

The background of the entire page is a solid blue color. Overlaid on this background is a white line-art illustration. On the left, a profile of a person's head is shown, facing right. A hand is positioned in front of a large, rounded rectangular shape that represents a screen or a digital interface. Inside this shape, there is a pattern of binary code (0s and 1s) that appears to be emanating from or interacting with the hand. The overall theme is digital health and data security.

A VISION OF A NORDIC SECURE
DIGITAL INFRASTRUCTURE
FOR HEALTH DATA:
THE NORDIC COMMONS



NordForsk



NordForsk

**A vision of a Nordic secure digital infrastructure for health data:
The Nordic Commons**

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An abstract graphic featuring a white line-art profile of a person's head on the left and a hand reaching upwards on the right. The background is a light gray. Overlaid on the hand and the right side of the head is a large, stylized shape containing a dense pattern of binary code (0s and 1s) in a light gray color. The text is positioned in the upper right quadrant of the image.

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PREFACE

For a number of years, NordForsk has worked to highlight the potential inherent in the utilisation of longitudinal register and biobank data across Nordic borders. These data sources have been referred to as a unique gold mine not available elsewhere in the world. However, there is a risk that this valuable resource will be lost unless it is made more easily accessible. Obstacles that impede data sharing include legal, technical and procedural bottlenecks. Over the years the potential and the challenges have been presented and discussed in several policy papers as well as through NordForsk's financing of Nordic pilot projects.

The need to reinforce data sharing within and between the Nordic countries has recently been acknowledged at the national political level and within Nordic policy bodies. Areas of particular interest are research, health care and industrial innovation. In some Nordic countries, implementation of a national health data strategy is already in the operational phase with allocated funding. This report on a step-wise implementation of a Nordic Commons for health data builds on national efforts. It would allow expansion to the Nordic level, with data more easily identified, shared, compiled and jointly analysed, and would give the Nordic region a competitive advantage.

NordForsk was commissioned to draw up this report as part of the "Nordic Cooperation for Better Health 2017-2019" priority project initiated under the Norwegian Presidency of the Nordic Council of Ministers 2017. Activities have been headed by a Nordic expert group on health data infrastructures and carried out with the invaluable efforts of three groups of Nordic experts within the areas of metadata, legal frameworks and digital infrastructures. The report includes suggestions for policy implications with specific recommendations directed towards the key actors required to implement a Nordic commons, e.g. the Nordic policy level, research and innovation funders, and data owners. Careful, coordinated and concrete actions are called for by all of these actors to realise the Nordic commons.

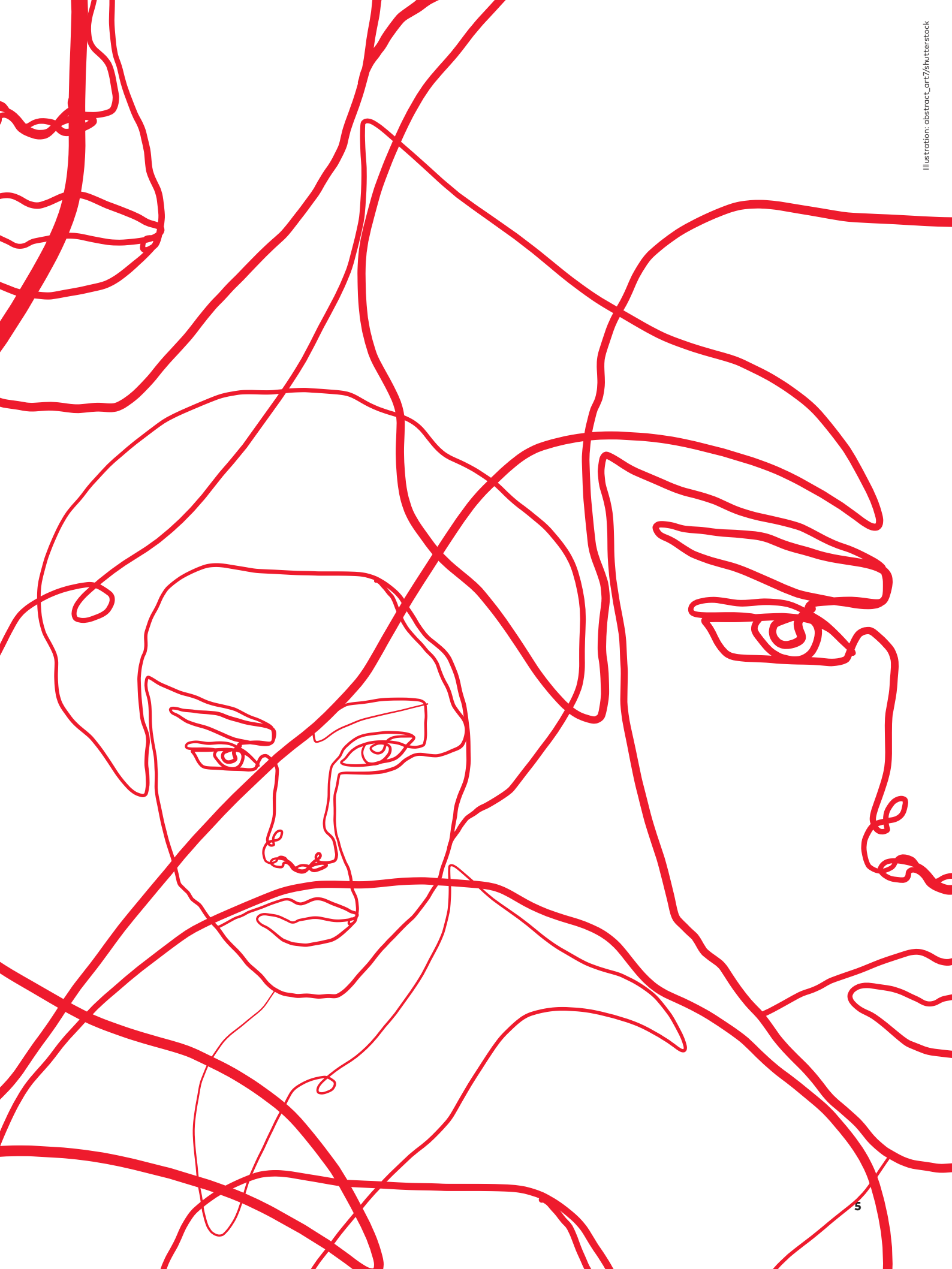
NordForsk would like to extend its sincere thanks to everyone involved in this effort. A special thanks to Professor Juni Palmgren, Karolinska Institutet, chair of the health data expert group and Maria Nilsson, NordForsk, for their coordinating roles in this effort.



Arne Flåøyen
Director NordForsk

Oslo, December 2019

EXECUTIVE SUMMARY



EXECUTIVE SUMMARY

Each of the Nordic countries has aggregate information about its citizens in administrative and health care registers or in biobanks, mainly compiled for statistical purposes or to improve health care. The vast quantity of information collected over the life course can be linked to the individual through a personal identification number (PIN), which is given to each person. The ability to combine person-based information from multiple sources via the PIN to conduct research and to study large cohorts is a competitive advantage for the Nordic countries. With its combined population of 27 million, the region has the potential to be world-leading in research and innovation utilising health data. By securing knowledge transfer to health care this will advance precision medicine.

The Nordic countries have individually and jointly identified the potential of utilising health data. The notion “data is the new oil” is frequently used. National policy efforts have recently been launched in Denmark, Finland and Norway to coordinate access to health data, with a focus on register data, biobank data, surveys and cohorts. Sweden has emphasised the importance of metadata and interoperability between data sources and will in coming years put additional focus on facilitation of the data access process. The focus in Iceland is on opening up clinical information. Details are given in Appendix 1.

National Health Data Programmes in the Nordic Countries (as elaborated in Appendix 1)

Although the Nordic national health data initiatives differ in scope and organisation, they share the ambition to provide users with a single entry point and shared data services to integrated national health data. The national initiatives are a key starting point for the present outline of a Nordic Commons.

What is a Data Commons?

A shared virtual space where scientists can work with digital research objects. This is a system that will allow investigators to find, manage, share, use and re-use data, software, metadata and workflows.

In order for the Nordic region to position itself firmly in the forefront of research and innovation, it is necessary to enhance data quality, increase the reproducibility of research results, and to provide a basis for open science and innovation. This means that research data need to be aligned with the FAIR¹ principles, i.e. to be findable, accessible, interoperable and re-usable.

Similarly, the operating procedures between data owners need to be improved to make data more accessible. Technical solutions for secure cross-border transfer, access, and analysis must be put in place, supported by a coherent legal and ethical framework. Respect for personal integrity is a critical element for maintaining trust in research among Nordic citizens.

¹ Wilkinson, M. D. et al. (2016). The FAIR Guiding Principles for scientific data management and stewardship. Scientific Data 3, Article number: 160018. DOI 10.1038/sdata.2016.18. <https://nature.com/articles/sdata201618>

The Vision of a Nordic Health Data Commons (as elaborated in Sections 2-4)

The vision is the Nordic region as a leading region for secondary use of health data. This requires:

1. A Nordic federated secure platform for processing sensitive personal data – a Nordic Health Cloud
2. Nordic health data described with rich metadata according to the FAIR principles – a Nordic Health Metadata Repository
3. A coherent legal and ethical framework supporting this
4. A research funding programme for technology and competence development.

This report elaborates on key elements in items 1 and 2 and ends with suggestions for concrete actions on all four items.

This report outlines a vision for a Nordic Health Data Commons that allows secondary use of sensitive health data in research, health care and industry. The Commons is populated with interoperable Nordic data sources that are co-located with computing infrastructures and software services for managing, analysing and sharing data. The report describes technology solutions for federated Nordic data access and computation – the Nordic Health Cloud - coupled with a Nordic metadata ecosystem for digital data documentation according to the FAIR principles.

The proposed Nordic systems and solutions draw on national efforts and will contribute to international technology and standards. Scenario-based technical solutions are described and recommendations for short term actions are outlined. The Nordic Commons will be a platform for conducting reproducible and open research for the benefit of Nordic public health and societies.

Recommendations (as elaborated on in Section 4)

- A. To establish a **high-level policy board** comprised of national actors from the health, research and innovation sectors. This board should help prioritise the overall work of aligning national initiatives and promoting access to resources. The board should also oversee alignment of relevant health data legislation in the Nordic countries, promote coordination of funding mechanisms and calls for proposals, and support development projects, experimentation and proof-of-concept type of projects.
- B. To **secure sustainable funding** from national and Nordic research and research infrastructure funders in order to initiate health data research in a manner that tests, utilises and contributes to the Nordic Health Data technology solution and to the Nordic metadata standards framework.
- C. To establish a **technology expert group** comprised of national representatives of digital infrastructures that deal with sensitive data. The group should be in charge of outlining the design and implementation of a Nordic Health Cloud, including setting up use cases.
- D. To establish a **metadata expert group** comprised of the national health data hosting organisations. The task is to set up a Nordic health metadata repository ecosystem for harvesting and consuming Nordic health data resources i.e. a digitalised system for data documentation using established standards.
- E. To establish an **expert group on legislation, ethics and trust** comprised of competencies in and perspectives on international legislation and policies. The task of the group is to map the fast changes in national legislation related to the health data domain in order to meet the technology demands of the Nordic Health Cloud.

Many Nordic stakeholders are currently active in international initiatives and it is important for the Nordic Commons to make the best use of their knowledge and experience in order to build on existing solutions and avoid duplication. The European Open Science Cloud (EOSC) is an important European initiative. Two relevant examples of European Union-funded Nordic activities are EOSC-Nordic (coordinated by NeIC, the Nordic e-Infrastructure Collaboration, see Introduction) and EOSC-Life (which includes most European life science research infrastructures in which the Nordics are actively engaged). In particular, the technical approach of the Nordic Commons may benefit from use cases in the EOSC-Nordic project. The Nordic countries are also key members of the ESFRI ELIXIR European bioinformatics infrastructure. The Nordic Commons is thus well equipped to carry out analyses and propose solutions for the data economy challenges presented in the European Digital Single Market Strategy.

A defining component for the proposed infrastructure is adherence to data protection and related legislation and to international principles for re-use of research data resources. Both the General Data Protection Regulation GDPR and relevant national legislation need to be honoured in a Nordic secure digital infrastructure for sensitive data. Note further that the national legislation in the Nordic countries needs to actively support data sharing for research. In this respect implementing the Public Sector Information (PSI) directive is a step in the right direction, as this highlights that public authorities need to make their data available for both research and use by industry and civil society.

Appendix 1 gives a summary of recent national Nordic health data programmes. Appendix 2 summarises the status in each Nordic country for national cloud computing for sensitive data. Appendix 3 describes the FAIR metadata status in a number of health data domains in each Nordic country and Appendix 4 describes the legal status relevant for a modern digital health data infrastructure. Appendices 2-4, written by experts in the respective fields, form important building blocks for the vision and for the actions recommended in this report.

Increased cooperation is needed

A dramatically intensified dialogue is needed between national register holders, such as health institutes and National Statistics Institutes on the one hand, and national computer and storage infrastructures for sensitive data on the other hand.

Increased cooperation is similarly needed between Nordic data holders on best practices and procedures for managing data for Nordic research projects.

1. INTRODUCTION



1. INTRODUCTION

The Nordic countries each have invaluable health data resources with contents collected over long time periods. These data are mostly collected for purposes other than research, such as for population statistics or quality assessment and development of the health care systems. These data collections are currently not being utilised to their full potential in research, health care and innovation. Together the Nordic countries have a population of over 27 million people, which in international comparisons forms a unique asset for studies of rare diseases or disease sub-classes in a longitudinal design. A larger population base is especially important when developing personalised diagnostics and treatment plans involving patient groups that are small. The fact that this unique Nordic data asset is underused has been documented in a number of Nordic reports [(Könberg (2014), Sandberg (2012), NOS-M White Paper (2014), Palmgren (2017), NordForsk Magazine (2018)]. While finding a solution has been high on the agenda for several years, more work is needed to improve the digital health data infrastructure before these data can be more broadly used across Nordic borders.

The broad range of health data sources in the Nordic countries is exemplified in Figure 1, which is an illustration of the Norwegian setting. The health data sources in the other Nordic countries have a similar structure. The different categories of health data can generally be divided into register data from public administrative registers collected mainly for statistical purposes, clinical registers (so called quality registers) in health care, biobank data collected mostly for health care purposes but also in research, and data from public health studies (cohort studies). The institutions responsible for the data may reside in the health care systems or governmental agencies, at universities, in non-profit tech or genome centres or in the pharma industry. In order to get access to the data for research purposes, the researcher must carry out several, often time-consuming, processes such as understanding detailed data content and comply with harms test by the register holder, ethical review etc. The processes may vary slightly between the Nordic countries and the type of study. They are described in more detail on national websites such as registerforskning.se, registerforskning.dk, findata.fi and helsedata.no.

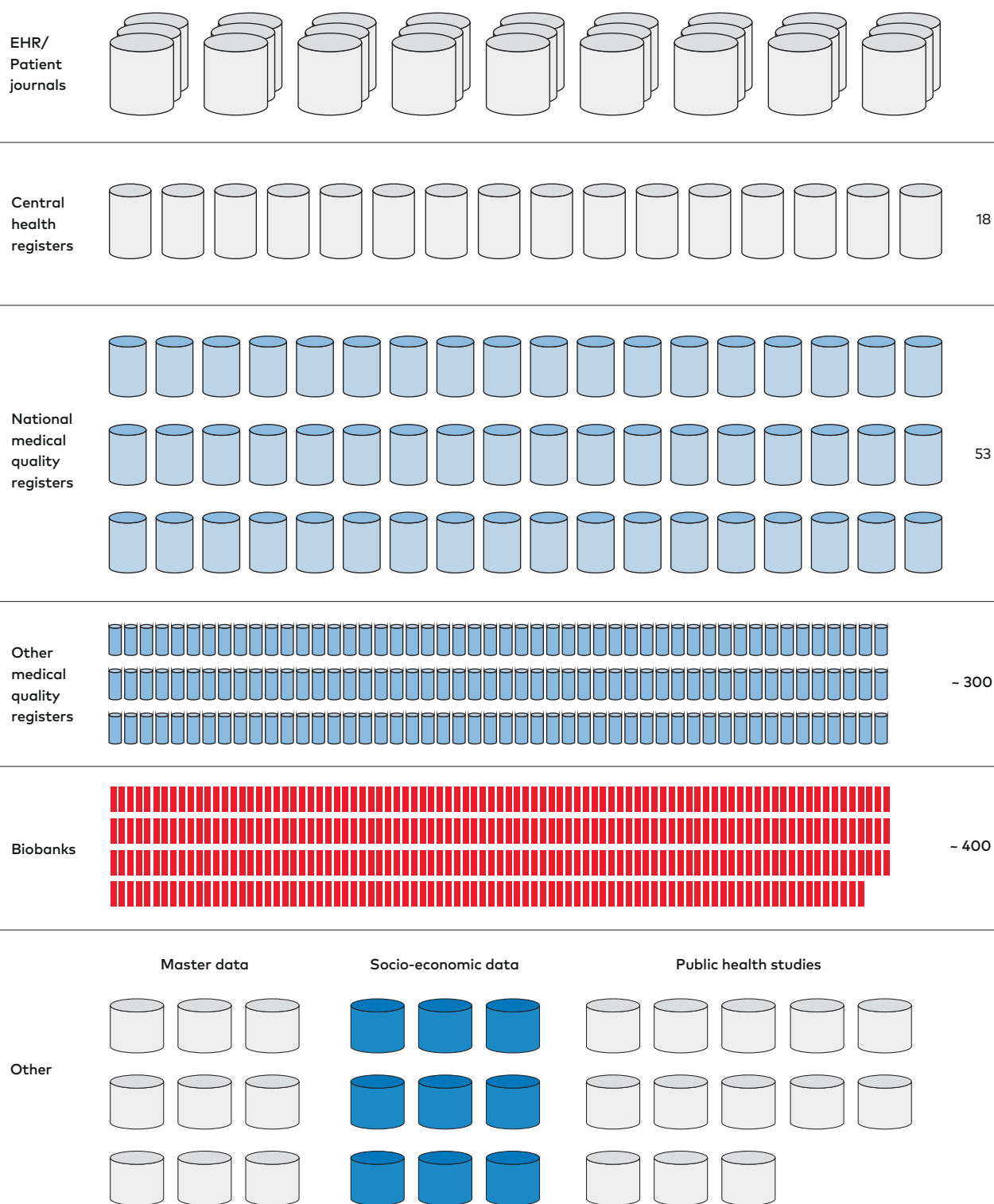


Figure 1: Health data sources in Norway (Developed with help from the Directorate of e-Health, The Norwegian Health Data Programme). The different data sources include Electronic Health Records (EHR), Central Health Registers, Medical Quality Registers, Biobanks and Other. Data from other sources include master data (such as population data from the National Register, data on certified health personnel from the Health Personnel Register, and data related to electronic communication in the health and care sector from the Address Register), socio-economic data from the data collections of Statistics Norway, and Public Health studies (such as the Norwegian Mother, Father and Child Cohort Study). Similar data sources exist in all Nordic countries.

Improvements are called for to facilitate the research process for health research and cut the time needed to assemble the data. During the last few years, NordForsk has highlighted the different obstacles impeding joint Nordic utilisation of data in several reports (e.g. NordForsk Policy Paper 5-2014). Focus has been on identifying organisational, technical, ethical and procedural hindrances and proposing ways to overcome these.

Importantly, NordForsk has funded Nordic pilot projects under its Nordic Programme on Health and Welfare that are to combine health and socio-economic data and map and report on the challenges encountered. It is evident that Nordic register-based research is problematic, time-consuming and very expensive. One of the initial challenges to the projects has been to identify the data needed for the study. The quality of the documentation of existing data sources varies. The documentation is not always accessible online, nor are the metadata descriptions rich enough. The fact that a variable has the same name does not entail that it has the same meaning across registers or countries. It is also evident that filing data applications just when a major new legislative framework, the General Data Protection Regulation (GDPR), is being implemented is not the best timing. Differing interpretations have caused delays in some projects. In the most drawn-out cases, and for complex data applications, the process has taken two years or more. As a result, projects may not only lose their competitive advantage, but may experience problems related to management as well as recruiting and maintaining staff. It can also complicate funding. Reports clearly indicate a need for a digital and trusted infrastructure for accessing and sharing data between register owners across borders. Final conclusions from the NordForsk-funded Nordic pilot projects will be drawn in 2020.

NordForsk also hosts the [Nordic Trial Alliance](#) (NTA) project, which aims to strengthen Nordic clinical studies cooperation. Since 2013, the NTA has worked to support research infrastructure and network initiatives aiming to improve the preconditions for conducting multi-centre trials in the Nordic region. The NTA has recently targeted efforts towards personalised medicine and has funded strategic network activities in that area. Established Nordic collaboration is also in place between other health organisations, such as the Nordic cancer registries, Nordic research biobank initiatives, as well as Nordic medical quality registers.

Nordic collaboration on digital technology has been well developed and highly successful over time. The NORDUnet collaboration between the national research and education network providers in the Nordics has played a key role in the development of services and a trusted identity federation as part of the European collaboration, GEANT. Nordic cooperation on e-Infrastructures and eScience gained wider focus through the two Nordic eScience Action Plans (2008 and 2012), both commissioned by the Nordic Council of Ministers. The 2012 Action Plan recommends increased cooperation on digital infrastructure for sensitive data.

The [Nordic e-Infrastructure Collaboration](#), NeIC, is the main instrument for implementing the 2012 Nordic eScience Action Plan 2.0. NeIC was launched in 2012 as an organisation under NordForsk, and has successfully established cooperation between the national academic e-Infrastructure providers in the Nordic countries and Estonia. NeIC facilitates development and operations of high-quality digital infrastructure solutions in areas of joint Nordic interest. The NeIC project [Tryggve](#), has employed a use case approach to develop e-Infrastructures for sensitive data in biomedical research. The Tryggve solutions play an essential role in the European ESFRI Bioinformatics Infrastructure ELIXIR. NeIC was recently awarded funding from the European Commission for the EOSC-Nordic project. This project aims to facilitate the coordination of EOSC (European Open Science Cloud) initiatives within the Nordic and Baltic countries. EOSC-Nordic exploits synergies to achieve greater harmonisation in policy and service provisioning, in compliance with EOSC agreed standards and practices. EOSC-Nordic contains elements that will support competence building and pilots for developing digital infrastructures for sensitive data.

The national policy efforts recently launched in Denmark, Finland and Norway to coordinate access to health data, with a focus on register data, biobank data, surveys and cohorts, form the basis for the Nordic Commons described here. Sweden has emphasised the importance of metadata and interoperability between data sources and will in coming years put additional focus on facilitation of the data access process. The focus in Iceland is on opening up clinical information. Details are given in Appendix 1.

Despite all the effort and investment up to the present, researchers still face major obstacles in the data acquisition process, such as a lack of information about the data that exist and lack of data interoperability, exacerbated by extremely time-consuming data access procedures. These are key issues addressed in the Nordic Commons.

2. A NORDIC HEALTH CLOUD



2. A NORDIC HEALTH CLOUD

The goal is to establish a Nordic Commons in the form of a federated, secure, scalable environment for using Nordic sensitive health data sets in research.

The capability to process sensitive personal data from different countries is a key to creating a flexible generic Nordic secure digital infrastructure for health data.

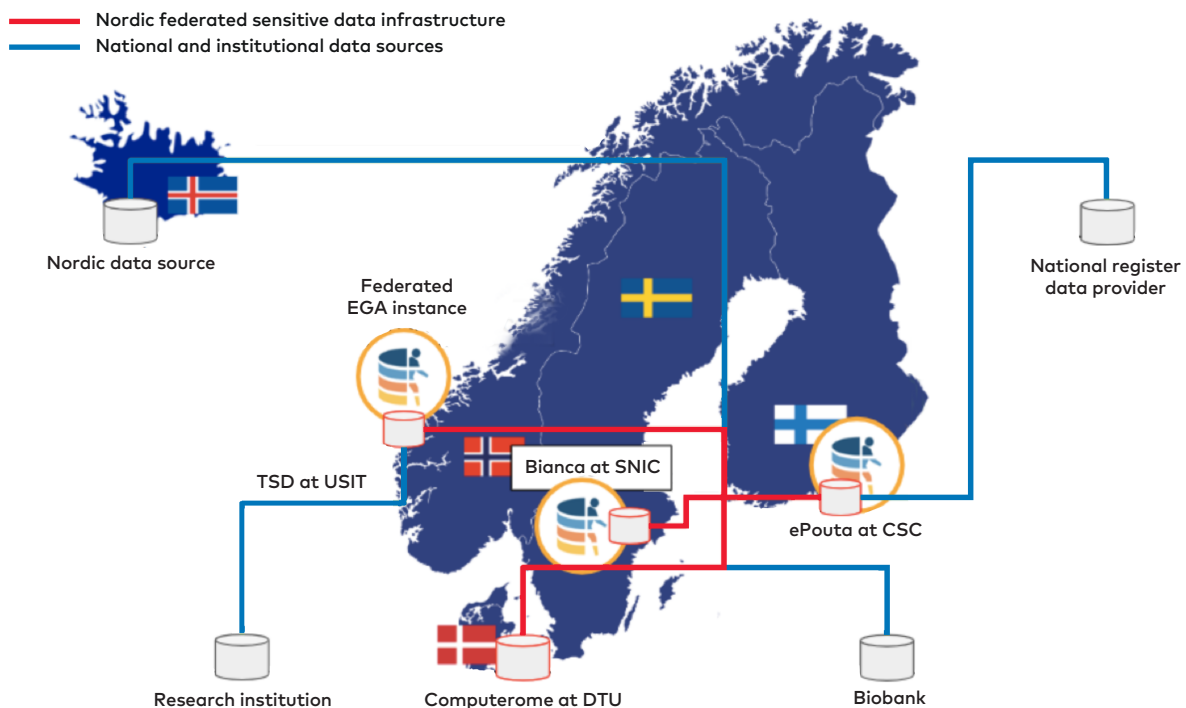


Figure 2: Illustration of a Nordic Commons where national data sources and digital infrastructures are linked through a layer of commonly agreed and trusted rules for participation, interoperability, security and code of conduct. Names of data sources are examples reflecting relevant actors present in the Nordic region.

Service provider: provides IT /data resources and services.

(Data) controller²: determines the purposes for which and the means by which personal data is processed.

(Data) processor²: processes personal data only on behalf of the data controller.

End-user: researcher or other person who makes use of the Nordic Health Cloud.

To establish the Nordic Health Cloud, the Nordic Commons must foster and sustain a “layer” of trust between service providers, data controllers and end-users through a commonly agreed framework that will ensure data sharing and processing across the Nordic countries, in compliance with the relevant national and European privacy regulations.

This framework must include:

- a. *Guidelines for the Nordic Health Cloud* concerning governance, risk management, and decision-making.
- b. *Rules of participation for service providers, data controllers, and end-users* that covers accountability, access, management of metadata, data logging, FAIR data, data lifecycle management as well as technology readiness and security requirements.
- c. *An interoperability framework* that encompasses legal, information security, operational, semantic, and technical interoperability.

We describe each item in turn.

a. *Guidelines for the Nordic Health Cloud*

The Nordic Health Cloud has to be an initiative that is jointly agreed on by the Nordic countries at the political level, where needs must be prioritised and aligned with currently ongoing national health data initiatives, described in Appendix 1, and in agreement with national legislation.

The common rules for governance/compliance, risk management, and decision-making with regard to the Nordic Health Cloud must be agreed on as soon as possible and prior to looking into developing technical infrastructure. In drawing up these rules and conditions, it is important to consider that the field is growing rapidly with more actors ready to participate with their data and new actors producing new and large amounts of sensitive data, such as in the area of genomics.

b. *Rules of participation*

The rules of participation are to be designed as the minimum set of requirements for service providers (data) (data controllers) and service providers (IT) (data processors) to be part of the Nordic Health Cloud. The Nordic Health Cloud should provide the data and IT infrastructure needed to that give Nordic research a place at the forefront of the global scientific community. Moreover, the Nordic Health Cloud should to the extent possible build on already available national or domain-specific digital infrastructures (see Appendix 2), and existing competencies.

Service Providers (Data)/Data Controllers: Data must be available to support cross-disciplinary investigations and lead to outcomes with the highest societal impact. The Nordic Health Cloud should provide the technical framework to protect personal privacy according to the GDPR and national statutory regulations, while ensuring easy access to the data under the paradigm “as open as possible, as closed as necessary”. FAIR data principles should be the driving force to foster the implementation of the paradigm. The implementation of FAIR should be technology-neutral and should be able to support national and domain-specific solutions as broadly as possible. The Nordic Health Cloud should not require the adoption of one global standard for metadata, but must recognise widely adopted standards for the metadata of repositories’ data. FAIR is also to be applied to data services

2 <https://gdpr-info.eu/art-4-gdpr/>

and analytical workflow to ensure portability and reproducibility of the results. Data created inside the Nordic Health Cloud should also follow the FAIR principles and the Health Cloud should support tools for (meta)data management and data management planning. When applicable, the (meta)data generated by the analysis process should be persistently stored in the original repositories in compliance with appropriate standards and the FAIR principles. The Nordic Health Cloud should strongly underpin the trust between data controllers and data processors through continuous dialogue and adoption of FAIR certifications for data and IT services.

Service Providers (IT)/Data processors: The Nordic Health Cloud should be based on the principle of inclusiveness. Any technical solution fulfilling the requirements may be part of the Nordic Health Cloud, provided that: i) the IT resource/service has a certain commonly agreed degree of technology readiness on a globally recognised scale; ii) the IT resource/service has an appropriate and commonly agreed level of security; iii) the service provider conducts systematic and risk-based information security activities with the support of a management system for information security (for example ISO/IEC 27001/2).

c. *An interoperability framework*

The interoperability framework will ensure the secure and trustworthy legal, information security, operational, semantic³, and technical interoperability between the service providers, data providers and end-users in the Nordic Health Cloud. The interoperability layer should be agreed upon at the Nordic level, and it should follow community standards. The interoperability framework should underpin:

A trusted system for authorisation and authentication

In order for the Nordic Health Cloud to be as flexible as possible, and as secure as necessary, the partners should encompass universally recognised and trusted systems for authorisation, and authentication of users across countries and legal entities. Within the Nordics, the federated authentication and authorisation infrastructure services provided by the national university networks, as part of the European GÉANT collaboration, is being used within each country for research and educational purposes. This could be expanded to a Nordic collaboration for the purpose of the Nordic Health Cloud.

Well-defined processes for GDPR

Mechanisms to implement the GDPR, such as collecting consents, exchanging information about the consented data, and when necessary deleting the data if consent is withdrawn, should be available and functional across countries and legal boundaries in the Nordic Health Cloud. Also, procedures should be established for data processing agreements within the Nordic Health Cloud.

Well-defined mechanism for allocation of the resources

The establishment of a Nordic resource allocation committee is envisioned to facilitate allocation of IT resources and services within the Nordic Health Cloud across countries and legal entities. The committee should be formed by representatives of the service providers, and should be able to evaluate the scientific project and allocate the resources on the basis of technical and legal feasibility. The committee should have advisory boards on both the technical and the legal feasibility.

Secure data processing environments

The Nordic Health Cloud will enable a number of different usage scenarios that require cross-border/cross-domain processing and which are at the time of writing not technically and legally feasible. Examples of a number of technical solutions that differ depend on the properties of the research problem, the nature of the data, and the requirements from the data controllers are illustrated in the scenarios described in box on next page.

³ See Section 2 "A Nordic Health Metadata Framework" of this report.

Scenarios requiring different technical solutions

Scenario A: Data Transfer between countries and/or legal entities

Data sets from different *countries and/or legal entities* need to be combined and analysed together in order to evaluate models. Data controllers agree to transfer and store the data at a given data processor according to some agreed instructions and for a given time period. A secure mechanism for data transfer, such as point-to-point encryption, monitoring of network traffic and logging of the data access should be in place.

Scenario B: Data streaming between countries and/or legal entities

Data sets from different *countries and/or legal entities* need to be combined and analysed together in order to evaluate models. The data controllers agree to transfer the data at a data processor in order to enable on-the-fly analysis according to an agreed time period and the agreed instructions. Data will never be stored at the data processor. Secure mechanisms to automatically clean in-memory storage should be commonly designed and agreed, together with measures to log data access.

Scenario C: Federated Orchestration

Data sets from different *countries and/or legal entities* can be analysed separately on facilities at the sites of the data controllers. Data controllers agree to allow access to a data processor according to an agreed time period and the agreed instructions. Secure cloud orchestration technologies should be used to issue processes from one site to a remote processing site. Anonymised or encrypted results from the remote processing should be transferred back according to secure transfer protocols. Logging and monitoring standards should be agreed.

Note that the scenarios in the box are examples. Other scenarios may also prove generically important. Each of these may be relevant within a purely national setting or through cross-border coordination of Nordic data sources. Each scenario supported by the Nordic Health Cloud needs to be evaluated separately with respect to European and national legislation, security regulations, and sustainability.

3. A NORDIC HEALTH METADATA FRAMEWORK





3. A NORDIC HEALTH METADATA FRAMEWORK

The goal is to create a Nordic common metadata repository ecosystem for harvesting and consuming Nordic health data resources.

Good data stewardship is rapidly becoming an essential part of modern science. It is a prerequisite for effectively finding, using and re-using data from several different sources in research and for innovation purposes. To facilitate good data stewardship and to promote open science, a broad community of international stakeholders¹ have developed the FAIR Data Principles. These principles summarise some of the most important areas to address in order to ensure the reusability and value of digital resources. The FAIR Data Principles propose that all scholarly output should be:

- **Findable:** easy to find for both humans and computers, with metadata that facilitate finding specific datasets,
- **Accessible:** stored for long term so that they can easily be accessed and/or downloaded, with well-defined access conditions (open access when possible), whether at the level of metadata, or at the level of the actual data,
- **Interoperable:** using common dictionaries, that can be used by humans and machines to interpret the meaning of the data, enabling automation, comparison and combination with other datasets,
- **Re-usable:** with attached clear conditions for re-use and descriptions of how the data were created, by whom (or what), by which methods and other resources in order to evaluate their reusability.

Using the FAIR principles as guidelines when creating, managing, using and reusing data in a Nordic context is a critical success factor for successfully forming a Nordic health data population cohort of 27 million people. The paradigm “as open as possible, and closed as necessary” should be applicable for sensitive data. New Nordic initiatives are needed in order to achieve machine-readable metadata descriptions of Nordic health data sources that facilitate comparability, interoperability and re-use. This can be carried out in a progressively automated manner by applying the FAIR principles in every part of the data lifecycle. Starting with metadata collection, the process of efficient data FAIRification would take place throughout the research data management activities within national and potentially Nordic metadata repositories, and in collaboration with the secure Nordic digital infrastructure solution, the Nordic Health Cloud.

A common Nordic foundation of clinical and health language as well as technical standards and operational procedures are mandatory prerequisites to achieve the envisioned goal of comparability, interoperability and re-use. In Appendix 2, and in a separate compilation available online (www.nordforsk.org/Nordic-Commons), the metadata status in four Nordic countries is briefly mapped for each of the health data domains health registers, clinical quality registers, biobanks, OMICS, laboratory data, health surveys/cohort studies and socio-economic registers. An overview of the status from this conceptual mapping in summer 2018 is shown in Table 1. It is clear here that in relation to the implementation of the FAIR principles, the data quality varies broadly over both domains and countries and a joint Nordic effort is warranted.

Domain		Findable	Accesible	Interoperable	Re-usable
Health Registers	DK				
	SE				
	FI				
	NO				
Clinical Quality Registers	DK				
	SE				
	FI				
	NO				
Biobanks	DK				
	SE				
	FI				
	NO				
OMICS	DK				
	SE				
	FI				
	NO				
Laboratory Data	DK				
	SE				
	FI				
	NO				
Health Surveys/Cohort Studies	DK				
	SE				
	FI				
	NO				
Socio-economic Registers	DK				
	SE				
	FI				
	NO				

Table 1. FAIR status per country of source data for seven health data domains as of August 2018. Blue: acceptable; Yellow: work is being carried out; Red: Not satisfying. The status might have been slightly improved since the compilation. For more details on how this summary has been put together see Appendix 2 and the online compilation report on www.nordforsk.org/Nordic-Commons

4. RECOMMENDED ACTIONS TOWARD A NORDIC SECURE DIGITAL INFRASTRUCTURE FOR HEALTH DATA – THE NORDIC COMMONS





4. RECOMMENDED ACTIONS TOWARD A NORDIC SECURE DIGITAL INFRASTRUCTURE FOR HEALTH DATA – THE NORDIC COMMONS

The recommendations A-E address the establishment of key groups that should be given the mandate to push the formation of a Nordic Commons forward. They also point to the need for Nordic alignment of legislation related to handling of health data, for the involvement of research funding bodies in setting up competitive funding schemes that drive technology development, and for higher education institutions to intensify competence development and education in data science on all levels.

A. A strategic policy board

In order to maximise the added value of setting up a Nordic Commons, a high-level strategic policy board comprised of national stakeholders from the health, research and innovation sectors needs to provide coordinated input on national initiatives and the prioritisation of tasks and resources. In particular the board should:

- Ensure a balanced focus on health, research and innovation in setting up the Nordic Commons.
- Oversee identification of stakeholders and a budget framework. The budget plan should cover costs for committee work and for technology development, including research funding. Given the fast development in the data digitalisation field, special emphasis needs to be given to development projects, experimentation and proof-of-concept type of projects.
- Map the national digital infrastructure and health data organisations that could take part in the build-up of the Nordic Commons.
- Appoint Nordic expert groups (e.g. those described in recommendations C, D and E below) for the Nordic Commons and oversee their work.
- Oversee the organisational form for the Nordic Health Cloud.
- Assess governance, risk management, and compliance of the Nordic Commons.

Responsible institutions: Ministries of Health in the respective Nordic countries, supported by Ministries of Education and Research and Ministries of Enterprise and Innovation. The Nordic Council of Ministers adopts a coordination role.

Timeline: 2019-2021

B. The role of national research funding bodies

Due to the diversity of the health data sources and the set of stakeholders involved in the Nordic Commons, the project cannot be implemented in a single step. It is an established practice to develop digital infrastructure through a work process, where the technology is adapted to different scenarios and types of projects (use cases) in a sequential fashion. Issuing competitive calls for research funding in the health sector that explicitly target technology and infrastructure development is expected to have a profound influence on how the field evolves. Tasks to be considered include:

- Initiating a set of Nordic calls by national and/or Nordic research funders with the explicit aim of promoting health data research in a manner that tests, utilises and contributes to the Nordic Health Data technology solution and to the Nordic metadata standards framework.
- Ensuring that the calls target a balanced set of health data-based research questions and require applicants to provide clearly formulated descriptions of how Nordic health data infrastructure components are intended to be used. Each call should give reference to available infrastructure components. Ideally the call text would require the inclusion of data from register-hosting institutions as well as researcher data in funded projects.
- Emphasising that relevant legislation and ethical procedures are described in the applications and that obstacles are reported in order to improve infrastructure components longer term.
- Articulating the need to include competence development activities as a visible part of funded projects. This includes navigating the technology infrastructure, understanding of and adherence to FAIR metadata and data principles, data management planning including data protection, legality of usage, data management and analyses protocols, etc., as well as other aspects relating to legislation and ethics.

Responsible institutions: The national (and/or Nordic) research and research infrastructure funding bodies. Scientists at Nordic universities carry out the work in collaboration with relevant infrastructure providers.

Timeline: First call 2020

C. A technology expert group

The technology expert group should outline the design and implementation of a Nordic Health Cloud. In particular this group should:

- Set up a *detailed design plan* for the architecture of the Nordic Health Cloud, which includes:
 - The definition of a set of authorisation and authentication procedures, using the knowledge base of existing National Research and Education Networks (NRENs).
 - A dynamic plan for allocating computer and storage resources from the respective national nodes to the Nordic Health Cloud, including allowance for expansion over time.
 - Mapping of competencies and services to be provided by the respective national nodes to the Nordic Health Cloud.
 - A plan for logging work on the Nordic Health Cloud.
 - Definition of the organisational form of the Nordic Health Cloud, to be endorsed by the strategic policy board
 - Identification of risks and mismatches from a technical point of view.
- Establish proof-of-concept for the Nordic Health Cloud solution in collaboration with health data providers.
- Set up a *detailed implementation plan* for the Nordic Health Cloud in collaboration with health data providers.
- Contribute to the formulation of calls for proposals and projects set up by national funding agencies in order to promote technology development for the Nordic Health Cloud.

Responsible institutions: Digital infrastructure organisations in the Nordic countries which deal with technology for sensitive data, as identified by the strategic policy board.

Timeline: 2019-2021

D. A metadata expert group

The task for the Nordic metadata expert group is to set up a digitalised system for data documentation using established standards. A Nordic metadata repository ecosystem for harvesting and consuming Nordic health data resources needs to be worked out by two complementary expert networks which cover Nordic (i) standards competence and (ii) domain expertise.

- The *standards group* (i) works on how data should be described in order to be effectively interpreted, understood and exchanged by machines and humans. This group coordinates the work on metadata for the Nordic Health Cloud and works *with the technology expert group* to create proof-of-concept for a Nordic metadata ecosystem by participating in the realisation of use cases.
- The *domain expertise group* (ii) sets up a common foundation for a clinical and health language, which describes and defines data in the health domain terminologies for health registers, biobanks, electronic health records, laboratory results, population registers, etc. International standards and international domain terminology are used where possible.

Note, that the use of coherent national and Nordic metadata repositories will contribute to the FAIRification of national health registers and thus make them more useful for research and for society at large. FAIR also provides the foundation for applying Artificial Intelligence (AI) technology on the health data sources.

Responsible institutions: Health data-hosting organisations and representatives of national metadata initiatives in the Nordic countries as identified by the strategic policy board.

Timeline: 2019-2021

E. A framework for Nordic legislation, ethics and trust

The establishment of a Nordic Commons needs to be compatible with both the GDPR and the national legislation in each Nordic country. A Nordic expert group on legislation, ethics and trust is likely needed, and should map the fast changes in national legislation in the health domain in order to meet the technology demands of the Nordic Health Cloud. Items to be considered in such mapping include:

- Formulation of a definition of trust and/or drafting of a code of conduct for the Nordic Commons as provided for in the GDPR (Articles 40 and 41), which potentially include certification by approved certification bodies, national data protection authorities and/or the European Data Protection Board as provided in the GDPR (Articles 42 and 43).
- Identification of barriers (legal or procedural) for handling sensitive data at the Nordic level, including analysis of legal responsibilities for the respective stakeholders within the Nordic Commons.
- Assessment of the legal status of the various technology solutions of the Nordic Health Cloud, with examples described in the box in Section 2, e.g. legal prerequisites for streaming data across national borders to a temporary, joint virtual Nordic space during analyses.
- Legal assessment of the organisational form of the Nordic Health Cloud.

Responsible institutions: Institutions identified by the strategic policy board which have competencies in and perspectives on international legislation and policies relevant for handling and sharing research data.

Timeline: 2019-2021

APPENDICES



APPENDIX 1

National policy programmes on integrated health data in the Nordic countries

The information has been overseen by members of the expert group.

National policy efforts have recently been launched in Denmark, Finland and Norway to coordinate access to health data, with a focus on register data, biobank data, surveys and cohorts. Sweden has emphasised the importance of metadata and interoperability between data sources and will in coming years put additional focus on facilitation of the data access process. The focus in Iceland is on opening up clinical information.

Although the Nordic national initiatives differ in scope and organisation, they share the ambition to provide users with a single entry point and shared services to integrated national health data. These integrated national efforts form the stepping stone and starting point for the outline of a Nordic Commons.

Denmark

In December 2016 the Danish Ministry of Health and the Danish regions presented a strategy for personalised medicine 2017-2020 *"Personalised Medicine for the benefit of patients."* This strategy marks the beginning of a three-year implementation plan for personalised medicine, including the decision to set up the Danish National Genome Centre (NGC). In June 2018, the government presented the strategy *"Sundhed i fremtiden"* [Health care for the future] for the digitalisation of health care provision and enhancing the security of and access to health data for science.

The National Genome Centre had been established as part of the realisation of the national strategy for personalised medicine 2017-2020 and is intended to ensure governance and coordination of the strategy's initiatives at the national level. Danish activities within personalised medicine are to focus on the patients.

The vision of NGC is to create a foundation for the development of more precise diagnoses, targeted treatment and strengthened research within the Danish health care system. To achieve this, the core mission of the NGC is to establish and operate a state-of-the-art, secure national infrastructure for personalised medicine in cooperation with the Danish regions and universities.

Finland

Growth and renewal in the health sector has received a boost from the national growth strategy for research and innovation that was first announced in spring 2014 and is being continued as a new government programme. The programme's implementation is jointly steered by three ministries (Ministry of Economic Affairs and Employment, Ministry of Education and Culture and the Ministry of Social Affairs and Health) and the providers of funding (Academy of Finland and Business Finland). The aim of the strategy is to systematically develop the sector's operating environment and ensure its competitiveness, increase investments and promote economic growth in the sector. The health sector growth strategy will also create opportunities for better health care and a basis for a more efficient social and health sector. As part of the growth strategy, a proposal for a national genome strategy has already been announced including the establishment of a [Finnish Genome Center](#). The eHealth and eSocial Strategy 2020 are also being implemented.

In Finland, the legislation relating to secondary use of social and health data was approved in March 2019. The new legislation will create a new data permit authority, Findata, as a single point of contact for secondary uses of Finnish social and health data. The new authority has the mandate to grant permission for secondary use of personal data collected in social and health services, social security/social benefits and national administrative registers. The permission is granted in conjunction with a valid plan for data usage, and possible use cases include scientific research, RDI-activities, as well as steering, management and supervision of public services including education. The new authority will provide central services for applying for permission to use data as well as for combining, accessing and securely handling the data. A national steering structure is expected to lead national activities and collaboration between register holders and data custodians. See more in Appendix 4 on national legislation in the Nordic countries.

Norway

The Norwegian health data programme was established in January 2017. The programme is based on an agreement with the Research Council of Norway, and is a joint effort between the health sector and national research institutions. The programme scope is to improve and increase the secondary use of health data, with a primary focus on health registers, health surveys and biobanks. The programme consists of four projects, including work on realising a national health analytics platform and a national metadata repository.

A report with alternative organisational models supporting the health analysis platform was delivered to the Ministry of Health and Care Services on 1 December 2018. This will serve as input to the legislation being drafted. New legislation will be approved and implemented at the earliest from 2021.

A contract has been signed for IT-support regarding system support and services development of a common "case management system" for the registries to interact and manage the applications for health data. The programme is also in the process of finalising a requirement specification for the health analysis platform, which will be the technical platform for collecting, storing, giving access to and analysing health data.

The programme published a report in March 2018 that explored how the introduction of an application programming interface (API) can lead to more automatic and standardised data transfer into, out of and between the health registers.

A single, searchable national entry point with overview and information about of the main national health registers and their variables (www.helsedata.no) was established in 2018. In 2019, this will be expanded with standardised metadata, health surveys, biobanks and a digital research application service.

Sweden

In 2014, the Swedish government commissioned the Swedish Research Council to set up infrastructures to improve access to Swedish register data for research, a notion that also includes biobank samples. A single national entry point, Registerforskning.se, has been set up and provides information on the register-based research process and on register contents via the digital infrastructure and metadata platform RUT (Register Utiliser Tool)), launched in 2015.

In 2018, the Swedish government established the Swedish Life Sciences Office (LSO), which aims to promote the development of knowledge, innovation and quality in health care, the care sector and at universities and colleges. The office also undertakes to improve the conditions for life sciences companies that set out to establish themselves and work in Sweden. In June 2018 the "Life sciences road map – pathway to a national strategy" was published. The roadmap identifies utilisation of digital health and health care data as a priority. Such utilisation will depend on a national legal basis and coordination to ensure interoperability of health data. The SLO is currently developing a national life sciences strategy for Sweden, which will align with other recent policy initiatives such as the [Vision for eHealth 2025](#) and the National Approach to Artificial Intelligence.

Other national Swedish health data initiatives include the strategic innovation programme for life science, SWELife, funded by the Swedish Innovation Agency Vinnova with partners from academia, industry and national health providers, and the Genomic Medicine Sweden (GMS) initiative. GMS aims to set up an infrastructure within Swedish health care that implements precision medicine at a national level.

Iceland

In 2016 the Icelandic Directorate of Health published the National eHealth Strategy 2016–2020, where the main aim is to ensure access to health data for health professionals and private individuals.

APPENDIX 2

Current status for national health data digital infrastructure for secure storage, sharing, analyses and archiving of sensitive personal data

The information has been compiled by the following Nordic working group

- Peter Løngreen, Danish Technical University DTU
- Ali Syed, Danish Technical University DTU
- Antti Pursula, Nordic e-Infrastructure Collaboration, NeIC
- Tommi Nyrönen, CSC, ELIXIR Finland
- Hanne Cecilie Otterdal, Ståle Fjogstad, Henrik Næss, Directorate of e-Health, Norwegian Health Data Programme, Norway
- Maria Francesca Iozzi, Sigma2, Norway
- Ann-Charlotte Sonnhammer, SNIC Uppsala University, Sweden
- Hanifeh Khayyeri, Swedish Research Council

The following subsections present currently (September 2019) supported national digital infrastructures in each of the Nordic countries, outlining some key features of the systems. The purpose of the section is to give an overview of capabilities that Nordic national infrastructures offer to support secure access, storage, sharing and analysis of sensitive personal data.

The national digital infrastructures today deal primarily with molecular information such as data resulting from e.g. omics and sequencing analyses. They sometimes handle research projects that have a molecular focus but may include e.g. register information. However, as a general rule, the national digital Infrastructures do not in a systematic way handle data from national register holders such as NSIs (National Statistics Institutes) or National Institutes for Health and Welfare.

Some of the national digital infrastructures already collaborate on the Nordic Tryggve project for sensitive data, which is set up through the Nordic e-Infrastructure Collaboration NeIC. Tryggve is organised as an EU ELIXIR (EU ESFRI Bioinformatics research infrastructure) collaboration in the Nordics, and is mainly focused on molecular data.

Denmark: Computerome

The DeIC (Danish e-Infrastructure Cooperation) National Life Science Supercomputer, Computerome, is the national dedicated digital infrastructure for health care and life sciences in Denmark. It supports Danish scientists and projects locally and in the European arena through its involvement in the ELIXIR Danish node and in the NeIC (Nordic e-Infrastructure Collaboration) Tryggve project.

The first generation of Computerome was founded through a partnership between the larger universities in Denmark (DTU, KU) and the national digital infrastructure provider in Denmark; DeIC. The Computerome architecture has been designed specifically for the health care sector and the field of life sciences, and their specific functional and security requirements. The system has been built using the security by design principle, favouring reliability and accessibility compared to traditional HPC systems around the world.

Computerome is built as a collaborative platform with over 1 600+ users and 380 projects between various research centres and health care institutions across Denmark, and hosts a large variety of data types and formats (both non-sensitive and sensitive research data) accessed by researchers and institutions across the globe, totalling nearly 9 PB of data (with large sections highly sensitive).

The National Computerome Center has started the process of establishing a new system which will still be called Computerome. The new system comprises 50 000 CPU cores and is present on the Top500 list of powerful supercomputers in the world. The new platform is being ramped up to take over from the existing system. The new system provides new capabilities and scaling options to all projects hosted at the Computerome while delivering complete continuity and minimising the impact on any ongoing projects (minimal or no migration will be needed). The platform is designed to deliver production-grade services for national projects and initiatives and provide services such as a state-of-the-art data management system, which automatically enforces the FAIR principles and paves the way for efficient and scalable data and metadata sharing.

One of unique features of the new system is automatic capture and tracking of the data usage and metadata generation, including full data lifecycle management as a service, making it possible to easily track data lineage from the moment data generation happens at the instruments, throughout analysis pipelines down to tracking of derived data by individual researchers.

Finland: CSC ePouta and sensitive data platform

CSC, Finland's IT Center for Science, hosts ePouta, a cloud computing environment designed for processing sensitive data. It is a closed environment that meets elevated information security level regulations. It is suitable for all fields of science, and also for government and research-sector organisations. The ePouta cloud service combines virtual computational resources with the customers' own resources.

The ePouta cloud service is easily scalable to customers' requirements and can be used to analyse sensitive data which require large amounts of memory, processing power and/or clustered I/O performance. The ePouta cloud is part of a secure data management platform being developed at CSC. This data management platform will combine secure layered storage, data access and an authorisation process, setting up a processing area of permitted data sets through a remote desktop. Already now users can request their virtual machines in the ePouta cloud to be optionally added with secure network access to specific sensitive data repositories at CSC. Moreover, the secure remote desktop approach will facilitate easier access to the secure cloud by removing the requirement for a private network connection between the customer's system and the cloud.

The new legislation (552/2019 in Finland) will create a new data permit authority, Findata, a single point of contact, for secondary uses of Finnish social and health data within the National Institute for Health and Welfare (THL). THL is the statutory institute for collecting population level register data and also runs a large biobank that is integrated in the national CSC digital infrastructure. THL aims to offer a single access point for requesting access for the secondary uses of social and health data. Findata will leverage CSC platform and technical expertise to establish data access authorisation service processes.

The ePouta cloud service of CSC is being routinely used by several user groups, including the national Center of Excellence for Tumor Genetics and the Finnish Institute for Molecular Medicine (FIMM), to securely compute on sensitive data. The secure data management platform concept is being piloted in collaboration with e.g. the THL and the Helsinki University Hospital, in a pilot study for the national genome centre. Moreover, Statistics Finland, the NSI of Finland, has indicated its trust in the CSC platforms for offering access to register data for secondary use.

Ongoing practical infrastructure service delivery collaboration includes Finnish biobanks (FINBB co-operative and THL), the Genome centre pilot involving THL and Helsinki University Hospital, and key international collaboration such NeIC Tryggve and the European Genome-phenome Archive at the EMBL-EBI.

Norway: TSD and the future national Health Analysis Platform

The project *“Tjenester for sensitive data”* [Services for Sensitive Data] (TSD) was initiated and is operated by the University Centre of Information Technology (USIT) at the University of Oslo in order to develop a service for researchers in Norway and abroad for storing and processing sensitive data, including health data. TSD is operated in compliance with the statutory regulations as regards individual privacy and health care. The partnership between the Norwegian national computer and storage infrastructure Sigma2 and TSD has recently been formalised in order to guarantee long-term sustainability and to facilitate the uptake of the service by institutions and research communities needing massive computing and storage resources. The partnership with Sigma2 has secured funding from the four major universities and the Research Council of Norway (RCN) making TSD an integral part of the national digital infrastructure for research. TSD represents the Norwegian secure data facility in the NeIC project Tryggve.

Presently TSD is hosting over 420 projects, more than 1 800 users and stores about 1.7 PB of sensitive data. The operational regime of TSD is compliant with the highest security requirements in term of automatisisation, logging, monitoring and patching. A comprehensive risk analysis is performed every year and any change in the infrastructure is to be approved by the Council of Changes, consisting of the UiO Security Officer, and technical and management team members.

The Norwegian Health Data Programme, established in 2017, is working on the establishment of a national health analysis platform which will be developed between 2018-2021. The programme is seeking to develop a health analytics ecosystem where 1) data suppliers can make their data available in a secure way through the platform, 2) scientists and other users can gain access to the data, and providers of data analytics tools can make their software available to users on the platform.

The platform is intended to offer services for handling both open data and sensitive data with restricted access - on the platform or by making data sets available through external infrastructures and services such as TSD (services for sensitive data). This concept, based on copies of the data sources, will not only be a potential gateway for Norway's data in a Nordic secure infrastructure for sensitive health data for data sets used for research, but could also provide services for exploring the content and metadata of the various data sources. There are several other infrastructures that offer functionality to users working with sensitive health data in Norway. These infrastructures do not have national status, but could potentially be relevant for integration in to a Nordic cloud solution. Two such infrastructures are described below:

SAFE (Sikker Adgang til Forskningsdata og E-infrastruktur) [Safe Access to Research Data and e-Infrastructure] is a solution offering dedicated resources to employees and students at the University of Bergen and external resources who are working with sensitive data for research purposes. The solution is based on NORMEN (Norwegian code of conduct for information security in solutions for health and welfare). SAFE has approximately 50 users.

HUNT Cloud delivers digital infrastructure that enables data owners and researchers to store, access and analyse sensitive data, also for researchers working on projects not related to the HUNT (Health Survey of Nord-Trøndelag) study. The solution has approximately 50 users.

Sweden: Bianca, RUT and MONA

There is currently no unified national cloud solution for sensitive personal health and welfare data in Sweden, but several actors offer their local solutions.

Bianca, is a research system dedicated to analysing sensitive personal data from large-scale molecular experiments and is hosted by the Swedish National Infrastructure for Computing (SNIC). Bianca and its underlying secure cloud were designed with the aim of providing researchers in Sweden with a national platform for analysing human genome data, as this was lacking. SNIC and the National Genomics Infrastructure at Science for Life Laboratory collaborated on the construction of Bianca. The secure cloud provides SNIC with the ability to provision platforms and services with similar legal requirements as human genome sequence data. A variety of bio-medical projects are being carried out on Bianca, with 166 active projects at present, and the number is growing. Bianca provides 3 200 cores, the storage system is currently 5.7 PB and is being upgraded with an additional 4 PB.

The National Bioinformatics Infrastructure Sweden (NBIS), which is coordinating the Swedish ELIXIR node, contributes the SNIC resource Bianca as a building block of the NeIC Tryggve system, and thus provides a dedicated secure computing environment for scientists using ELIXIR data.

Statistics Sweden's (SCB) Microdata Online system (MONA) offers remote access to register data. The MONA system is the standard tool for accessing personal data from socio-economic registers. Users can process their data from MONA via a remote-access solution without the data leaving SCB. Data from SCB is processed using statistical software in the MONA system. The users can receive the results via email, but processed microdata never leaves the MONA system. The National Board for Health and Welfare have discussed whether they ought to offer MONA as a platform for access to their microdata as well.

The Swedish Register Utiliser Tool (RUT) is built by the register infrastructure platform at the Swedish Research Council (SRC). It is expected to support all of the above access platforms in setting up a metadata structure adhering to the FAIR principles. RUT aims to keep information at the metadata level from administrative registers (such as those owned by Statistics Sweden and the National Board of Health and Welfare), national clinical quality registers, biobank sample collections and major research databases.

The objective of RUT and the website Registerforskning.se is to support the researcher during the entire research process. Note that the notion of a register is used here to cover all of the above data sources, including e.g. biobanks and research databases. The RUT support includes harvesting register metadata at the variable level as close to the source as possible (i.e., from the register the variables are located in), making it available throughout the research process, and to re-use metadata descriptions when concluding and storing the results. RUT aims to include an analysis area, displaying related provenance metadata. Provenance metadata describes the samples, source data sets, methods, etc. that have been used in the research process, as well as their origin. The Swedish Research Council has an ongoing dialogue with the register owners in order to facilitate the administrative processes related to applications for data, data retrieval and access from registers included in RUT.

APPENDIX 3

Current status for national metadata and FAIR

The information has been compiled by the following Nordic working group:

- Magnus Eriksson, Swedish Research Council
- Jeppe Klok Due, Det koordinerende organ for registerforskning, KOR, Denmark
- Arto Vuori, National Institute for Health and Welfare, Finland
- Truls Korsgaard, Norwegian Directorate for e-Health

The need to find and utilise data resources across the health data domains and the Nordic countries requires a common searchable, accessible, and reusable resource supporting interoperability based on rich metadata⁴, common semantics and the use of persistent identifiers. *Today this is not provided in a Nordic context.* Re-use of data resources throughout the Nordic countries also needs to be backed up not only by rich metadata and semantics describing the data sets and resources but also by metadata describing the process, entities, activities, resources and people that produced the data set, i.e. provenance metadata. The provenance metadata need to span across the health data domains in order to support re-usability in an efficient way. This also ensures that attribution to all involved sources and actors.

In Table 1 we present a matrix summarising the FAIR status for metadata for four Nordic countries in the following domains: health registers, clinical quality registers, biobanks, OMICS data, laboratory data, health surveys/cohort studies and socio-economic registers.

We proceed for each domain by briefly describing country-specific strengths and weaknesses from a FAIR data perspective.

Health registers

Within the health register domain there are searchable resources in place in the Nordic countries that provide metadata to describe data sets, and in many cases metadata are provided on the variable level.

There are ongoing national initiatives that aim to provide rich metadata based on international standards. The Norwegian EUTRO/Nesstar (DDI.x) is being further developed within the HealthTerm/Helsedata.no, the Swedish digital infrastructure Register Utiliser Tool (RUT) (GSIM and Semantics) is successively incorporating new registers, as is the Finnish "Aineistoeditori" (GSIM and DDI 3.2) and the Danish Sundhedsdatastyrelsen solution (GSIM and DDI.x).

The common clinical and technical language needed to provide both better findability and interoperability is progressing, but the use of concept systems, ontologies and terminologies is not yet well developed. This important part of the findability and interoperability puzzle can initially be time-consuming, but the potential return of the investment is large, especially in a cross-country context.

In today's national solutions the provenance metadata are in general provided in document type form and the richness of the metadata varies.

⁴ Metadata describing relevant attributes on data set and content level with reference to semantics describing meaning in the relevant context.

Domain		Findable	Accesible	Interoperable	Re-usable
Health Registers	DK				
	SE				
	FI				
	NO				
Clinical Quality Registers	DK				
	SE				
	FI				
	NO				
Biobanks	DK				
	SE				
	FI				
	NO				
OMICS	DK				
	SE				
	FI				
	NO				
Laboratory Data	DK				
	SE				
	FI				
	NO				
Health Surveys/Cohort Studies	DK				
	SE				
	FI				
	NO				
Socio-economic Registers	DK				
	SE				
	FI				
	NO				

Table 1. FAIR status per country of source data for seven health data domains as of August 2018. Blue: acceptable; Yellow: work is being carried out; Red: Not satisfying. The status might have been slightly improved since the compilation.

Clinical quality registers

Within the clinical quality register domain there are national searchable resources in place in Sweden, Norway and Denmark. The richness of the metadata and the level of standardisation of associated clinical language and terminologies used varies. In addition, the provision and management of versioning vary a great deal *i.e* when implementing longitudinal studies,

In Sweden and Norway there is ongoing work relating variables to terminologies/ontologies which will continuously help to improve the quality of the register variables - the findability, the interoperability and the re-usability - and form the basis for a common, standardised and structured Electronic Health Record (EHR).

In Denmark the Danish Clinical Registries is responsible for all the databases of clinical quality which are described with rich metadata in a standardised template.

Persistent identifiers are in use but only on subsets of the metadata, that is the code-lists/classification parts. Provenance metadata are not readily accessible.

Biobanks

Within the Nordic biobank domain there are examples of national infrastructures, such as in Denmark, which provide solutions for searching and accessing basic metadata on a sample level. In the other Nordic countries there are developments pointing in that direction, such as the Swedish digital infrastructure RUT, which provides rich metadata but does not yet have national coverage, or the Finnish THL National Biobank that can provide sample level metadata but not in a standardised format. The use of persistent identifiers to uniquely identify data sets and/or metadata is not widespread.

Today, in general, the searchable metadata that are easily accessible are on a higher level, describing the biobanks and/or sample collections but not the samples themselves. In order for the researcher to find appropriate samples of a certain type, handled in a way necessary for the specific analysis needs, rich metadata on a sample level need to be searchable and accessible on a national and Nordic level.

Utilising sample metadata on a Nordic level will require interoperability between the national infrastructures. The national infrastructures need to provide rich metadata that describe samples using common standards

or mappings between national standards on the data set⁵, framework⁶ and implementation level⁷, and even more importantly, a common technical language with terminologies needs to be used on all levels.

The provided re-usability within the biobank domain is also to some extent related to the laboratory data domain, since this domain holds the test and result metadata that are a result of using the biobank samples. Since the samples are a finite resource, and in order to secure their re-usability, the provenance metadata will be important.⁸ This is not handled from a national perspective within the Nordic countries today. Neither is the licensing clearly delineated.

OMICS data

The OMICS domain is not homogeneous and the standards and semantic resources that are used differ between the subdomains. *Metadata and semantics together with solutions to support FAIR data are not managed at the national level in the Nordic countries today.* The researchers who use national infrastructure data for their research often turn to international repositories to upload metadata and semantics. One example of this is repositories where data need to be provided in relation to publications. Other examples involve initiatives such as the European Genome Archive (EGA) or the Nordic Tryggve project, which develop federated EGA structures that separate centrally stored metadata from local EGAs that can store data on national nodes.

There are many international repositories which are driving development of metadata standards and semantics/ontologies, resulting in a rather fragmented ecosystem. Provenance metadata are collected, but there are wide differences in the requirements and standardisation.

None of the Nordic countries have national infrastructures in place in which metadata standards and semantic resource work are carried out today. Efforts such as mapping, development, evaluation and provision of guidelines and recommendations are not managed on a national or Nordic level.

In summary, this means that although the OMICS domain is one of the more developed when it comes to development of ontologies and metadata standards, the lack of coordination causes fragmentation that affects findability, interoperability and re-use.

Laboratory data

The laboratory data domain is the least developed when it comes to provision of national resources for findability, accessibility, interoperability and re-usability within the Nordic countries. In Sweden there is an ongoing project to access laboratory data through the National Service Platform (a platform that enables systems and e-services within health care to communicate with each other) at Inera⁹. The project has delivered a first version of the service that is being tested and evaluated in a separate project together with a selection of regions. In Finland there are no national resources in place at the moment.

Denmark, however, is the exception since they already provide one national database that holds metadata on hospital laboratory analysis performed at departments of clinical biochemistry at the hospitals. The Danish solution uses NPU (Nomenclature for Properties and Units) codes and terminology for representation.

In Norway there are no national resources providing metadata at the moment but a governmental review recently recommended creation of a national database for laboratory data. The database is planned to be housed in the National Health Analytics Platform when this is established in 2020.

5 e.g. DataCite, DCAT-AP etc

6 e.g. GSIM etc

7 e.g. HL7FHIR etc

8 <https://www.w3.org/TR/prov-overview/>

9 Company for digitalisation in health care and welfare owned by i.e. the Swedish regions and municipalities.

Health surveys and cohort studies

The health survey and cohort metadata are perhaps the most fragmented in the Nordic countries, i.e. the different surveys and cohorts are not available in one place but in different searchable resources. The exception is Denmark where most of the metadata are available at the Danish Data Archive as part of the National Archives.¹⁰ The datasets are here provided with PIDs (Persistent Identifiers) in the form of digital object identifiers (DOI). Metadata are provided according to the DDI metadata standard and often on variable level.

In Sweden some of the health survey and cohort metadata are made available via the Swedish National Data Service (SND), mainly on the data set level, using standardised metadata and technical language/terminologies. Other cohort metadata are provided by among others the Swedish Cohort Consortium (Cohorts.se) via the Maelstrom platform but without usage of a metadata standard and without PIDs. Finally, cohorts will be curated into RUT, according to GSIM, with metadata on a variable level, related to richly described technical language/terminologies.

In Finland the metadata regarding health surveys and cohorts are also provided in different locations. Some are available via the National Institute of Health and Welfare (THL) Biobank and some in the "Aineistoeditori". The "Aineistoeditori" metadata are based on GSIM and the attributes have been mapped to DDI.

In Norway the metadata are provided by the Norwegian Institute of Public Health (FHI) and the Norwegian Centre for Research Data (NSD) and the different cohort's own sites. Tromsøundersøkelsen is ready to export metadata to HealthTerm. The goal is to import metadata from them main national health surveys in 2020.

The fragmented nature of the health survey and cohort landscape makes interoperability even more important since there are several different sources even within the domain.

Licensing is clearly delineated in some parts depending on the place where the metadata are being provided.

Socio-economic registers

The Nordic National Statistical Institutes (NSIs) manage the registers within the socio-economic domain and provide metadata describing its contents, in some cases complemented by metadata described by other national initiatives that they are collaborating with, such as the Norwegian Centre for Research Data (NSD) or the Swedish Research Council (SRC).

The NSIs provide variable level metadata and make them findable on the web, but the use of PIDs is not widely implemented. The use of different metadata standards is quite well developed within the domain and has been ongoing for some time. There are however a lot of legacy solutions making use of older standards or versions of standards. All the Nordic NSIs or their collaborating partner initiatives are using, planning to use, or mapping their metadata to the GSIM standard. The extent of metadata provided in relation to GSIM varies though, which of course affects the findability, interoperability and re-usability of the socio-economic register content. The metadata provided by the NSIs themselves are in general rich when it comes to metadata regarding representation, i.e. code-lists and classifications, and the usage or mapping to international standards is also well developed. This is a subsection of the metadata that has been in focus within the domain for some time. Descriptions of the populations and variable names and variable descriptions are provided, but the common technical language needed to enable comparability, interoperability and re-use are not well developed. This is the part that was not well supported in the older standards but has been the focus of the effort towards statistical modernisation.

Provenance metadata are in general described in document form which makes it less accessible to the researchers.

¹⁰ <http://dda.dk/simple-search?lang=en>

APPENDIX 4

Current legislative status in the Nordic countries in relation to processing of health data for scientific research purposes

The information has been compiled by the following Nordic working group:

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- Manolis Nymark, Swedish Association of Local Authorities and Regions
- Ragnhild Angell Holst, Norwegian Ministry of Health and Care Services
- Lars Emde Poulsen, Danish National Genome Center

Building an interoperable and seamlessly functioning regulatory framework for cross-border health research in the Nordic countries is not only in the interest of the research community and industry, but will also have the potential to benefit public health. In order to take full advantage of the possibilities offered by the new technologies proposed here, consideration must be given to the General Data Protection Regulation (GDPR) as well as to different national policies. The national legislation relating to processing of health data in the Nordic countries is currently undergoing change. In order to achieve a functioning Nordic regulatory framework we need a coherent interpretation of relevant national laws and practices that backs up Nordic research cooperation.

In the following we will provide an overview of the main national regulations that will have an impact on how cross-border health research projects will be carried out within the Nordic secure digital infrastructure. In some Nordic countries there is an ongoing legislative revision that will have an impact on the secondary use and access to health data. This has to be taken into account when reading the overview of national laws.

Denmark

The legal basis for processing of health data in Denmark is given in the Danish Health Act (Sundhedsloven, no. 1202, 14 November 2014). Processing of health data in research is based on Section 46 of the Danish Health Act and Section 10 in the complementary Danish Data Protection Act (Databeskyttelsesloven). Processing of biological material in research is based on Danish Health Act Section 32.

The national Danish complementary Data Protection Act (lov nr. 502, 23.5.2018) states in Section 10 that special categories of data, such as health data, may be processed when the processing takes place for the sole purpose of carrying out statistical or scientific studies of significant importance to society and when such processing is necessary in order to carry out these studies. The data may not subsequently be processed for other than scientific or statistical purposes. The same is to apply to processing of other data carried out solely for statistical or scientific purposes under Article 6 of the GDPR.

Special categories of data may only be disclosed to a third party with prior authorisation from the supervisory authority when such disclosure:

- 1) is made for the purpose of processing outside the territorial scope of the GDPR;
- 2) relates to biological material; or
- 3) is made for the purpose of publication in a recognised scientific journal and the like.

The supervisory authority may lay down general terms for the disclosure of special categories of data and more detailed terms for the disclosure of data relating to biological material or for publication in a scientific journal, or for third country transfers of personal data.

A major reform of Danish health research legislation was carried out in summer 2018 when the amendment (Lov nr. 728 af 08/06/2018) to the Danish Health Act was passed in the Parliament laying out the legal basis for establishing the National Genome Center (NGC). The bill and preparatory work regarding the bill concludes that written informed consent is needed to derive genetic information from biological material. This written informed consent is required for transferring data collected in connection with patient treatment to the National Genome Center (NGC). The same principle applies to genetic data collected through scientific research: genetic information may only be transferred to NGC if informed written consent has been obtained in connection with the subject's participation in the research project.

According to the principle of self-determination, the patient can decide that genetic information transferred to NGC may only be used for the treatment of the patient and for purposes with immediate relation to the treatment. This is carried out through registration in an opt-out register for biological materials (Vævsanvendelsesregisteret [Tissue Utilisation Register - VAR], Danish Health Act Section 29). A patient can also demand the destruction of biological material (Section 33). The same register is also used for opting-out of storage of biological samples and their further utilisation.

Prior to obtaining the patient's informed consent for a treatment involving genetic analysis, the attending health care professional must inform the patient of the right to make such a decision.

NGC will be required to consult the Tissue Utilisation Register - VAR and, if necessary, refuse use of genetic information transferred to NGC if the use goes beyond treatment of the patient and for purposes with immediate relation to the treatment.

The Act on Research Ethics Review of Health Research Projects (no. 593, 14 June 2011) is currently under revision. At the moment ethical approval is required for all research projects related to humans as well as for research utilising biological samples or genetic material. Scientific research which is solely based on other types of official registries is not subject to ethical review. It is proposed that the processing of data derived from biological or genetic material should also be subject to ethical approval. It is further proposed that the permission from the central patient security authority relating to use of patient records for research should be replaced by approval from an ethical committee.

Finland

In Finland the processing of health-related personal data for scientific research purposes is regulated by the Medical Research Act (488/1999), the GDPR, the complementary Data Protection Act (1050/2018), the Act on the Electronic Processing of Client Data in Social and Health Care (159/2007), the Biobank Act (688/2012) and the recent Act on Secondary Use of Health and Social Data (552/2019).

The complementary Data Protection Act entered into force in the beginning of 2019. In relation to the processing of health related data for scientific research in the context of the Secure Nordic Digital infrastructure, the most relevant provision is found in Section 6, which provides an exemption to the prohibition on the processing of health data for research purposes, and includes a list of safeguards to be implemented for the processing activity. These safeguards include, i.a., logging information, pseudonymisation of data, internal organisational safeguards which prevent unauthorised persons from accessing the data, data encryption and carrying out a data protection impact assessment.¹¹

Article 89.2 of the GDPR provides for a possibility not to apply certain rights of data subjects in a scientific research project, and pursuant to the terms of Section 31 of the Data Protection Act this may be applied *in casu* presupposing that

- 1) processing of personal data is based on a research plan;
- 2) there is a designated person or a group responsible for the research project; and
- 3) personal data is used or handed over only for historical or scientific research or other compatible purpose and care is taken that the data is not disclosed to outsiders.

Furthermore, with regard to utilising this exemption in relation to health data and other special categories of data, the Act requires as further safeguard carrying out a data protection impact assessment or drawing up a code of conduct approved according to GDPR Article 40.

No GDPR administrative fines may be imposed on the governmental or municipal authorities, independent public institutions or governmental enterprises in Finland.

A new Act relating to the processing of health and social data for research and other secondary use purposes was approved in March 2019. It provides for a one-stop-shop for permits and data regarding the processing of health and social data for scientific research purposes. A special licensing authority is being set up within the National Institute of Health and Welfare. The Authority has a mandate to collect and match health and social data from official registers, including data from the centralised E-health Record (Kanta), which collects health records from both public and private health care providers, as well as data from national population based registers. The Authority combines a data set in accordance with the researcher's application. In principle the data can only be delivered in a secure on-line environment and may not be taken out of that environment. However, in exceptional cases the Act also provides for a possibility to deliver the data set outside this environment into a comparable secure environment. Only anonymised datasets may be taken out of this environment.

11 Full list of safeguards (in Swedish as no English translation is available (September 2019))

- 1) åtgärder för att det i efterhand ska kunna säkerställas och bevisas vem som har registrerat, ändrat eller överfört personuppgifter,
- 2) åtgärder för att höja kompetensen hos den personal som behandlar personuppgifter,
- 3) utnämning av ett dataskyddsombud,
- 4) den personuppgiftsansvariges och personuppgiftsbiträdets interna åtgärder för att förhindra tillträde till personuppgifter,
- 5) pseudonymisering av personuppgifter,
- 6) kryptering av personuppgifter,
- 7) åtgärder för att fortlöpande säkerställa konfidentialitet, integritet, tillgänglighet och motståndskraft hos behandlingssystemen och tjänsterna i anknytning till behandlingen av person- uppgifterna, inbegripet förmåga att återställa tillgängligheten och tillgången till uppgifterna i rimlig tid vid en fysisk eller teknisk incident,
- 8) ett förfarande för att regelbundet testa, undersöka och utvärdera effektiviteten hos de tekniska och organisatoriska åtgärder som ska säkerställa behandlingens säkerhet,
- 9) särskilda förfaranderegler för att säkerställa att dataskyddsförordningen och denna lag iakttas när personuppgifter överförs eller behandlas för något annat ändamål,
- 10) utförande av en konsekvensbedömning avseende dataskydd enligt artikel 35 i dataskyddsförordningen.
- 11) andra tekniska, förfarandemässiga och organisatoriska åtgärder.

The Act also provides for a possibility to deliver social and health data in aggregate statistical form for development and innovation purposes. These purposes should aim for

- i. advancing public health or social services
- ii. developing social or health care services or service system
- iii. protecting health and welfare of individuals or secure their rights and freedoms

Data subjects are not provided with a general choice of opting out from the secondary use of their data according to this Act.

There is no mandatory ethical review for the secondary use of health and social data stipulated in the Act. Ethical review in Finland is required only for research which is directly in contact with the research subject (Medical Research Act 488/1999).

Data from Statistics Finland and data collected according to the Statistics Act by the Institute of Health and Welfare is provided for research according to the Statistics Act (280/2004). Statistics data is anonymised or pseudonymised by the statistics authority and delivered for research purposes through the secure online service of Statistics Finland or other comparable secure online environment. Only anonymised data may be taken out from the on-line environment.

The Act on the Electronic Processing of Client Data in Social and Health Care (159/2007) is currently being revised. The Finnish Biobank Act (688/2012) is also currently under revision. An act relating to the genome centre is also under preparation.

Norway

In Norway the Personal Data Act (*Lov om behandling av personopplysninger*, 15 June 2018/38) is applied to the processing of personal data, including health data. The Act entered into force 20 July 2018 and implements GDPR. The regulations in this Act are supplemented by regulations specified for the processing of health data.

At the general level, the Personal Data Act stipulates that, for the processing of special categories of data for scientific research purposes with or without consent, the controller must consult the data protection officer in order to assess whether the processing of personal data satisfies the requirements of the data protection regulation and applicable national law. As regards research, the lawful basis may also for example, be Article 6(e). It will then be necessary to have a supplementary lawful basis; see Article 6(3). For research projects that include health data or other special categories of personal data, the exceptions in Article 9(2)(j) may be relevant. Such a national supplementary lawful basis (see Article 6(3) or Article 9(2)(j)) may be authorised in law or a decision concerning exemption from the duty of confidentiality.

The processing of personal health data in connection with health records in hospitals and other health care institutions, is subject to the Patient Record Act (*Lov om behandling av helseopplysninger ved ytelse av helsehjelp*, 20 June 2014/42). The data controller may grant access to personal data in patient records for other than health care purposes, such as scientific purposes. This must be based on the patient's consent or be provided for by law (Section 20, Patient Record Act).

The secondary processing of personal health data is regulated primarily by the Health Register Act (*Lov om helseregistre og behandling av helseopplysninger*, 20 June 2014/43). The Health Register Act applies to the processing of personal health data for the purposes of statistics, health analysis, research, planning, preparedness and quality measurements in the public health administration and public health services. The Act provides for the legal basis for the processing of health data for these purposes. Specific public registers are set up by regulations, such as the Norwegian patient register (*Norsk pasientregister*¹²), the primary health care register (*Kommunalt pasient- og brukerregister*¹³) or the Cancer register (*Kreftregisteret*¹⁴). The registers have different data controllers, among them Norwegian Institute of Public Health (*Folkehelseinstituttet*) and the Directorate of Health (*Helsedirektoratet*). The Health Register Act also applies to the processing of health data for archival purposes in the Norwegian health archive. A regulation relating the processing of quality registers recently came into force.

Processing of personal health data in health research projects is governed by the Medical and Health Research Act (*Lov om medisinsk og helsefaglig forskning*, 20 June 2008/44). Personal health data may only be processed for scientific purposes based on the consent of the data subject unless otherwise provided for by the law. A health research project must be approved in advance by the regional committee for medical and health research ethics (Section 9). Substantial changes to the objective, methods schedule or organisation of the research project must also be approved by the same regional ethics committee which has granted the original approval (Section 11). Commercial exploitation of research participants, human biological material and personal health data in general is prohibited by law (Section 8).

¹² Forskrift om innsamling og behandling av helseopplysninger i Norsk pasientregister, FOR-2007-12-07-1389

¹³ Forskrift om kommunalt pasient- og brukerregister, FOR-2017-08-25-1292

¹⁴ Forskrift om innsamling og behandling av helseopplysninger i Kreftregisteret, FOR-2001-12-21-1477

Sweden

In Sweden the general provisions of the GDPR are applied to the processing of health data for research. The legal implementation of GDPR Article 9.2 (j) permitting the processing of special categories of data for scientific research is provided in the complementary Data Protection Act (lag [2018:218] om kompletterande bestämmelser till EU:s dataskyddsförordning). Ethical review is required for all processing of special categories of data for scientific research regardless whether the processing is based on consent or not. However, under Section 5 of the Act (2003:460) concerning the Ethical Review of Research Involving Humans (the Ethical Review Act), ethical review is only applicable on research conducted in Sweden. The Ethical Review Act thus has a narrower territorial scope than the complementary Data Protection Act and GDPR.

The rules governing processing of personal data within health and medical care can be found in the Patient Data Act (2008:355). The Patient Data Act is applied by all care providers, both public and private. As the GDPR is directly applicable as Swedish law, care providers must thus apply the GDPR and the complementary Data Protection Act and Patient Data Act if these are compatible with the GDPR.

In health and medical care there are national and regional quality registers that are used to develop and secure the quality of care systematically and on a continuous basis. The legal basis for processing personal data in quality registers lies in the Patient Data Act. The Patient Data Act contains provisions to the effect that the patient has the right to be given information about the registration, the right not to be registered in a quality register (opt-out), and the right to subsequently be erased from the register. If the patient opposes the processing of personal data after the care has already begun, data must be erased from the register as soon as possible. Patient data from quality registers may be processed for research purposes.

The Freedom of the Press Act (1949:105) and the Public and Secrecy Act (2009:400) govern whether and how information from official registers in Sweden may be disclosed. Secrecy applies to the specific activities of authorities that produce statistics for the data relating to an individual's personal or financial circumstances and that can be attributed to the individual. Data used for research and statistical purposes and information that is not by name or similar directly attributable to the individual may be disclosed if it is clear that the information can be disclosed without damage or harm for the individual or any related party.

Secrecy in the health and medical care sector applies to information about an individual's health status or other personal circumstances, unless it is clear that the information can be disclosed without harm to the individual or any related party. Secrecy does not prevent an authority that conducts activities in the health and medical services within a municipality or a county council from providing information to another such authority for research, if it is clear that the information can be disclosed without harm to the individual or any related party. The secrecy may be waived by the individual for research purposes.

Each authority is to decide independently whether a disclosure of information can be made in accordance with applicable legislation. If an authority has rejected a request to obtain a document or if it has supplied an official document subject to a reservation, the applicant is generally entitled to appeal the decision. Appeals are usually presented to an administrative court of appeal. The decision of such a court may be appealed to the Supreme Administrative Court. If the party whose application has been rejected is a central government authority, the appeal is presented to the Government instead of to an administrative court of appeal.

APPENDIX 5

Members of the expert group and working groups for the Nordic Commons project

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