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of Ministers

Ethical governance of secondary use of health data in the Nordic countries: *challenges, comparisons and future collaboration under the EHDS*

Report X.X
Value from Nordic health data – VALO2 project

Day September 2026

Document info

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0.2 Keywords

Keywords	Health data, Nordic, EHDS, ethics

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Contents

Executive summary

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

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

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

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

The report concludes that continued Nordic collaboration and shared interpretation will be essential to support successful EHDS implementation and improve predictability for cross-border projects. It also emphasises that ethics committees and ethical expertise should be actively involved in EHDS implementation now, rather than only once the first secondary-use applications are submitted. Early involvement will help identify practical challenges, promote consistent interpretation of national requirements and strengthen cooperation between ethics committees, Health Data Access Bodies and other stakeholders before the EHDS becomes fully operational.

1 Introduction

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

Art. 54(1)(e) of the EHDS provides that access to and processing of electronic health data shall not take place where such processing would conflict with ethical provisions laid down in national law. Although the EHDS creates a harmonised European framework for secondary use of health data, ethical requirements remain governed by national legislation.

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

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

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

The VALO2 ethical expert group consisted of experts from different ethical committees, with varying capacity, from all Nordic countries. The work focused on mapping the national legislation governing ethical requirements relevant to the secondary use of health data. The ethical expert group was established in March 2026 and had therefore been operational for only approximately four months when the first version of this report was prepared.[1] As the experts had not previously participated in the VALO2 project, part of the work involved familiarising the group with VALO, the EHDS, its objectives and the specific questions relevant to secondary use of health data. Due to the limited timeframe available, it was

[1] The national mapping exercise within the VALO2 project was conducted in March/April 2026 by bioethics and ethics committees or their representatives in the Nordic countries. See Annex 1.

unfortunately not possible to involve ethical experts from the observer countries, Estonia and Lithuania, in the mapping exercise. Their perspectives would be a valuable addition to any future continuation of this work.

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

The findings demonstrate that an applicant seeking access to health data from several Nordic countries may encounter different ethical requirements depending on the country, the type of data requested, the purpose of the project and, in some cases, the territorial scope of the applicable national legislation[2]. Some of these differences, such as application language requirements or administrative procedures, may be relatively straightforward to address through administrative changes. Others, including the distinction between scientific research and quality assurance, national ethical review triggers and broader legislative differences, are more deeply rooted in national legal systems and will require continued dialogue and, potentially, legislative reform.

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

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

2 National triggers for ethical review in the Nordic countries

The following chapters provide country-specific summaries based on the national mapping exercises carried out within the VALO2 project. Information on the institutions and experts responsible for each national mapping is provided in Annex 1. The country summaries are followed by a comparative analysis of the key findings.

2.1 Finland

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

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

This does not mean that ethical review does not exist in Finland. Rather, ethical review is linked to other types of research. Medical research involving interventions on human participants is regulated by the Medical Research Act (488/1999), while non-medical research involving human participants is assessed under the ethical guidelines of the Finnish National Board on Research Integrity (TENK) (1). These frameworks are outside the scope of EHDS secondary use and therefore do not generally apply to register-based research using existing health data.

Finland nevertheless has a well-established system of research ethics governance. In addition to the statutory ethics review system established under the Medical Research Act, universities, research organisations and many healthcare organisations maintain ethics committees for research falling outside the scope of that Act, and the principles of good scientific practice promoted by the Finnish National Board on Research Integrity (TENK) are widely followed (2). In practice, some data holders or organisations responsible for handling data access requests may, in individual cases, request applicants to obtain an ethics committee opinion where a project raises particularly sensitive ethical issues. Such practices reflect institutional governance and established research ethics practices rather than a general statutory requirement applicable to the secondary use of health data. According to TENK's guidelines, an ethics committee opinion may also be requested where this is required by a research funder, collaborative partner, the subject of the research or a scientific publisher, even where Finnish legislation does not otherwise require an ethical review of the project. Ethical review may therefore be requested for several non-statutory reasons, including funding or publication requirements and institutional policies. The existence of these established ethics review structures demonstrates that Finland already possesses a mature research ethics governance framework. Should future legislative developments related to the EHDS make statutory ethical review more widely applicable to the secondary use of health data, implementation could build upon these existing mechanisms rather than requiring the creation of an entirely new system.

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

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

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

2.2 Sweden

The legal basis for ethical review in Sweden is the Ethical Review Act (2003:460) concerning the Ethical Review of Research Involving Humans (*Lag (2003:460) om etikprövning av forskning som avser människor*) (3). For EHDS secondary use, this is the primary legislation

determining whether ethical review is required, although other national legislation and EU legislation may also apply.

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

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

Secondly, according to the guidance published by the Swedish Ethical Review Authority (FAQ) (4), ethical review is required in Sweden whenever any part of the so-called implementation phase of a research project is to be carried out in Sweden. The activities comprising the implementation phase include the recruitment of research participants, the collection of research data or other research material, the conduct of research procedures or interventions, and the analysis and processing of research data.

Where a foreign researcher intends to collect data in Sweden—for example, by collecting or obtaining data—for the purpose of conducting further research in another country, Swedish ethical approval is required for the data collection activities (5, 6). The storage of research data constitutes part of the research. Consequently, even where a Swedish researcher collects data abroad, the research is considered to be conducted in Sweden once the data collection results in the storage of research data in Sweden.

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

Furthermore, Sweden distinguishes between scientific research and QA. Projects classified as QA or quality development generally do not require ethical review, whereas projects classified as scientific research generally require ethical review where the research involves special categories of personal data or biological material. The distinction between these two categories is not always straightforward and is discussed in more detail in Chapter 5 .

Ethical review is generally not required for:

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

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

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

2.3 Norway

The legal basis for ethical review in Norway is primarily the Health Research Act (Act of 20 June 2008 No. 44) (*Helseforskningsloven*) (7). Other relevant legislation includes the Health Personnel Act (*Helsepersonelloven*) and the Health Register Act (*Helseregisterloven*). For EHDS secondary use, the Health Research Act is the primary legislation determining when ethical review is required.

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

The Health Research Act applies to all medical and health research conducted on Norwegian territory, or to research performed under the direction of a person or body established in Norway. The Norwegian territorial or institutional connection therefore does not independently create an ethical review requirement. The project must first constitute medical and health research involving personal health data.[3] If those substantive conditions are met and the project falls within the territorial scope of the Act, ethical review is required. Ethical approval must be obtained before access to the data is granted.

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

Ethical review is generally not required for:

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

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

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

The absence of an ethical review requirement does not necessarily mean that no further approval is needed. Where personal health data are used without consent for the proposed use[4], an exemption from the duty of confidentiality may still be required under the Health Personnel Act or the Health Register Act. Depending on the type of data and the purpose of the project, the exemption may be granted by a Regional Committee for Medical and Health Research Ethics (REC), the Norwegian Health Data Service (HDS), the Norwegian Directorate of Health or the relevant institution.

Applications for ethical review are generally submitted in Norwegian, although another language may be accepted where properly justified. Ethical review is carried out by one of the Regional Committees for Medical and Health Research Ethics (8). The National Committee for Medical and Health Research Ethics acts as the appeal body.

2.4 Denmark

In Denmark, register research *solely* based on health data (e.g. from administrative or patients register) does not require ethical approval, unless it concerns certain sensitive data, which at present only includes genome- and image data and there is Danish research activity. Thus, making these two criteria cumulative. The legal basis for ethical review is the Committee Act (*Lov om videnskabsetisk behandling af sundhedsvidenskabelige forskningsprojekter og sundhedsdatavidenskabelige forskningsprojekter*) (9).

Ethical review is required for scientific research based on the secondary use of sensitive bioinformatic data originating from clinical care or from a previous research project, where the project involves extensive genomic mapping or diagnostic imaging, cf. § 21 b of the Committee Act. The relevant EHDS data categories include genomic data and imaging data corresponding to Art. 51(f) and, depending on the source of the data, Arts. 51(m), 51(n) and 51(q). Register-based research requires ethical review only where it involves these categories of sensitive bioinformatic data. However, if health data is also used as a part of a clinical medicine trial, a medical device trial, or a general health research intervention trial, the ethical rules governing those trials in Denmark will apply (10, 11, 12).

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

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

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

Ethical review is generally not required for:

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

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

2.5 Iceland

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

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

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

Ethical review is generally not required for:

- QA and quality improvement activities;

- administrative or statistical uses of health data that do not aim to generate new scientific knowledge.

The ethical review requirement is not linked to the nationality of the applicant. Instead, it is primarily connected to Icelandic data and participants. The Act applies where Icelandic health data are used, or the participants are located in Iceland. Applications are generally submitted in Icelandic, although English may be accepted in exceptional cases. The principal investigator may also need to demonstrate proficiency in Icelandic on a case-by-case basis. Ethical approval must be obtained before data are accessed. Ethical review is primarily carried out by the Icelandic National Bioethics Committee, although studies conducted entirely within Landspítali University Hospital or Akureyri Hospital may instead be reviewed by the institutional review board of the respective hospital. The assessment is substantive and considers, among other things, whether the acquisition, use and disclosure of health data are proportionate to the research objectives, whether the requested data are adequate and relevant, and whether participants' dignity, rights and privacy are adequately protected.

2.6 Comparison of the Nordic approaches

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

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

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

The comparison further showed that, although all Nordic countries recognise that secondary use of health data may be carried out for different purposes, the legal significance of these purposes varies. In Sweden, Norway, Denmark and Iceland, the distinction between scientific research and QA may determine whether ethical review is required. In Finland, by contrast,

this distinction does not determine whether a statutory ethical review is required for the secondary use of health data.

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

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

- application language requirements;
- the territorial applicability of national ethical review legislation in cross-border projects; and
- the distinction between QA and scientific research.

These topics are discussed in the following chapters.

3 Application language

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

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

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

However, language requirements may also create an unnecessary administrative barrier for international applicants. Where local partners are involved primarily to prepare or submit ethical review applications rather than because of their scientific expertise, collaborations risk becoming driven by administrative necessity instead of scientific value. This may be

particularly challenging for multinational projects seeking access to health data from several Nordic countries, where applications may need to be prepared in multiple languages.

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

4 Territorial applicability of national ethical review legislation

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

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

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

The expert group acknowledges that territorial rules are a natural feature of national legislation, ensuring that ethical committees exercise jurisdiction only over projects with a

sufficient connection to the country concerned. However, from the perspective of international applicants, these rules are not always easy to identify or interpret, particularly in multinational research consortia where research tasks are shared between several organisations.

The expert group also notes that differences in the territorial applicability of national ethical review legislation may unintentionally influence the composition of multinational research consortia. Where the involvement of a partner from a particular country may result in additional ethical review or procedural requirements, there may be an incentive to allocate research activities to partners in other jurisdictions or to limit the involvement of organisations from countries where additional requirements apply. Such considerations could reduce opportunities to involve the most appropriate scientific or clinical expertise and may undermine the objective of the EHDS to facilitate effective cross-border collaboration in the secondary use of health data. Greater transparency regarding the territorial applicability of national legislation, together with greater harmonisation where appropriate, could help ensure that consortium composition is driven primarily by scientific expertise and project needs rather than differences in national regulatory requirements.

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

5 Quality assurance v scientific research

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

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

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

The practical implications of these differences were also demonstrated during the Work Stream 3 pilot of the VALO2 project (remote access to secure processing environments), where the classification of a project as scientific research rather than QA affected the

applicable legal requirements and the time needed to obtain access to health data. The pilot experiences are discussed further in Chapter 6

The following chapters describe how QA and scientific research are currently understood in the Nordic countries, how they differ and align. The scientific research definition is then reflected against the European Data Protection Board Guidelines 01/2026 on the processing of personal data for scientific research purposes and the TEHDAS2 Joint Action Guideline 5.2 for Health Data Access Bodies on minimum categories and limitations on the reuse of electronic health data.

5.1 Finland

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

5.2 Sweden

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

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

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

5.3 Norway

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

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

A proposed approach is to concentrate on three key issues:

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

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

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

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

5.4 Denmark

Quality control and quality development do not have to be reported to the Research ethics committee.

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

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

5.5 Iceland

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

In its assessment, the Committee seeks to evaluate the project, based on the information provided in the application. Factors considered may include, among other things, the

background of the researchers, the study population (healthy individuals or patients), and the purpose and objectives of the project. The mere fact that questions are asked about physical or mental health do not make project health research. Quality improvement projects have generally not been considered subject to approval by the Committee. Quality improvement projects are understood to be projects carried out entirely within an institution by its own staff, with the genuine purpose of improving practice, for example by enhancing procedures or workflows. Such projects have therefore not generally been regarded as falling within the Committee's approval requirements. Example: A project examining whether a change in the registration process for patients attending an out-of-hours primary care service resulted in shorter waiting times would typically be considered a quality improvement project rather than research requiring ethical approval.

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

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

QA is understood as an activity that:

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

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

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

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

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

regulations and related provisions and are linked to the responsibility of healthcare providers to ensure the quality and safety of their activities.

- Denmark assesses whether an activity falls within the definition of a health research project under the Committee Act rather than constituting QA or patient care. The term “health research” encompasses treatment, diagnosis, prevention and rehabilitation. Research is understood as a planned activity aimed at systematically acquiring knowledge within these fields. Whether the results are intended for publication may be taken into account, but this is not in itself decisive.
- Finland does not have specific guidance distinguishing QA from scientific research when assessing applications for secondary use of health data.

- Interpretation in practice
  - Sweden, Norway, Denmark and Iceland all reported that distinguishing QA from scientific research may be challenging, particularly where existing health data are analysed using scientific methods.
  - The experts also noted that interpretations differ not only between countries but, in some cases, also between organisations and individual ethical committees or other competent authorities.
  - In Norway and Iceland, a project may be submitted to the competent ethics committee for an assessment if it is unclear whether the activity constitutes research or QA.
- Practical consequences
  - In all Nordic countries, except Finland, the classification of a project as QA or scientific research forms the starting point for assessing whether ethical review is required. Where a project is classified as scientific research, the applicable national legislation must then be assessed to determine whether the remaining legal conditions for ethical review are fulfilled. Classification as research does not therefore mean that ethical review is automatically required.

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

5.7 Scientific research in the EHDS and GDPR framework

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

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

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

The EHDS preserves the application of national ethical requirements through Art. 54(1)(e). However, while Member States remain competent to determine when ethical review is required under their national legislation, the concept of scientific research should be interpreted consistently with the broader European legal framework. Consequently, when assessing whether a project constitutes scientific research or QA, national approaches should be considered in light of the EHDS, the GDPR and the relevant European guidance. The following sections examine these European instruments and their relevance for interpreting the distinction between QA and scientific research.

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

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

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

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

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

The guideline further states that scientific research:

- must have a clear scientific aim and methods;

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

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

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

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

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

The EDPB Guidelines 1/2026 on the processing of personal data for scientific research purposes (14)[5] take a similar approach. The Guidelines acknowledge that there is no single exhaustive or universally applicable definition of scientific research under EU law.
Instead, the EDPB identifies six indicative factors that should be considered when assessing whether an activity can be regarded as scientific research:

1. a methodical and systematic approach;
2. adherence to recognised ethical standards;
3. verifiability and transparency;
4. autonomy and independence;
5. scientific objectives; and

[5] The Guidelines were subject to public consultation between 16 April and 25 June 2026. At the time of writing this report, no revised version had been published.

6. the potential to contribute to existing scientific knowledge or to apply existing knowledge in novel ways.

Importantly, the EDPB emphasises that these factors must be assessed in light of the relevant scientific field. The way in which these indicators manifest themselves may differ between disciplines such as biomedical research, epidemiology, social sciences, humanities or technological research.

The EDPB does not present these factors as strict cumulative legal requirements. Rather, they are intended to assist controllers and supervisory authorities in assessing the nature of the activity. According to the Guidelines, where all indicators are present there will generally be a strong presumption that the activity constitutes scientific research. Where fewer indicators are present, additional justification may be necessary to demonstrate why the activity should nevertheless be regarded as scientific research.

5.7.3 Implications for the Nordic interpretation

The Nordic approaches identified in the mapping show several points of convergence with both the TEHDAS2 Guideline's interpretation of Art. 53(1)(e) EHDS and the EDPB Guidelines. In particular, the emphasis placed in several Nordic countries on scientific methods, systematic activity and the generation or acquisition of new knowledge is also reflected in the European sources. However, the Nordic countries do not apply a uniform legal definition or a single common test for identifying scientific research, and the degree of alignment therefore varies according to the applicable national framework.

At the same time, the European framework provides additional elements that may assist ethics committees when assessing difficult borderline cases. In particular, the EDPB places greater emphasis on transparency, scientific independence, ethical standards and the broader context in which the activity is conducted. The assessment is therefore not limited to asking whether a project seeks to generate new knowledge.

Thus, the EHDS and GDPR frameworks are broadly compatible with the national approaches identified in the Nordic mapping. They reflect similar core characteristics of scientific research while providing a broader and more structured set of indicators for assessing whether a project should be regarded as scientific research or as another type of activity, such as QA, quality improvement, service development or operational monitoring.

The most significant development concerns projects involving innovation activities, algorithm development, machine learning and AI. Art. 53(1)(e) EHDS expressly recognises that such activities may fall within scientific research. However, neither the TEHDAS2 Guideline nor the EDPB Guidelines suggest that they automatically do so. Instead, they must be assessed against the broader characteristics of scientific research.

In conclusion, the EDPB's approach may even operate as a limiting factor. While Art. 53(1)(e) EHDS broadens the range of activities that may potentially qualify as scientific research, the EDPB's six indicative factors require a structured assessment of whether the activity genuinely possesses a scientific character. Consequently, the relevant question for ethics committees is not whether a project uses AI, develops an algorithm or creates an innovative product, but whether the project, viewed as a whole and within its relevant scientific field, displays the characteristics of scientific research recognised under both national law and the broader European framework.

6 Practical lessons learned from the Work Stream 3 pilots

The experiences gained during the Work Stream 3 pilots of the VALO and VALO2 projects illustrate how the distinction between QA and scientific research may influence both the regulatory pathway and the overall project timeline in cross-border research. In this case, it was the Norwegian law that caused delays and additional administrative burden whereas the Danish and Finnish law did not impose such burden or delays.

The first pilot (VALO) was classified as QA. Consequently, no ethical review was required in Norway. However, because the project involved the use of personal health data without obtaining consent from the participants, an exemption from the duty of confidentiality was still required under Norwegian law. The exemption was granted and the pilot proceeded as planned. The analyses were carried out locally in Finland, Denmark and Norway, and only aggregated results were shared with the researchers in Norway.

The second pilot (VALO2) was based on the same cohorts and pursued the same overall objective. The principal difference was methodological rather than scientific. Whereas the VALO pilot relied on a federated analysis model in which each participating organisation executed the analyses locally and only aggregated results were shared, the VALO2 pilot was designed to evaluate a model more closely reflecting the future EHDS framework. Researchers were granted remote access to secure processing environments, allowing them to work directly with pseudonymised individual-level data within the secure environments, refine the analysis script where necessary and execute the analyses without transferring the underlying data across national borders. This represented a substantially different operational model from the federated approach used in VALO, despite the scientific objectives of the two pilots remaining largely unchanged.

The project was initially submitted to the same local hospital ethics committee in Norway, that had previously assessed the VALO pilot as QA. During the assessment, however, the committee concluded that the VALO2 project should instead be regarded as scientific research. As a result, the project could no longer be handled through the local institutional process but instead entered an entirely different regulatory pathway. Responsibility for the ethical assessment transferred to the Regional Committee for Medical and Health Research Ethics (REC), making the project subject to the REC's application procedures and submission timetable. Because the decision was communicated only after the submission deadline for the next REC meeting had passed, the project had to wait until the following application round before the ethical review process could begin.

Following the REC's assessment, ethical approval was granted. As in the VALO pilot, the project also required an exemption from the duty of confidentiality because personal health data were used without obtaining consent from the participants. Unlike in the first pilot, however, the exemption was granted subject to additional conditions. Before access to the data could be provided, all living participants in the cohort had to be informed about the project and given an opportunity to opt out, whereas the REC approved the use of data relating to deceased participants. This required additional administrative work to identify and contact the participants, organise the notification process and wait until the four-week opt-out period expired before access to the data could be granted.

The practical delay was therefore not caused solely by the requirement for ethical review. Rather, it resulted from the way in which the classification of the project as scientific research

fundamentally altered the applicable regulatory pathway. The classification transferred responsibility for the assessment to the REC, introduced dependence on the REC's submission timetable and, following ethical approval, resulted in a conditional exemption from the duty of confidentiality that required participant notification and completion of the opt-out period before access to the data could be granted. The combined effect of these sequential procedural requirements resulted in a delay of approximately five months compared with the original project timetable. The timetable for VALO2 had been prepared based on the experience gained during the VALO pilot, where the applicable legal pathway had been considerably less complex. Although the overall objective, study population and scientific aims of the project remained essentially unchanged, a different assessment of the project's nature resulted in a substantially different regulatory pathway and several additional procedural requirements that could not reasonably have been anticipated at the outset of the project.

The purpose of presenting this example is not to question the individual decisions taken by the competent authorities. Rather, it illustrates how relatively small methodological changes in a cross-border project may lead to a different legal assessment and, consequently, substantially different procedural requirements. From the perspective of applicants, such outcomes may be difficult to predict in advance and may significantly affect project planning, resource allocation and implementation timelines.

The experiences from the VALO and VALO2 pilots demonstrate that the distinction between QA and scientific research is not merely a theoretical legal question. It may determine the entire regulatory pathway applicable to a project, including the competent authority, the procedural steps required before access to data can be granted and, ultimately, the overall project timeline. In the VALO2 pilot, the conditions attached to the exemption from the duty of confidentiality, not the ethical review itself, became the most time-consuming element of the approval process.

The pilots also highlighted three broader implementation issues that extend beyond the individual project. First, differences in the practical interpretation of QA and scientific research may reduce predictability for applicants seeking access to health data from several Nordic countries. Secondly, the Norwegian requirement for an exemption from the duty of confidentiality demonstrates how national procedural requirements may continue to influence access to health data under the EHDS despite the introduction of a harmonised European framework. Thirdly, discussions within the consortium suggested that the transition from federated analyses to remote researcher access within secure processing environments may affect how projects are interpreted in practice. Although the VALO2 experience does not permit conclusions about the reasons for the Norwegian assessment, the pilots illustrate the importance of monitoring how this operational model, which is central to the EHDS, is interpreted during implementation. These observations suggest that, in addition to legislative implementation, there is a need for continued practical cooperation and dialogue on ethical governance within the Nordic countries. The VALO2 pilot also demonstrated that ethical governance forms only one part of the broader operational ecosystem required for successful cross-border secondary use of health data, alongside secure processing environments, researcher onboarding, data provisioning, operational support and output release

processes.[6] The experiences gained through VALO2 provide a valuable foundation for such future work, which is discussed further in the following chapter.

7 Continued Nordic collaboration on ethical governance

The work carried out within VALO2 demonstrates that ethical governance remains an important component of the future EHDS ecosystem. While the EHDS establishes a common European framework for the secondary use of electronic health data, national ethical requirements continue to play a significant role whenever national legislation requires ethical review. The comparison of the Nordic countries and the experiences gained during the Work Stream 3 pilots showed that, although many similarities exist, practical differences remain that may affect the predictability and efficiency of cross-border access to health data.

The ethical expert group established within VALO2 has provided a valuable forum for discussing these issues across the Nordic countries. As the project comes to an end, the work should not conclude with the publication of this report. Rather, it should continue through a more structured and long-term Nordic collaboration on ethical governance.

The Nordic Model developed within Work Stream 1 provides a natural starting point for such cooperation. At present, the Nordic countries do not have a formal established community of practice[7] for ethical committees comparable to those that already exist in several other areas of health data governance[8]. Building upon the network created through VALO2 would therefore provide an opportunity to establish a regular forum where ethical experts can exchange experiences, discuss emerging issues and learn from one another in preparation for the EHDS. The future composition of such a forum should be further assessed. While the VALO2 ethical expert group provided an excellent starting point, broader representation from each Nordic country would strengthen the continuity of the work and ensure that relevant expertise from different ethical committees and organisations is represented.

As an initial priority, continued collaboration could focus on the practical distinction between QA and scientific research. Although the Nordic countries have overlapping practical understandings of QA and scientific research, the work carried out during VALO2 demonstrated that differences remain in how borderline cases are interpreted in practice. Continuing the dialogue through the discussion of practical examples and difficult cases could gradually improve consistency and predictability without requiring changes to national legislation or limiting the independence of ethical committees.

The work could also build directly upon the findings of this report by identifying additional areas where greater Nordic alignment may be beneficial. One example is the Norwegian requirement for an exemption from the duty of confidentiality, which represents a procedural requirement not found in the other Nordic countries. Continued dialogue could help identify whether similar national procedural issues exist elsewhere and whether practical approaches could be developed to improve predictability for applicants while maintaining the safeguards

[6] This matter is thoroughly discussed in the VALO2 Data Governance Workstream lessons learned report.
[7] For now, the meetings arranged have been unformal and between secretariats of the Nordic national research ethic committees.
[8] e.g. Nordic eHealth group, Nordic Standardisation group, Nordic Baltic Mortality Group, Nordic Data Protection Authorities (Nordic DPA).

established under national legislation. It may also be valuable to examine whether such a requirement can continue to be maintained under the EHDS and, if so, how it can be implemented in a sustainable manner, particularly if it results in large numbers of information notices being sent to Norwegian citizens.

The work undertaken during VALO2 also demonstrated that the topics examined in this report represent only a first step. During the comparison, several additional ethical questions emerged that could not be analysed in greater detail within the timeframe of the project. One example concerns the use of national quality registers, which illustrates particularly well how difficult the practical distinction between QA and scientific research can become.

Finland and Norway maintain extensive national quality-register infrastructures whose primary purpose is to support quality improvement within healthcare. At the same time, these registers are frequently used for scientific research. In Finland, research based on quality registers often aims to improve the quality of the registers themselves by identifying best practices and improving patient care. Such projects may simultaneously generate new scientific knowledge while directly supporting quality improvement, making it difficult to classify them exclusively as either QA or scientific research. Norway faces similar challenges. Although the primary purpose of the national quality registers is quality improvement, the same registers are regularly used for medical and health research, and the applicable approval pathway depends on how the activity is classified and whether additional data sources are involved. Sweden likewise emphasises that its quality registries primarily exist to improve healthcare while simultaneously serving as an important resource for research.

These examples demonstrate that the distinction between QA and scientific research extends well beyond the examples discussed in this report. They also illustrate that many practical questions remain unresolved and would benefit from continued Nordic dialogue and the exchange of experiences between ethical experts.

Another issue concerns the governance of AI and algorithm development under the EHDS. None of the national mappings identified AI development or the training, testing and evaluation of algorithms as an independent statutory trigger for ethical review. At the same time, Art. 53(1)(e) EHDS expressly recognises these activities as examples of scientific research when carried out for scientific purposes. The ethical exercises conducted within VALO2 also gave rise to a broader legal discussion on the interpretation of Art. 68(1)(b) EHDS, which is examined in the report prepared by the VALO2 legal expert group (16). If national legislation does not provide for ethical review of AI-related secondary use and Art. 68(1)(b) EHDS is interpreted as not permitting HDABs to take even basic ethical considerations into account, Member States may consider introducing additional national legislative provisions to address this perceived gap. Divergent national legislative responses could create new barriers to cross-border research, reduce predictability and lead to unnecessary differences between the Nordic countries. Continued Nordic dialogue would enable the identification of such issues before national implementation decisions are finalised, exchange experiences and jointly explore possible solutions. This would help ensure that national decisions are made on the basis of shared knowledge and a common understanding of the legal issues, thereby reducing the risk of unnecessary divergence while fully respecting each country's legislative autonomy.

Finally, the ethical expert group should be regarded as an important stakeholder in the broader implementation of the EHDS. To date, much of the implementation work has focused

on legislation, HDABs and technical infrastructure. However, wherever national legislation requires ethical review, ethics committees will continue to play an essential role in enabling access to health data. Their practical experience will also be valuable to the other collaborative groups established under the Nordic Model, in the same way that legal and technical expertise is already shared across work streams. It is therefore important that ethical experts become actively involved in national and Nordic EHDS implementation already during the implementation phase, rather than only once the first EHDS secondary-use applications are expected in 2029. This would provide an opportunity to identify practical bottlenecks, develop common understanding and improve preparedness before the EHDS becomes fully operational.

Continued Nordic cooperation should not seek to replace national decision-making or undermine the independence of national ethical committees. Rather, its purpose should be to provide a permanent Nordic community of practice where ethical experts can exchange experiences, discuss difficult cases and contribute to the practical implementation of the EHDS. The Nordic Model developed through VALO2 provides a natural foundation for such cooperation. Building on the existing network would allow the work to continue beyond the lifetime of the project, although the future composition of the group should be further assessed to ensure broad representation from all Nordic countries.

The forum could initially focus on the themes identified in this report, including the practical distinction between QA and scientific research, the interaction between ethical review and national procedural requirements such as the Norwegian exemption from the duty of confidentiality, and other emerging ethical questions arising during EHDS implementation. Beyond serving as a platform for exchanging experiences, the forum could also identify areas where greater Nordic harmonisation would be beneficial, assess whether differences arise from legislation or practice, and develop proposals for how these could be addressed. This would allow the Nordic countries to distinguish between areas where legislative harmonisation is desirable, areas where greater practical alignment is sufficient and areas where national differences should remain. In this way, the collaboration could support both practical implementation and, where considered appropriate by the Nordic countries themselves, future legislative or policy development while fully respecting national competence and the independence of ethical review bodies.

By building upon the collaboration established during VALO2, the Nordic countries have an opportunity to strengthen both the predictability and the attractiveness of their health data ecosystems. A permanent Nordic forum for ethical governance would support mutual learning, facilitate EHDS implementation, provide evidence-based recommendations for future development and help ensure that the Nordic countries continue to be recognised as international leaders in the responsible secondary use of health data.

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Annex 1 Responsible ethical committees and institutions for the national mappings

Country	Committee/Institute	Name
Finland	The Finnish Institute for Health and Welfare	Pieta Näsänen-Gilmore Jenina Soimala Sirpa Soini Sampo Viiri
Sweden	National Board of Health and Welfare	Johanna Holm Michal Korek
Norway	The National Committee for Medical and Health Research Ethics (NREC) and Regional Committees for Medical and Health Research Ethics (REC)	Camilla Bø Iversen Ingvild Haaland Margit Ramberg
Denmark	National Research Ethic Committee (NREC)	Susanne Pihl Jakobsen
Iceland	The National Bioethics Committee / Directorate of Health	Aslaug Einarsdottir Védís Helga Eiríksdóttir

These are the people and organisations that have given their written contribution to the sections concerning their respective country's current national landscape on the matter.

Annex 2 Action suggestions

Need to incorporate the ethical committees into the EHDS implementation work sooner rather than later

Ethics committees should be actively involved in EHDS implementation at an early stage.

Applicants seeking access to health data under the EHDS will continue to be subject to national requirements concerning ethical review where such requirements apply. In addition, the EHDS foresees a role for ethics expertise within the secondary-use governance framework, including the possibility for ethics committees to support HDABs or to participate directly in their activities. Ethics committees are therefore important stakeholders in the implementation of the EHDS.

Based on discussions conducted within the VALO2 project, awareness of the EHDS and its implications for ethical review processes currently appears limited among some ethics committees. Delaying their involvement in national implementation efforts may create challenges related to legal certainty, consistency of interpretation, operational readiness, and alignment between existing national frameworks and the requirements of the EHDS.

Early engagement would allow ethics committees to assess how their current practices, procedures and mandates interact with the EHDS framework and to identify any areas where legislative, procedural, or organisational adjustments may be needed. It would also support more consistent decision-making and facilitate smoother cooperation between ethics committees, HDABs, and other actors involved in secondary use governance.

For these reasons, ethics committees should be included in EHDS implementation activities as early as possible to ensure that they are adequately prepared for their future role, and that national implementation is both effective and legally coherent.

Enhance and prioritise continued collaboration between ethical committees by focusing first on the distinction between quality assurance and scientific research

The work carried out within VALO2 demonstrates the value of bringing together ethical experts from across the Nordic countries. At present, however, there is no established Nordic community of practice through which ethics committees can exchange experiences, discuss emerging questions related to the EHDS or develop a common understanding of its practical implementation.

One of the first priorities for such collaboration should be the practical distinction between quality assurance and scientific research. Although the national legal frameworks are broadly similar, the mapping and discussions demonstrated that this distinction remains challenging in several countries and that interpretations may differ not only between countries but, in some cases, also between ethics committees or other competent authorities within the same country. Continued dialogue on practical examples and borderline cases would improve transparency, predictability and mutual understanding while fully respecting the independence of national ethical review bodies.

As the network becomes established, its work could gradually expand to other practical questions identified in this report. These include the interpretation of new EHDS scientific research purposes, such as the development, training, testing and evaluation of AI systems and algorithms; the interaction between ethics committees and HDABs; national procedural requirements that affect access to health data; and the exchange of experiences on emerging borderline cases during EHDS implementation. A structured community of practice would provide an effective forum for developing a shared understanding of these issues while respecting differences in national legislation.

The ethical expert network established through VALO2 and the Nordic Model provides a natural foundation for this cooperation. A permanent forum would enable ethics committees to maintain direct links with the legal, technical and policy experts involved in EHDS implementation, allowing experiences and practical challenges to be shared across disciplines instead of being addressed in isolation.

Future collaboration should also be expanded to include the Baltic countries. As Estonia and Lithuania were not able to participate in the mapping exercise within the timeframe of VALO2, their perspectives are currently missing. Including them in future work would strengthen regional cooperation and support more consistent implementation of the EHDS across the Nordic-Baltic region.

The future composition of such a forum should be carefully considered. While the VALO2 ethical expert group provided an excellent starting point, broader representation from each Nordic country would strengthen the continuity of the work and ensure that relevant expertise from different ethical committees and organisations is represented. Experience from VALO2 demonstrates that successful Nordic collaboration depends not only on the participation of all countries, but also on ensuring that each country is able to dedicate sufficient expertise and resources throughout the work. The preparation of this report also highlighted the importance of allocating sufficient resources for participation in Nordic collaboration. Differences in the availability of experts and the time they could dedicate to the work inevitably influenced the depth of discussions and the extent to which national perspectives could be reflected in the report. Future collaboration would therefore benefit from ensuring that all participating countries are represented by experts with both the mandate and the resources to contribute actively throughout the process. This would help ensure that future work benefits from balanced representation, a broader exchange of national experiences and a stronger common understanding of emerging ethical questions under the EHDS.

Application language barriers should be considered and removed when possible

The ethical expert group acknowledges that requiring ethical review applications to be submitted only in the national language may encourage the involvement of local partners. However, such involvement may often be driven by administrative necessity rather than scientific need. Language requirements can therefore create an unnecessary barrier for international applicants and reduce the attractiveness of Nordic health data resources for cross-border research.

Allowing ethical review applications and guidance materials to be submitted and accessed in English would lower these barriers and enable researchers to engage directly with the application process. This would likely increase international interest in Nordic health data and

create more opportunities for meaningful scientific collaboration. Rather than promoting partnerships primarily for administrative purposes, an English-language process would encourage collaborations based on scientific expertise and added value, supporting the objectives of the European Health Data Space (EHDS) and strengthening the Nordic region's competitiveness as a research environment.

Territorial ethical review requirements may influence consortium composition

The comparison identified that the territorial applicability of national ethical review legislation differs between the Nordic countries. Denmark, Norway and Sweden apply explicit territorial conditions, although the relevant national connection is defined differently in each country. Applicability may depend not only on the characteristics of the project itself but also on where research activities are conducted, where data are collected, analysed, processed or stored, and whether a person or institution established in the country has scientific responsibility for the project. In multinational consortia, the mere inclusion of a Danish or Norwegian organisation does not, by itself, make the respective national legislation applicable. Nevertheless, the allocation of research activities and scientific responsibilities may determine which national ethical review frameworks apply. These differences may create uncertainty for international research collaborations and multinational consortia.

International consortia may therefore need to assess carefully which national ethical review systems apply to different parts of a project. Without clear guidance, this may increase administrative complexity, create uncertainty regarding regulatory obligations and influence how research activities and responsibilities are allocated within a consortium. In practice, there is a risk that research tasks are assigned in a way that avoids additional ethical review requirements rather than making the best use of the scientific expertise available within the consortium. This may reduce opportunities for experts from some Nordic countries to participate fully in international collaborations.

To support equitable cross-border collaboration and strengthen the Nordic region’s competitiveness in health research and innovation, the expert group considers that the territorial applicability of national ethical review legislation should be communicated as clearly as possible. Common guidance for multinational research projects should explain which research activities and institutional connections establish territorial applicability, including how the collection, analysis, processing and storage of data are treated. It should also distinguish the territorial jurisdiction of an ethics committee from any separate documentation that a data-granting authority may require when a project is conducted and ethically reviewed in another country. Greater transparency would improve legal certainty for applicants while supporting the objectives of the European Health Data Space.