benefit health and well-being, and economic prosperity”**

This vision builds on the region’s distinctive strengths while addressing the opportunities created by EHDS implementation and growing global demand for responsible health data use. The value proposition is supported by four foundational elements that translate the vision into tangible benefits for stakeholders and the broader region (see Figure 1).

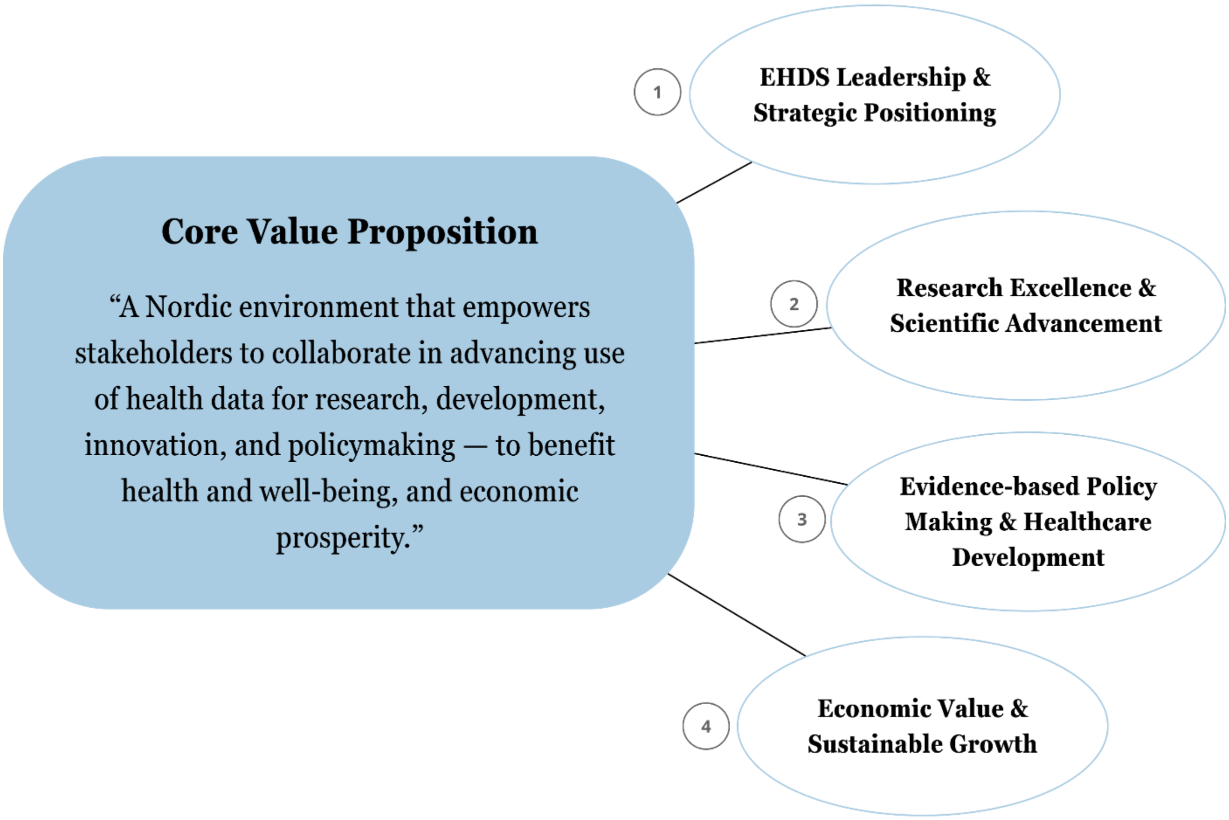

Figure 1. Value Proposition and supporting elements.

1. **EHDS Leadership & Strategic Positioning**

   The proposition aims to establish Nordic regional leadership in responsible health data governance within the EHDS framework. The region's comprehensive population health registers, advanced data linkage capabilities, and high public trust create natural advantages for leadership within health data governance, positioning the Nordic region to set standards and drive innovation in cross-border health data use.

   Coordinated EHDS implementation ensures that European requirements enhance rather than diminish Nordic regional advantages. This unified approach prevents regulatory fragmentation while positioning the region to influence continental policy development and establishes global standards for responsible health data use.

2. **Health Research Excellence & Scientific Advancement**

   The proposition aims to enhance the region's health research capabilities through pooled expertise and larger datasets that enable robust scientific studies impossible for individual countries. Combined Nordic populations provide statistical power necessary for studying rare health conditions and exposures, while cross-border research networks accelerate knowledge generation and validation.

   Academic health research would benefit from streamlined approval processes, harmonised data access procedures, and shared methodological expertise. This enhanced research environment attracts international partnerships and funding while ensuring that scientific discoveries translate into improved healthcare practices throughout the region.

3. **Evidence-based Policy Making & Healthcare Development**

   Coordinated health data analysis supports evidence-based policy decisions across multiple domains including healthcare planning, public health interventions, and health system optimisation. Access to cross-border health data enables policymakers to validate interventions across different healthcare systems and populations.

   Healthcare service development benefits from shared insights about treatment effectiveness, patient outcomes, and health system performance. This knowledge supports the development of clinical guidelines, quality improvement initiatives, and healthcare delivery models that improve patient care while optimising resources utilisation.

4. **Economic Value & Sustainable Growth**

   This proposition has the potential to generate economic value through multiple mechanisms. By harmonising how the Nordic countries implement EHDS, it reduces the complexities companies and researchers face when operating across borders, while enhancing competitiveness and increasing industry engagement. Reduction in the complexity when operating cross-border not only generates immediate economic value but also ensures the long-term sustainability of Nordic health data collaboration by reducing ongoing compliance costs and administrative burden.

   Infrastructure investments would be optimised through shared development of standardised solutions. This approach could attract investment in the region while ensuring that economic benefits support rather than compromise the primary objectives of improving health outcomes and advancing scientific knowledge.

> Realising this economic potential will require knowledge sharing across Nordic countries with complementary strengths in technical infrastructure and commercialisation.

The Nordic region possesses unique strengths that position it for global leadership in responsible health data use. High-quality health registers provide population-level coverage with longitudinal data spanning decades, enabling research and policy analysis of depth and reliability. Exceptional public trust that allows health data to be used in ways that supports both research activities and policy development. This trust foundation, combined with transparent governance processes, enables the region to demonstrate how health data can serve public interests while maintaining citizen confidence.

The proposition aims to combine strong academic institutions, effective healthcare systems, and supportive government policies. Shared values emphasising transparency, equality, and evidence-based decision-making create natural alignment that facilitates cross-border cooperation across research, policy, and development activities.

4 Nordic model for collaboration on secondary use of health data – a proposal

The project *Value from Nordic Health Data* (VALO) proposes the development of a Nordic model intended to facilitate the establishment and adoption of harmonised and efficient mechanisms for collaboration on the secondary use of health data, building on the core value proposition outlined in the previous section. The model seeks to transform individual national capabilities into an integrated regional advantage, serving diverse stakeholders while upholding high standards of privacy, ethics, and scientific integrity.

The following sections describe the core concept and theoretical foundations of the model, followed by detailed description of each component.

4.1 Core concept and architecture

This vision is operationalised through three specialised components, each serving distinct stakeholder communities while being unified through a central coordination mechanism referred to as the “Driver”. First, **Knowledge sharing on systems and structures** component will coordinate policy and governance functions across the region. Second, **Research collaborations and statistics** will advance scientific excellence and evidence generation through joint initiatives. Third, **Innovation and industry** will facilitate economic development and technology advancement (see Figure 2). This architecture ensures that while each component can operate autonomously to serve its specific constituency, the overall system functions as a cohesive whole that amplifies the collective impact of Nordic health data capabilities. Each component is described in detail later in the report.

Each component is aimed to connect relevant stakeholders and create opportunities for collaborative dialogue on shared health data challenges. By bringing together diverse actors across national borders, the framework conceptualises an interconnected system addressing five fundamental areas of collaboration on health data utilisation: policy harmonisation, research excellence, innovation development, evidence-based decision-making, and citizen engagement. Designed to serve a wide range of stakeholders, the Nordic model aims to improve health outcomes, advance scientific knowledge, support evidence-based policy making, and generate sustainable economic value. Rather than operating in silos or prioritising a single outcome, these objectives could be advanced through coordinated governance, ensuring that benefits emerge gradually as stakeholder participation deepens across research, policy, development, and economic domains. The model recognises that effective collaboration requires both specialised expertise and coordinated governance. Each component addresses specific needs, while the central Driver ensures strategic alignment, resource optimisation, and sustainable operation of the entire ecosystem.

This approach aligns strategically with the Nordic Council of Minister’s (NCM) political priorities for 2025-2030 (6), supporting research excellence objectives while advancing health and social affairs priorities through improved population outcomes and evidence-based policy development. Initial regulatory harmonisation and knowledge sharing would create foundations for more comprehensive cooperation, while maintaining the trust and transparency that define Nordic approaches to health data governance and serving the full spectrum of stakeholders’ needs. This approach becomes particularly important as EHDS implementation proceeds, ensuring Nordic systems can communicate effectively while maintaining regional coordination advantages (1) and preserving the unique data quality and trust foundations that characterise the region.

4.2 Theoretical foundations and stakeholder connections

This conceptual approach builds upon Nordic traditions of voluntary cooperation, balancing regional coordination with national autonomy. The model draws inspiration from established collaborative frameworks, including the Nordic Council of Ministers, existing cross-border research networks, and democratic engagement festivals, e.g. Arendalsuka (7) in Norway that demonstrate effective inclusive dialogue and citizen participation in policy discussions.

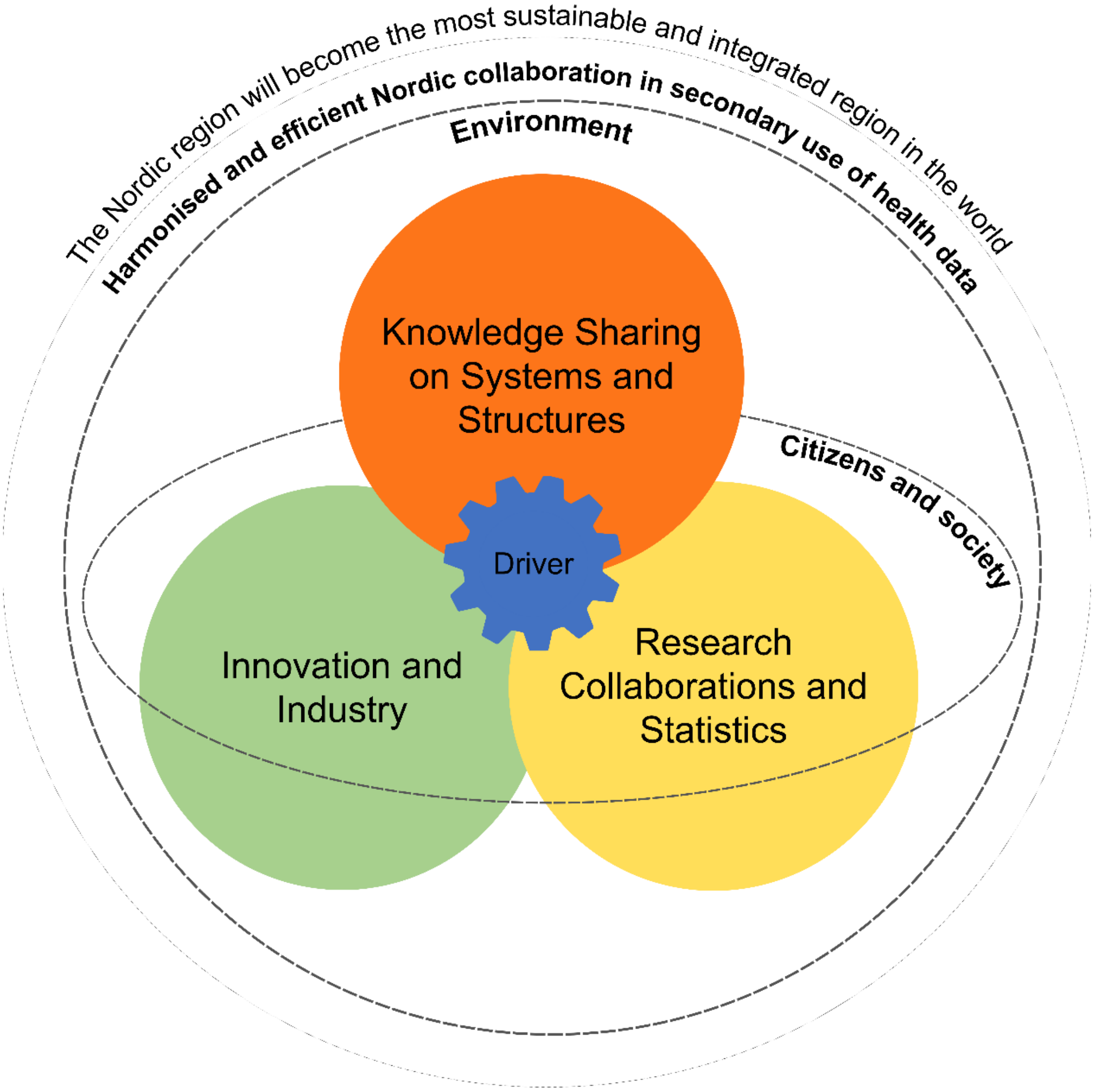

Figure 2. Nordic model for collaboration on the secondary use of health data – a proposal supporting Nordic 2030 goals: A Competitive, Green, and Socially Sustainable Nordic Region.

Building on these collaborative traditions, the Nordic model aims to connect stakeholders and create collaborative opportunities on shared health data challenges. To demonstrate the concrete benefits of this approach, the model would create value for diverse stakeholder groups across government, research, industry, healthcare systems, and civil society (see Table 2).

Table 2. Value creation for different stakeholders within the Nordic collaboration model.

Government	through coordinated policymaking and enhanced regional evidence.
Research	through easier access to larger datasets and streamlined processes.
Industry	through partnership opportunities and support of simplified market access.
Healthcare systems	through evidence-based improvements validated across multiple contexts.
Citizens	through improved health outcomes, transparent governance, and meaningful participation in decisions when it comes to collaboration in secondary use of health data.

These stakeholder benefits are realised through a coordinated data ecosystem. As illustrated in Figure 3, data generated by society – through healthcare systems, patients, and citizens – feeds into three key areas for secondary use: Knowledge Sharing on Systems and Structures, Research Collaborations and Statistics and Innovation and Industry. These specialised components work together through coordinated Nordic efforts to deliver improved outcomes across multiple dimensions. The model envisions generating both improved public health outcomes and economic benefits, including reduced healthcare costs, higher productivity, and stronger innovation ecosystems that attract international investment and foster new partnerships.

However, realising this vision requires more than conceptual design. The framework acknowledges that successful implementation of the model depends on several critical factors: sustained commitment from all participating countries, clear governance structures, sustainable financing mechanisms, and broad stakeholder engagement across government, research, industry, healthcare, and civil society. Turning this theoretical framework into practical reality demands detailed planning and coordination, as outlined in the following chapter on operationalising the Nordic model. With these foundations in place, the region could take a leading role in the responsible and effective use of health data within the EHDS. By combining established Nordic strengths with innovative approaches, the model provides a strong basis for enhanced cross-border collaboration.

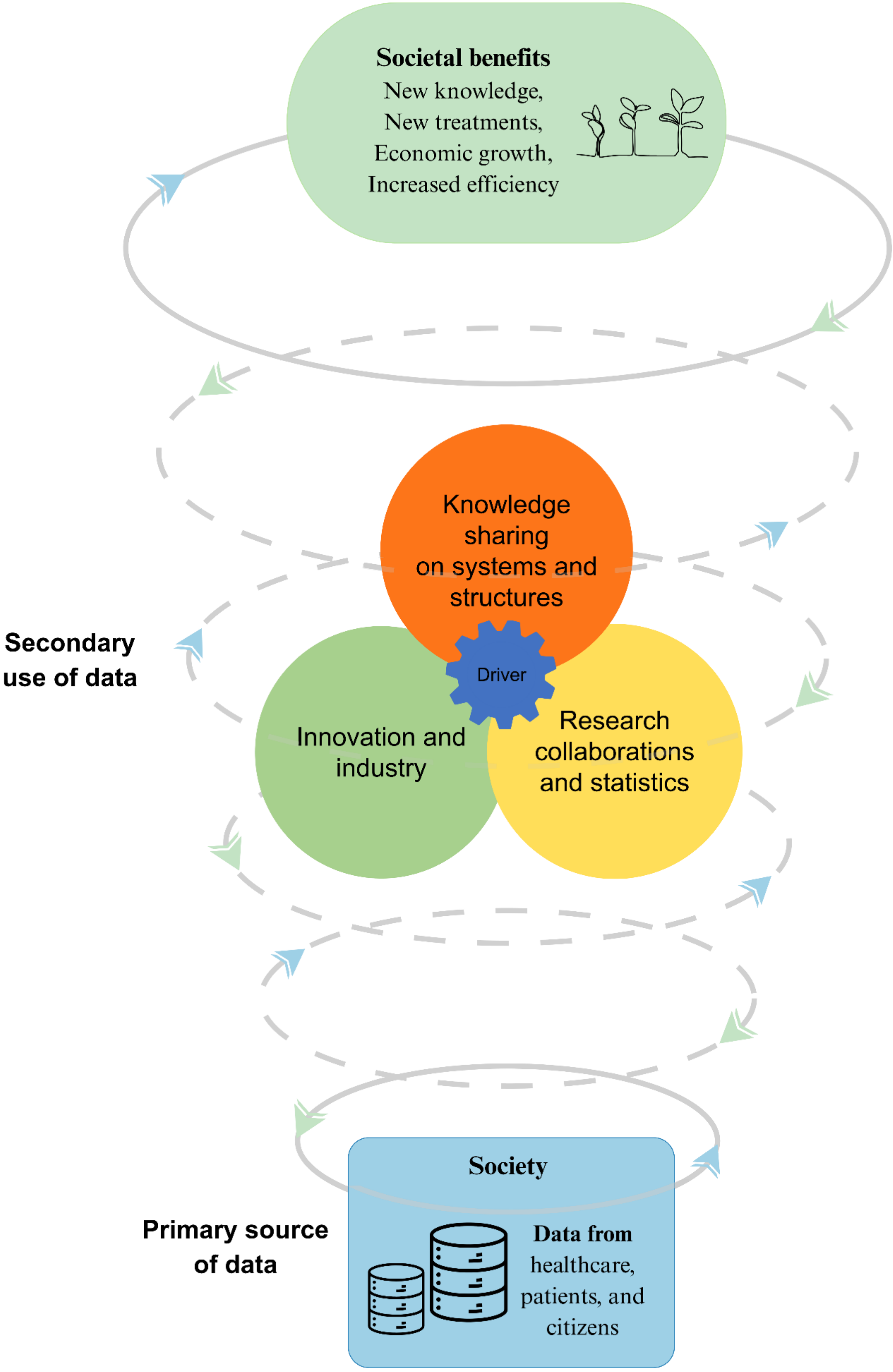

Figure 3. Visualisation of the data flow in the context of the proposed Nordic model.

4.3 Components of the proposed Nordic model for collaboration on secondary use of health data

The Nordic model operates through three specialised components unified by a central coordination function (the Driver). Before describing each component, three fundamental design principles apply across the entire model: **facilitation over provision**, **institutional boundaries**, and **EHDS alignment**, described in Table 3.

Table 3. Design principles that apply across the Nordic model for collaboration on secondary use of health data.

Design principles	Description
Facilitation over provision:	Components coordinate existing services rather than duplicating them. They create connections and share knowledge rather than replacing national functions.
Institutional boundaries:	The model respects existing mandates. It does not make binding decisions for member countries, replace national regulatory authorities, or supersede established research councils and innovation agencies.
EHDS alignment:	All components build explicitly on emerging EHDS infrastructure ensuring that Nordic coordination leverages rather than conflicts with European requirements.

Table 4 provides an overview of the components and driver of the Nordic model for collaboration on secondary use of health data.

4.3.1 Knowledge Sharing on Systems and Structures

The Knowledge Sharing component addresses a critical challenge identified in stakeholder interviews: the varying approaches to health data governance across Nordic countries. This component coordinates policy and regulatory harmonisation while respecting national sovereignty, creating a forum where health ministries, governmental health data authorities, HDABs, data protection authorities, and national statistical offices can develop shared understanding and common approaches. The Nordic EHDS2 Competence Forum provides an existing operational forum that could be formalised with long-term governance, secure funding independent of project timelines, and expanded scope from narrow EHDS implementation to broader health data policy coordination. Rather than creating entirely new structures, this approach leverages proven mechanisms for facilitating dialogue and building consensus across Nordic institutions.

4.3.2 Innovation and Industry

Building on the policy coherence established through Knowledge Sharing, the Innovation and Industry component creates structured channels for industry engagement through knowledge sharing and coordination rather than direct service provision. This component serves pharmaceutical companies, medical technology developers, health data analytics companies, startups, innovation intermediaries, and relevant public sector partners. A key focus involves facilitating knowledge transfer about successful commercialisation strategies—addressing the varying capabilities across Nordic countries in identifying and capturing economic value from health data initiatives revealed in stakeholder discussions. The component complements rather than competes with national innovation agencies, commercial consulting services, and existing industry associations, with its unique value lying in cross-country coordination and facilitating connections that individual organisations cannot easily create.

4.3.3 Research Collaboration and Statistics

The Research Collaboration component completes the triad by facilitating cross-border research coordination while carefully avoiding duplication of extensive national research support services. This component primarily facilitates coordination between national organisations—research institutions, statistical bureaus, and research funders—rather than providing direct services to individual researchers. Individual researchers benefit indirectly through improved coordination of national services, better information about cross-border opportunities, and enhanced matchmaking for multinational projects. The component builds on mature Nordic cooperation mechanisms like Nordic Health & Welfare Statistics (8), focusing specifically on health-related statistical collaboration, facilitating integration of health register data with other statistical data sources, and supporting development of comparable health indicators across countries.

4.3.4 The Driver function

The Driver provides the essential coordination that transforms these three specialised components from independent initiatives into an integrated ecosystem. Without the Driver, the components risk operating in silos, duplicating efforts, and missing opportunities for synergy where policy coherence enables industry engagement and research collaboration, while research evidence informs policy development. The Driver ensures strategic alignment across all components with EHDS requirements, coordinates shared infrastructure to prevent duplication, develops performance metrics to ensure accountability, and maintains the ethical standards and citizen engagement essential for public trust. Critical questions for VALO2 include determining the Driver's institutional home (Nordic Council of Ministers, new entity, or coordination mechanism), governance structure balancing political oversight with operational autonomy, resourcing model combining various funding streams, and mechanisms for incorporating currently underrepresented voices such as citizens, patients, healthcare providers, and data protection authorities.

Table 4. Overview of the components and driver of the Nordic model for collaboration on secondary use of health data.

Component/ Driver	Core functions	Target stakeholders	Example/approach	Potential success indicators
Knowledge Sharing on Systems and Structures	Facilitate dialogue between ministries and HDABs and other relevant actors. Create shared knowledge bases of EHDS regulatory interpretations. Coordinate approaches to emerging policy challenges. Share implementation experiences.	Health ministries, governmental health data authorities, HDABs, data protection authorities, national statistical offices.	Health ministries and HDABs jointly developing standardised EHDS approaches while respecting each country's unique characteristics.	EHDS implementation harmonisation across Nordic countries. Reduced interpretation variations. Shared best practices.
Innovation and Industry	Facilitate knowledge exchange. Coordinate industry input without compromising independence. Connect companies with academic/healthcare partners. Best practices for ethical collaboration.	Pharmaceutical companies, medical technology developers, health data analytics companies, startups, innovation intermediaries, public sector partners.	Knowledge transfer on commercialisation strategies; connecting researchers with business development expertise. Pre-procurement technical requirements coordination.	Reduced regulatory complexity Increased cross-border partnerships. Retained health technology investment in Nordic region.
Research Collaboration and Statistics	Connect national research institutions for streamlined cross-border applications. Make it easier for researchers to connect and collaborate through multinational research. Coordinate Nordic responses to EU funding opportunities. Share methodological approaches.	Research institutions, national statistical bureaus, individual researchers, research infrastructure providers, research funders.	Information-sharing hubs ("satellites") distributed across countries providing details on available data, connecting studies, offering commercialization guidance.	Increased multinational projects. Improved researcher access to cross-border opportunities. Enhanced Nordic research competitiveness.

The Driver	Strategic alignment across components. Identify gaps and overlaps. Coordinate shared infrastructure. Performance monitoring and accountability. Maintain ethical standards. Facilitate citizen engagement.	All component stakeholders plus citizens, patients, healthcare providers, data protection authorities, technical specialists.	Central coordination ensuring policy coherence enables industry engagement and research collaboration while research evidence informs policy.	System-wide coherence. Efficient resource allocation Demonstrated value creation; sustained political support.

5 Operationalising the Nordic Health Data Collaboration Model: From Framework to Function

The previous section presented the conceptual framework for the Nordic model, including brief descriptions of its interconnected components. This section addresses the practical implementation challenges: how to establish governance structures, secure financing, and phase implementation to transform the conceptual model into operational reality.

Rather than establishing an entirely new institution or a body to host the proposed activities, it is suggested that they be anchored in and reinforce existing Nordic cooperation mechanisms. Building on this foundation, translating the conceptual Nordic model into operational reality requires addressing fundamental questions of governance, organisation, financing, and implementation sequencing.

To navigate these operational challenges, this chapter outlines practical approaches for establishing the framework described in the previous section. We recognise that successful implementation depends on sustained political commitment, stakeholder engagement, and adaptive management as circumstances evolve.

5.1 The Driver component: Core functions and operational infrastructure

As described in section 4.6, the Driver component serves as the operational backbone, providing strategic oversight, coordination, and administrative support across the three specialised components, described above.

Key functions of the **Driver** could include:

Strategic coordination:

Facilitating alignment between knowledge sharing, innovation and industry, and research collaboration activities while maintaining coherence with overall Nordic health data objectives and EHDS implementation requirements.

This coordination could build on existing NCM mechanisms while consolidating or expanding their scope and mandate.

Resource management:

Coordinating shared infrastructure development, optimising investments across participating countries, and ensuring efficient allocation of both financial and human resources to maximise regional impact.

This could involve harmonising existing funding mechanisms like NordForsk (9) *and domestic funding frameworks for research and innovation.*

Performance monitoring:

Developing clear metrics to assess the model's effectiveness, monitor progress towards harmonisation goals and implement accountability mechanisms that ensure stakeholder trust and political backing – even through changing political cycles.

This could e.g. build on initiatives such as the Nordic eHealth Research Network (NeRN) (10)*, subgroup of the Nordic Council of Ministers eHealth Group.*

Stakeholder engagement:

> Ensuring broad-based participation and legitimacy through structured, ongoing communication with key stakeholders – including government representatives, research institutions, industry partners, healthcare organisations, and citizen groups.

A dedicated digital infrastructure (e.g. website/platform) could serve as the operational foundation for Nordic collaboration on the secondary use of health data, building on existing Nordic digital platforms and coordination tools. This infrastructure could provide:

Enhanced communication systems:

> Strengthening of existing Nordic communication channels and creating new ones where gaps exist, enabling more systematic information sharing between institutions, countries, and stakeholder groups.

Coordinated event management:

> Integrated calendar and coordination systems that build on existing Nordic meeting structures while reducing overlap and improving participation across multiple institutions and initiatives.
>
> *This could e.g. be included in the event calendar on Nordic Council of Ministers website.*

Knowledge management:

> Centralised access to resources supporting Nordic health data collaboration, leveraging existing repositories while developing new shared knowledge bases where gaps exist.

Membership coordination:

> A clear framework for participation should be established, outlining what is expected from participants and what they can expect to receive in return. This ensures consistent stakeholder engagement and fair distribution of benefits.

Regular interaction mechanisms would maintain momentum and ensure continuous progress by strengthening existing Nordic cooperation patterns:

Regular hybrid meetings:

> Virtual sessions enabling routine coordination, progress updates, and collaborative problem-solving without requiring extensive travel, making participation accessible to diverse stakeholders across the region.

Annual strategic event:

> In-person gathering rotating among Nordic countries, providing intensive collaboration opportunities, high-level strategic planning, and relationship building that strengthens long-term collaboration commitments.

Specialised working groups:

> Task-focused teams addressing specific challenges such as EHDS implementation coordination, cross-border research protocols, or industry partnership development, operating with defined mandates and timelines while coordinating with existing Nordic working groups.
>
> *This could build upon existing Nordic working groups (e.g. NordClass* (11) *and Nordic EHDS2 Competence forums breakout sessions).*

Citizen engagement integration:

> Public forums and consultations building on Nordic democratic traditions (e.g. Almedalsveckan (12) and Arendalsuka (7)) that help secure legitimacy and sustain public trust by actively involving citizens, addressing concerns transparently, and demonstrating ethical, beneficial use of health data.

The VALO project's Nordic EHDS2 Competence Forum demonstrates effective cross-border coordination in practice. Operating through three breakout sessions-focusing on HDABs (and related element), metadata standards, and legal harmonisation. The forum creates trusted space for discussing implementation challenges and developing common approaches. This structure directly addresses the reality that Nordic countries are already investing in HDAB establishment for EHDS compliance. Rather than creating entirely new structures, this forum could be formalised and expanded as a core component of the Nordic model's operational infrastructure. The Competence Forum's experience in harmonising EHDS implementation provides a foundation for the broader collaboration framework proposed here.

5.2 Governance and organisational structure

The implementation of the proposed Nordic model should strengthen and better coordinate existing institutional frameworks rather than creating parallel structures. This approach leverages established relationships, proven governance mechanisms, and existing mandates while adapting them for enhanced health data collaboration within the EHDS framework. Within this vision, the model builds naturally on institutions already operating at multiple levels across the region.

The Nordic Council of Ministers could serve as the driver of the model (see Figure 4), with the Health and Social Affairs (MR-S) (13) policy area consolidating its coordination role by providing political oversight and clear strategic direction for health data collaboration. Business policy (MR-VÆKST) (13) and Education and Research policy areas (MR-U) (13) could contribute their expertise to innovation and research aspects. The Nordic Welfare Centre (14), with its core mission to serve as a platform for cooperation in social affairs and public health, would leverage established expertise and networks. Meanwhile, NordForsk (9) would expand beyond traditional funding roles to include operational coordination for cross-border research facilitation. Formal coordination mechanisms would connect other relevant counterpart national authorities and institutions, e.g. national health data authorities, statistical offices, and future HDABs, to ensure coherent approaches across all participating countries without duplicating their independent operation functions.

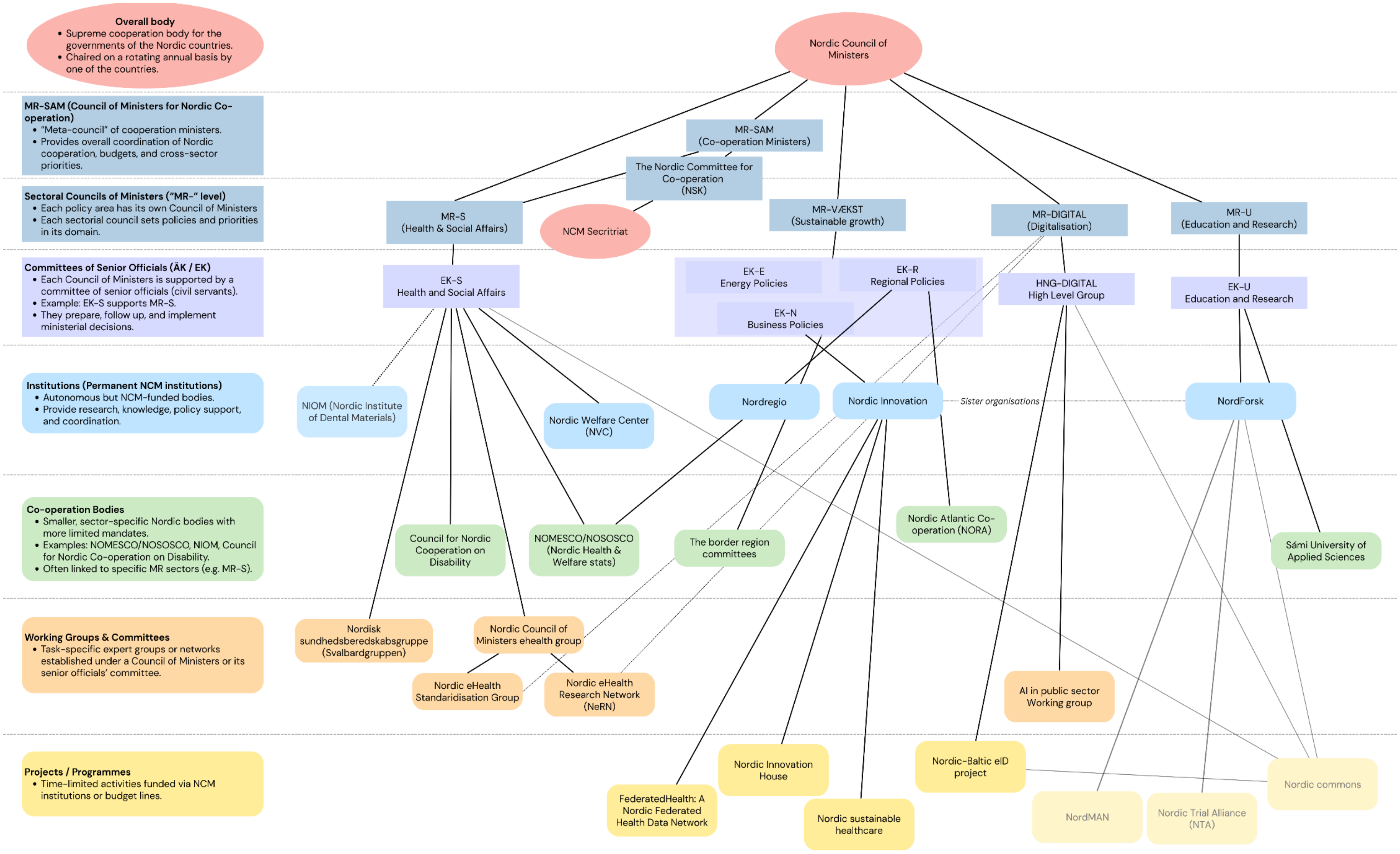

Figure 4. VALO mapping of the Nordic Council of Ministers (NCM) Sectoral Councils of Ministers and projects related to health data.

Within the current vision of the Nordic model, the transition to enhanced institutional coordination requires a phased approach that builds trust and demonstrates value before requiring significant commitments from participating countries and institutions. This institutional strengthening could be implemented through multiple phases that build trust and demonstrate value before requiring significant commitments. The transition could begin with comprehensive assessment and planning, mapping existing capabilities and developing coordination agreements. This foundation enables pilot coordination through specific EHDS implementation challenges, allowing the model to demonstrate value and refine mechanisms based on practical experience.

It could also be valuable to examine ongoing or completed initiatives and drive lessons from them. An evaluation of the success of the VALO EHDS2 Competence forums would be relevant in that respect. How effective has this forum been in harmonising the implementation of the EHDS regulation in the Nordic region. Success in these initial phases would support systematic integration, building stronger institutional connections through formal coordination mechanisms with regular effectiveness evaluation (see Table 5).

Table 5. Implementation phases of the Nordic model for collaboration on secondary use of health data.

Phase 1 **Assessment and planning**	Comprehensive mapping of the network of existing Nordic institutions', working groups and committees' capabilities, mandates, and potential contributions to health data collaboration, followed by development of coordination agreements and role clarifications.
Phase 2 **Pilot coordination**	Testing enhanced cooperation through specific EHDS implementation challenges, demonstrating value and refining coordination mechanisms based on practical experience. *e.g. Nordic EHDS2 competence forum.*
Phase 3 **Systematic integration**	Building stronger institutional connections based on demonstrated success in phase 2, with formal coordination mechanisms and regular evaluation of effectiveness.

Rather than requiring entirely new funding streams, this approach optimises existing Nordic funding mechanisms while building on established financial cooperation patterns. Modest increases to institutional budgets for coordination activities, shared across participating countries, would support project-based funding through existing Nordic programs while ensuring coherence. The model anticipates efficiency gains through reduced duplication that offset coordination costs, allowing gradual expansion based on demonstrated value and stakeholder commitment.

This operationalisation approach prioritises sustainability and realistic implementation over ambitious structural change, providing a pragmatic pathway for transforming conceptual collaboration into operational reality through institutional strengthening rather than institutional creation.

6 Bridging over to VALO2

The proposed Nordic model represents a significant opportunity to transform the region’s health data utilisation capabilities into a coordinated competitive advantage. However, translating this vision into reality requires coordinated actions across multiple dimensions and stakeholder groups. The convergence of EHDS requirements, growing global competition, and stakeholder consensus on Nordic advantages creates both urgency and opportunity for coordinated action.

While this report focuses on Nordic collaboration mechanisms, VALO2 extends regional engagement through Baltic observer participation. Estonia and Lithuania will join the project activities, enabling knowledge exchange on EHDS implementation and secondary use frameworks. This provides structured engagement allowing both Nordic and Baltic countries to assess collaboration value as operational mechanisms mature.

Our analysis reveals five interconnected priority areas that must be addressed systematically to ensure successful model implementation.

Expanding stakeholder engagement beyond current boundaries

Current stakeholder interviews provide valuable directional guidance, but sustainable collaboration requires broader legitimacy. Comprehensive dialogue with patients, citizens, healthcare providers, data protection authorities, and government representatives across the region are essential to validate the value proposition and build democratic consensus that Nordic cooperation traditions demand.

Coordinated EHDS implementation

Immediate priority lies in coordinated EHDS implementation across Nordic countries. Continued collaboration between health ministries is essential to ensure consistent regulatory interpretations while preserving distinctive Nordic advantages in data quality and trust. This coordination provides the foundation for enhanced cooperation while preventing regulatory fragmentation.

Regional coordination extends through VALO2 to include Baltics as observers. Estonia and Lithuania will engage in EHDS implementation discussions, through the Nordic EHDS2 Competence Forum, sharing experiences and challenges while assessing longer-term collaboration potential. This phased approach recognises different infrastructure maturity levels while building foundations for potential future integration.

Clear success metrics

Maintaining Nordic leadership requires measurable indicators tracking progress toward clear goals. Focus should be on research collaboration frequency, cross-border project success rates, industry investment retention, and international recognition of Nordic governance leadership. Sustained investment in the collaboration model itself serves as a practical indicator of perceived value.

Shared values foundation

Sustainability depends on explicit guiding principles reflecting Nordic Council values: transparency, equity, sustainability, democratic participation, and regional solidarity. This values foundation maintains the model's distinctive character while providing continuity through political changes and helping resolve stakeholder conflicts.

Sustainable operations

> The three-platform model requires concrete institutional arrangements, clear governance structures, and accountability mechanisms surviving political transitions. Implementation should build on existing Nordic institutions rather than creating new structures, with financing through enhanced coordination, shared budget increases, and project-based funding through existing programs.
>
> Economic sustainability represents an operational dimension requiring attention. Stakeholder feedback identified knowledge gaps around identifying commercial opportunities and capturing economic value from health data initiatives. Once established, the Nordic model should facilitate knowledge exchange on business development and economic impact assessment across countries with complementary strengths. VALO2 aims to develop guidelines for how such knowledge-sharing mechanisms could function, recognising that economic returns alongside health outcomes contribute to the model's long-term financial sustainability.

The Nordic and Baltic countries face limited time to establish enhanced collaboration before European requirements reshape the health data landscape. EHDS timelines create urgency, but sustainable institutional cooperation requires addressing these fundamental priorities through concrete implementation steps.

The proposed model offers a pathway for transforming individual national assets into integrated regional advantage, but success depends on moving beyond concepts to build the institutional commitment, stakeholder engagement, and operational clarity essential for sustainable Nordic cooperation.

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Annex 1: Perspectives on Nordic health data collaboration

Research Community Perspectives

Interview methodology and participants

The research stakeholder interviews were conducted as semi-structured qualitative interviews with representatives from academic institutions, and research organisation within the Nordic region. Participants were identified through a two-stage process: first, key research institutions and national health data authorities in each Nordic country were mapped; second, recommendations were sought from VALO project partners to identify individuals with substantial experience in cross-border health data research and their involvement in Nordic collaborative projects.

A total of five research stakeholders participated, including senior researchers and register managers. Participants were selected based on their extensive experience with cross-border health data research and their involvement in Nordic collaborative projects. The interview protocol covered current collaboration experiences, perceived strengths and challenges of Nordic cooperation, regulatory and administrative barriers, technical infrastructure needs, and perspectives on future opportunities including EHDS implementation. Interviews were conducted on site and remotely, lasted approximately 60-90 minutes each, and were analysed by identifying patterns of agreement and divergence across participants and countries. The analysis is based on a limited number of interviews, representing different perspectives rather than comprehensive sector cover. While these insights provide valuable directional guidance, findings should be interpreted as indicative of stakeholder views rather than statistically representative of the broader research and industry communities.

Areas of strong consensus among researchers

Statistical power through combined data:

> All research interviewees emphasised that the fundamental value proposition of Nordic collaboration lies in pooling data across countries to create populations large enough for studying rare conditions and exposures. As one participant noted, individual Nordic countries often lack sufficient population size for meaningful analysis of rare diseases, but combined Nordic datasets provide the power necessary for robust research findings.

Exceptional register quality:

> Researchers unanimously highlighted the superior quality of Nordic health registers compared to international alternatives. The comprehensive population coverage, long-term data collection, and high data quality standards were consistently praised. Multiple participants specifically mentioned how this quality attracts international research partnerships and funding.

Demonstrated clinical impact:

> Researchers provided concrete examples of Nordic collaborative research directly influencing clinical practice and regulatory decisions. One example led to guideline

changes. Participants emphasised that this track record of clinical relevance strengthens the case for continued and enhanced Nordic collaboration.

Shared challenges identified by researchers

Extended and variable timelines:

All research participants described frustratingly long and unpredictable timelines for obtaining data access approvals and subsequently delivery of requested dataset. The process typically requires 1-2 years from the initial ethics committee application to the actual data delivery, with additional time needed for analysis. Participants noted that these delays often exceed the duration of research funding periods, creating significant practical challenges for project implementation.

Regulatory fragmentation:

Despite the intention to harmonise the implementation of the GDPR, researchers consistently reported different interpretations and implementation across the Nordic countries. This fragmentation requires legal expertise in multiple jurisdictions and creates uncertainty about approval requirements. Several participants described situations where identical research proposals received different regulatory responses in different countries.

Data movement restrictions:

Denmark and Finland were identified as having the most restrictive policies on transferring data beyond their borders. This often leads to a suboptimal research design where all data must be transferred to the most restrictive country rather than allowing for more efficient collaborative approaches. Participants noted that these restrictions, rather than scientific considerations, sometimes determine research methodology.

Administrative inefficiencies:

Multiple interviewees highlighted the burden of redundant application processes, even within individual countries. Researchers described situations requiring separate applications to different register holders within the same national system, each with distinct requirements and timelines. This administrative complexity was seen as a significant barrier to initiating cross-border collaborative projects.

Institutional and governance challenges

Beyond operational research barriers, researchers identified fundamental structural challenges that undermine Nordic collaboration sustainability and effectiveness:

Lack of institutional commitment:

Researchers emphasised that successful Nordic collaboration requires formal institutional mandates and dedicated resources rather than voluntary or pro bono participation. As one participant noted, organisations must have allocated time, staff, and clear responsibilities for Nordic initiatives to succeed. The shortcomings of previous initiatives have largely been attributed to a reliance on individual enthusiasm rather than institutional commitment.

Governance and coordination gaps:

Multiple participants highlighted coordination challenges both within and between countries. Effective Nordic collaboration requires proper coordination within national systems first - without strong domestic coordination, cross-country initiatives inevitably fail. Researchers noted silos between ministries and unclear lines of authority for Nordic health data initiatives.

Lessons learned:

Researchers reflected on previous Nordic collaboration attempts, particularly the Nordic Commons project and earlier Nordic model initiatives from NordMAN project. Although these initiatives did not reach their full intended impact they provided valuable learnings, experience and shared understanding across the Nordics. Key lessons highlighted the importance of having dedicated personnel, formal mandates, and clear value propositions that go beyond general statements about Nordic cooperation.

EHDS integration uncertainty:

With the implementation of the European Health Data Space, researchers expressed uncertainty about how Nordic collaboration will align with new European frameworks. Questions remain about the role of national Health Data Access Bodies (HDABs) in Nordic initiatives, whether researchers will be able to get access to de-anonymised data through national procedures, and how Nordic structures will coordinate with European governance mechanisms.

Organisational leadership challenges:

Researchers identified uncertainty about which organisation should lead enhanced Nordic collaboration. Existing Nordic institutions (NordForsk, Nordregio, Nordic Council of Ministers) each have limitations - NordForsk primarily functions as a funding platform rather than operational coordinator, while NCM has limited direct influence on national policies. This creates a leadership vacuum for systematic Nordic health data collaboration.

Divergent perspectives among researchers

Access to specific data types:

While all participants praised Nordic data quality in general, experiences varied regarding access to specific data elements. Researchers noted that data minimisation principles are interpreted and applied differently across the Nordics, with some being more restrictive regarding access to comprehensive coding systems (e.g. ATC and ICD). As one participant observed: “Sometimes we have to settle for less precise analysis because we need consistency across all participating countries, so we default to the lowest common denominator.”

Country-specific research strengths:

Participants identified different national advantages:

- Denmark was consistently praised for strong population registers and excellent analytical capabilities.
- Finland was praised for innovative industry collaboration opportunities and healthcare system integration.
- Iceland was recognised for leadership in genetic research and genotyping facilities.
- Norway was noted for particularly strong birth register and maternal health data.
- Sweden was highlighted for comprehensive quality registers for diverse medical conditions.

Preferred solutions for data sharing barriers:

Researchers proposed different approaches to address current limitations:

- Pooled analysis preferred consolidating all data in a single secure location.
- Federated analysis approach where same (or very similar) algorithms are run in each country, eliminating the need to transfer data across borders.
- Use of SPE based on their experience and institutional preferences.

Organisational models for future collaboration:

Researchers proposed different structural approaches for sustainable Nordic collaboration:

- Dedicated Nordic platform: Some advocated for creating a specific Nordic structure for secondary health data use, potentially building on EHDS national HDABs.
- Integration with existing institutions: Others preferred working through established Nordic organisations like NordForsk, but with enhanced mandates and resources.
- Sector integration: Some emphasised the need to break down silos between health, research, and statistics sectors at both national and Nordic levels.

Trust and coordination mechanisms:

Despite shared legal frameworks and similar safety standards, researchers noted persistent trust issues between Nordic countries' data systems. Some advocated for harmonised application processes and mutual recognition of approvals, while others emphasised the need for practical demonstration of added value before expecting institutional changes.

Industry Perspectives

Interview methodology and participants

Industry interviews were conducted using a semi-structured approach with representatives from pharmaceutical companies, technology providers, and consulting firms involved in Nordic health data utilisation. Industry participants were identified through VALO project networks, Nordic health data initiatives, and professional recommendations. The selection prioritised organisations with significant Nordic operations and established health data practices.

A total of six industry stakeholders participated, representing multinational pharmaceutical companies, major technology providers, and specialised consulting firms. Participants included senior executives, epidemiologists, data scientists, business development managers, and regulatory specialists with direct experience in Nordic health data projects.

The industry interview protocol examined current health data usage patterns, cross-border collaboration experiences, regulatory compliance challenges, EHDS implementation expectations, and perspectives on proposed Nordic collaboration frameworks. Interviews were conducted remotely, lasting 45-75 minutes, and analysed thematically to identify sector-specific viewpoints and common challenges. the analysis sought to understand how commercial imperatives and operational realities shape industry approaches to Nordic health data collaboration.

This analysis represents diverse industry perspectives rather than comprehensive sector coverage. While these insights provide valuable directional guidance for policy development, findings should be interpreted as indicative of stakeholder experiences rather than statistically representative of the broader industry landscape.

Shared perspectives among industry participants

Universal access time challenge:

All industry participants identified data access delays as their primary operational barrier. Representatives consistently reported access times ranging from several months to over a year, with one pharmaceutical executive noting that “access time is the single biggest challenge” affecting competitiveness of Nordic industry. This challenge spans all Nordic countries, though with varying degrees of severity.

Regulatory fragmentation despite common framework:

Industry participants universally experienced complications from differing national interpretations of EU regulations, particularly GDPR. Technology providers specifically highlighted how solutions developed for one Nordic country face entirely new regulatory questions when expanding to neighbouring countries, despite shared legal foundations. This fragmentation forces companies to navigate multiple compliance frameworks even within the Nordic region.

Single-country strategy preferences:

All participants reported avoiding true cross-border data integration due to complexity and time costs. The prevailing approach involves conducting studies in one Nordic country and applying insights to others, rather than merging datasets across borders. As one pharmaceutical representative explained, “It’s very rare that we collect data in all Nordic countries and merge them together because it’s too complicated.”

Data quality appreciation with operational constraints:

Industry participants consistently acknowledged superior Nordic data quality, particularly register completeness and linkage ability. However, they also noted that operational requirements often necessitate using lower quality but more accessible data from other regions. One epidemiologist described having to “unlearn everything” about high-quality Nordic health data to work with more readily available US datasets.

Collaboration approach necessity:

All industry representatives operate through multiparty collaborations involving vendors, academic institutions, and healthcare providers. No participant directly accesses raw health data; instead, they work through approved vendors with established data permits and academic partnerships.

EHDS cautious optimism:

Industry stakeholders viewed EHDS as potentially transformative while expressing concerns about implementation quality. All participants welcomed the prospect of single application points and standardised data formats, but pharmaceutical representatives specifically worried about “lowest common denominator” data quality outcomes.

Industry sector differences

Pharmaceutical sector perspectives:

Pharmaceutical representatives emphasised global market requirements that often conflict with Nordic-focused approaches. While acknowledging Nordic data superiority, they noted regulatory pressures to use US data for FDA submissions due to perceived population differences and market size considerations. Their primary value drivers centre on clinical trials, observational studies for reimbursement support, and real-world evidence for safety monitoring. Pharmaceutical companies showed strongest enthusiasm for EHDS potential, viewing it as a possible “game changer” for European competitiveness in drug development.

Technology provider viewpoints:

Technology companies positioned themselves as infrastructure enablers rather than data users, handling data on behalf of customers without ownership. They emphasised the critical importance of the “pre-procurement phase” when healthcare organisations develop technical requirements, suggesting that pooled Nordic expertise during this phase would result in better-defined specifications and more successful implementations. Technology providers showed particular interest in business opportunities arising from EHDS infrastructure requirements.

Consulting firm approach:

Consulting representatives focused on creating lasting value for customers through improved operational efficiency. They reported shifting toward Central European partnerships while maintaining Nordic relationships, emphasising the need to avoid creating “unnecessary boundaries” with broader European collaboration. Consulting firms showed most concern about proposed Nordic model becoming mere "talking clubs" without concrete outcomes.

Geographic collaboration preferences:

Industry participants demonstrated varying geographic priorities based on sector needs. Pharmaceutical companies often preferred global approaches including US markets for regulatory requirements, while technology providers identified Nordic countries, UK, and Netherlands as forming a "*closest circle of similarity*" for healthcare systems characteristics. Consulting firms reported increasing European integration while appreciating Nordic data quality advantages.

Industry-specific recommendations

Accelerated access mechanisms:

Industry participants emphasised urgent need for streamlined approval processes across Nordic countries. Recommendations included harmonised interpretation of EU regulations, predictable timeline commitments from data access bodies, and standardised application procedures to reduce administrative burden and improve competitive positioning against other regions.

Multi-stakeholder governance framework:

Industry representatives stressed the importance of equal representation in any Nordic collaboration platform. Successful models should include healthcare providers, government authorities, and industry partners with clear mandates, defined roles, and sustainable funding mechanisms. As one pharmaceutical executive noted, "*End users should be around the table in decision making*" to ensure practical relevance.

Pre-procurement collaboration enhancement:

Technology providers specifically recommended Nordic cooperation during healthcare organisations' requirements development phases. Pooled expertise could result in better defined specifications, more effective implementations, and reduced individual country burden for complex procurement processes. This approach could improve outcomes regardless of eventual vendor selection.

Value proposition clarification:

Industry stakeholders emphasised the need for clear, measurable benefits for each participant type. The Nordic model should move beyond networking functions to deliver concrete outcomes such as faster data access, reduced regulatory complexity, or improved technical standards. Without tangible value creation, industry participation becomes difficult to justify commercially.

Unified Nordic positioning:

Industry representatives recommended maintaining cohesive Nordic approaches to avoid internal competition and maximise collective influence in European initiatives. As one executive observed, "*Individual Nordic countries are relatively small, but when brought together, they become stronger and can learn from each other*." This unified positioning should leverage combined strengths while remaining open to broader European collaboration opportunities.