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Value from Nordic health data – VALO project

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Executive summary

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

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

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

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

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

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

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

1 About the legal group and the countries

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

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

The legal group was initially established as a discussion forum that met during the VALO2 Competence Forums. As the implementation of the EHDS progressed, the need for more structured legal cooperation became evident. The participants themselves also expressed a wish to move beyond general discussions and establish more concrete objectives, including documenting common interpretations and recommendations in writing. At the beginning of 2026, the group's working methods were therefore revised. Monthly online meetings were introduced between the Competence Forums, supported by recurring agendas that revisited unresolved legal questions until a common understanding could be reached. The development of this document became a standing agenda item, providing a structured basis for discussions and ensuring that the group's conclusions were documented for future use.[1] In addition, each meeting allowed time for ad hoc legal questions arising from ongoing national implementation work.

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

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

[1] The articles and topics were selected because they were considered particularly relevant or challenging for Nordic implementation of the EHDS at the time of the analysis. As the group had no decision-making mandate and official national positions had not yet been established, it focused on legal questions that could be discussed without prejudging ongoing national implementation processes or positions.

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

2 Purpose of this document

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

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

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

The legal group considers Nordic cooperation particularly important because the EHDS offers significant opportunities for the secondary use of health data but also presents implementation challenges that may reduce the attractiveness of Nordic data if national approaches diverge unnecessarily. The comparative mapping carried out in Work Stream 1 demonstrated that, despite the high quality of Nordic health data, administrative complexity and differences in national implementation may discourage applicants from conducting multinational studies. Differences in national interpretations, for example regarding the granularity of opt-out mechanisms, the identification of health data holders or the scope of assessments carried out by Health Data Access Bodies, may affect the comparability of datasets and the practical feasibility of using Nordic data across borders. For example, if one Nordic country interprets a particular registry or public authority as a health data holder while another does not, or if datasets are made available with different levels of detail, applicants may no longer be able to conduct comparable analyses across all Nordic countries.

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

3 Need for harmonisation in the Nordics

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

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

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

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

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

Recent academic literature has also highlighted the ethical challenges that may arise where data originally collected on the basis of informed consent become subject to the mandatory data-sharing obligations introduced by the EHDS, particularly where this may alter the

expectations created by the original consent process and potentially affect public trust in research(1).

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

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

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

3.2 Policy and HDAB group related

The legal group discussed both the implementation of the EHDS opt-out mechanism and the protection of intellectual property rights and trade secrets (IPR&TS) under the EHDS framework. While certain legal considerations were identified, the group concluded that both topics are primarily operational and policy-related in nature and therefore fall within the remit of the VALO2's HDAB group. The following chapters summarise the discussions held within the legal group, the considerations identified and the information shared with the HDAB group at the Competence Forum in Gothenburg on 4 May 2026.

3.2.1 Opt-out

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

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

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

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

The group further observed that differing national approaches would reinforce an existing challenge already identified by researchers. Researchers have reported that differences in data minimisation principles and regulatory complexity already require them to “settle for less precise analysis because we need consistency across all participating countries, so we default to the lowest common denominator.”(2) As a result, data made available by some countries may ultimately be excluded from a project because equivalent data cannot be accessed from another country. Further divergence in opt-out models could therefore make the lowest common denominator even more restrictive, further reducing the comparability and usability of Nordic data and diminishing the attractiveness of applying for access to cross-border datasets.

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

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

3.2.2 Intellectual property rights and trade secrets (IPR&TS)

The EHDS places responsibility on HDABs for assessing and protecting the IPR&TS of data holders when processing data access applications. This has raised concerns among private-

sector stakeholders, who have expressed doubts as to whether HDABs, which may not possess detailed knowledge of the underlying datasets, will be able to adequately identify and protect commercially sensitive information. While the topic has been addressed within the TEHDAS2 Joint Action (TEHDAS2), including through a dedicated workshop and planned guidance, no established solutions have yet emerged at the European level.

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

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

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

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

4 Interpretation and implementation of specific EHDS Art's

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

The definition of a health data holder under Art. 2(2)(t) EHDS has been the subject of discussion within the legal and metadata groups and among national authorities. In particular,

Statistics Sweden has taken the position that they are not be regarded as a health data holder under the EHDS (3). This position was discussed at the Competence Forum in Gothenburg on 4 May 2026. After the meeting in Gothenburg the legal group analysed the matter and agreed that, in general, statistical bodies should be considered as health data holders under the EHDS.

Statistics Sweden's interpretation is primarily based on the view that it does not operate within the healthcare or care sector and does not develop products or services intended for those sectors. To the extent that Art. 2(2)(t) can be read as linking the concept of a health data holder solely to activities carried out within the healthcare or care sector, this interpretation cannot be dismissed outright and therefore deserves consideration.

However, the legal group considers that such an interpretation places decisive weight on only one part of the definition while giving insufficient consideration to the wording of the provision as a whole, as well as to the broader objectives and structure of the EHDS Regulation.

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

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

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

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

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

Under this interpretation, an entity does not need to belong to the healthcare or care sector to qualify as a health data holder. For example, we consider that a statistical authority that processes electronic health data to produce health statistics falls within the second category, despite not being part of the healthcare or care sectors. Accordingly, an entity may qualify as a health data holder either because of its institutional role or because of the nature and purpose of the activities it carries out.

It should be noted, however, that falling within one of these three categories is not, in itself, sufficient to qualify as a health data holder. The entity must also satisfy the conditions laid down in Art. 2(2)(t)(i) or Art. 2(2)(t)(ii).

Several textual, systematic and practical considerations support this interpretation.

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

Second, this interpretation is reinforced by Recital 6, which explicitly states that electronic health data include data that were initially collected for "research, statistical, health threat assessment, policymaking or regulatory purposes" and that such data should be made available in accordance with the rules laid down in the Regulation. The recital therefore recognises that electronic health data may originate and continue to exist outside traditional healthcare delivery settings. A narrow interpretation excluding statistical authorities would therefore be difficult to reconcile with this explicit reference to statistical data.

Third, the systematic structure of the Regulation points in the same direction. Art. 51 covers numerous categories of electronic health data that are frequently held by statistical authorities, including data relating to determinants of health, socioeconomic factors, population-level information, and linked datasets used for research and policymaking. A restrictive interpretation under which statistical authorities are excluded from the concept of health data holder would therefore risk creating a significant gap between the categories of data covered by Art. 51 and the entities responsible for making that data available under the EHDS.

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

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

From a functional perspective, national statistical authorities frequently fulfil the characteristics associated with health data holders under the EHDS framework. They collect, maintain, process, link, and provide access to electronic health data and health-related datasets for research, policymaking and statistical purposes. Excluding such authorities would remove important categories of data from the EHDS secondary-use framework and undermine the Regulation's objective of facilitating access to electronic health data across the Union.

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

Accordingly, where a statistical authority holds or processes electronic health data falling within Art. 51, and where its role corresponds to one of the criteria laid down in Art. 2(2)(t)(i) or (ii), it should generally be considered a health data holder under the EHDS. The narrower sector-based interpretation remains one possible reading of Art. 2(2)(t), but the legal group considers it too restrictive when assessed against the wording of Recitals 1 and 6, the broad categories of electronic health data listed in Art. 51, the overall architecture of the EHDS and the functional interpretation reflected in TEHDAS2 Guideline 6.1.

For these reasons, the legal group considers that whether an entity qualifies as a health data holder under the EHDS should not be assessed solely on the basis of its institutional placement or sectoral affiliation. Rather, the assessment should focus on the activities carried out by the entity, the electronic health data it holds or processes, and whether the entity fulfils the conditions laid down in Art. 2(2)(t)(i) or (ii).

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

So far, the other Nordics and Baltics have not made any official decisions regarding the matter. Nevertheless, this is a topic that the statistical authorities in every country should work on and agree on.

4.2 Art. 50(3), possibilities of health data intermediation entities (HDIE)

4.2.1 Meaning of “certain categories of data holders”

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

The discussion focused on the level of granularity that may be applied when defining categories of data holders, including whether categories could be defined by combining characteristics such as the type of data holder and the type of data held. The group concluded that categories of data holders may be defined based on different attributes. Consequently, a HDIE would not necessarily need to assume the duties of all data holders within a broad category, such as all small and medium-sized enterprises or all registries but could instead assume the duties of only certain data holders belonging to the same category.

4.2.2 Organisation and role of HDIE

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

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

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

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

4.2.3 Fees

The legal group considers that an HDIE may charge applicants the same fees that would otherwise be charged by the health data holder in accordance with the EHDS. The involvement of an HDIE should not result in higher statutory fees for applicants seeking access to health data. On the contrary, it should rather result in lower statutory fees, as the HDIE already have the necessary tools and resources to make data available, while some health data holders have not and will need to build an EHDS-compliant framework themselves, which will be both time- and money consuming

The legal group further considers that the EHDS does not regulate the commercial arrangements between the health data holder and the HDIE beyond the provisions governing

the fees payable by applicants. Accordingly, the financial arrangements between the health data holder and the HDIE, including the remuneration of the HDIE for the services it provides, should be determined by the parties.

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

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

4.2.4 HDIE's legal responsibility and controllership

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

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

The legal group did not have enough time to reach a common interpretation on this question.

4.2.5 Designation of HDIEs and allocation of duties

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

Where a Member State has exercised the national discretion provided by Art. 50(3) EHDS and has established in national law the possibility for health data holders to use HDIEs, each health data holder should remain responsible for deciding whether to make use of an HDIE and for selecting the HDIE with which it wishes to cooperate. The relationship between the

health data holder and the HDIE should be based on a contractual arrangement that clearly specifies which of the health data holder's EHDS duties are carried out by the HDIE on its behalf. The allocation of duties should therefore occur through the contractual relationship between the health data holder and the HDIE, rather than through legislation identifying individual HDIEs. Thus, it would be possible for the HDIE to only take some of the duties of the health data holder instead of all of the duties. Moreover, allowing the health data holder to use several HDIEs if considered necessary. This contractual allocation of EHDS duties is conceptually similar to the possibility under the GDPR for a controller to entrust certain processing activities to a processor.

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

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

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

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

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

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

Art. 61(5) Duties of health data users

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

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

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

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

In Finland, however, the Act on the secondary use of social and welfare data Section 58 (6) sets the procedure for handling clinically significant and actionable findings in register-based research. The law has not been applied during its existence. In brief, the researcher contacts the Data Permit Authority (Findata) which can reidentify the person, if needed.

The finding must be assessed by a special group in the Finnish Institute of Health and Welfare in terms of its significance, relevance etc. The person may already be treated for the condition, or he/she may have passed away long time ago. The individuals concerned are never contacted directly but via his or her local health care system. The ethical principle right-not-to-know applies, so the persons can opt-out for receiving this information in advance by registering to Findata's register or when being contacted for potential health related information later.

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

In Denmark, the criteria for when a data subject *can* be informed vary based on the type of project (10, 11, 12, 13).[2] For instance, for notifiable health science research projects, the data subject must either suffer from or be certain or highly likely to be at risk of developing, a life-threatening or clearly serious illness, which can be treated, prevented or alleviated. By contrast, for health-related statistical and scientific studies carried out pursuant to § 10 of the

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

Danish Data Protection Act, the data subject must suffer from a life-threatening or clearly serious illness, which is also infectious and which can be treated.

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

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

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

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

4.4 Art. 62, Fees

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

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

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

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

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

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

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

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

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

Art. 54(2)(e) prohibits the use of electronic health data where the intended activity conflicts with ethical provisions laid down in national law. However, it does not necessarily mean that, in the absence of such provisions, ethical considerations are entirely excluded from the HDAB's assessment.

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

The legal group supports an interpretation that this assessment cannot always be carried out solely as a technical or administrative exercise. Evaluating whether the data requested in the data permit application is genuinely necessary, adequate and proportionate for the proposed purpose may, in certain cases, require the HDAB to assess whether the proposed project is scientifically appropriate. This does not amount to a separate ethics review but rather forms

part of the HDAB's obligation under Art. 68(1)(b) to assess whether the requested data are justified in relation to the stated purpose. Where appropriate, this assessment may also require the HDAB to consider whether the proposed use raises fundamental ethical concerns that are relevant to determining whether the requested data is necessary, adequate and proportionate for the stated purpose.

For scientific research projects, this may require the HDAB to consider whether the research plan demonstrates that the requested data is necessary to answer the proposed research question. Depending on the study design, this may include internationally recognised elements of scientific quality, such as an appropriate study design, a justification for the requested dataset, and, where applicable, a statistical power calculation or other equivalent methodological justification. At the same time, the legal group recognises that the assessment must remain proportionate to the nature of the project. For example, exploratory or hypothesis-generating studies may legitimately require broader datasets, making traditional data minimisation assessments less straightforward. In such cases, the appropriateness of the requested data should be assessed in light of the chosen study design and methodology rather than by applying rigid criteria.

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

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

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

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