# Quality and Research Registers – Division of Clinical Neuroscience

## Strategy and Action Plan 2023-2025

By: Cathrine Tverdal (stab), Kristian Bernhard Nilsen (FoU), Kaja Selmer (FoU) and Lotte Larsen (stab)

## Table of Contents

# Introduction

The Neuroclinic at Oslo University Hospital (OUS) currently has many local medical quality registers of varying sizes and quality. Medical quality registers contain information about the treatment of a specific patient group based on individual treatment courses (Norwegian Directorate of Health, 2022a). We aim for better utilization of local registers, with a focus on improving the quality of treatment.

## Vision

The Neuroclinic utilizes quality registers for continuous professional development and improvement of treatment.

## Goals

The Neuroscientific register should be actively used at all levels of the organization to achieve high-quality patient pathways with satisfied patients. The register should incorporate new technology and facilitate medical research. The Neuroclinic aims to have quality registers with high coverage and quality that can be used for continuous quality assurance, treatment improvement, patient follow-up, and professional development.

## Subgoals

1. Utilize Data from Quality Registers in Management/Evaluation of Operations and Professional Leadership
    - Defined quality indicators for each (sub)register.
2. Clarify Frameworks for the Operation of Registers and Biobanks Incorporated into Clinical Activities
3. Achieve Good Infrastructure:
    - All existing and new internal quality registers in the Neuroclinic should be incorporated into the Neuroscientific Register and Biobank.
    - Common standardized variables and the possibility to obtain broad consent.
    - Coordination and linking with national registers.
4. Develop Digital Infrastructure for the Future:
    - A common digital platform with the capability for patient-reported data, accessible for both operations, research, and quality projects.

# Background and guidelines – the big picture

With this document, the Neuroclinic at Oslo University Hospital (OUS) will present a strategy with specific measures on how to create a better structure and standard for local medical quality registers. This aims to enable a more extensive utilization of data from the registers for management, evaluation, and research. The following chapter will provide a brief overview of the background and guidelines.

There are strong political directives to use health data in the development of healthcare, in close collaboration with the business sector and research. As Norway's largest healthcare provider, Oslo University Hospital HF (OUS) plays a crucial role in the development and use of health data. OUS must eventually expect increased expectations for data sharing. OUS recently completed input for the "Consultation - Regulation on a National Solution for Accessibility of Health Data," which also addresses how OUS should share data in Norway.

Significant European legislation is forthcoming, affecting EEA countries like us; the European Health Data Space, The Artificial Intelligence Act (AI Act), in addition to the existing General Data Protection Regulation (GDPR). The European Health Data Space (EHDS) is a proposal for a regulation for a common European infrastructure for health data. The proposal is currently under consultation, and the duration is uncertain, likely to be a few years (Directorate of e-health, 2022a). The principles of the proposal are (European Commission):

- Supports individuals to take control of their own health data
- Supports the use of health data for better healthcare delivery, better research, innovation, and policymaking
- Enables the EU to make full use of the potential offered by a safe and secure exchange, use, and reuse of health data

In recent years, the Parliament and the government have launched several strategic documents that are of great significance for how we use and develop quality registers, such as:

- St. meld. nr. 6 (2017-2018) Quality and Patient Safety (Ministry of Health and Care Services, 2017b)
- St. meld. nr. 18 (2018-2019) The Health Industry – Together for Value Creation and Better Services (Ministry of Trade, Industry and Fisheries, 2019)
- New national e-health strategy from 2023 (ongoing consultation) (Norwegian Directorate of Health, 2022b)
- National Brain Health Strategy (2018–2024) (Ministry of Health and Care Services, 2017a)
- Directorate of e-health:
    - Establishment of Health Data Service (Directorate of e-health, 2021)
    - E-health trends: Development Trends 2022 (Directorate of e-health, 2022b)

Helse Sør-Øst has two strategies that include the use of quality registers, "Regional Sub-strategy for Patient Safety and Quality Improvement," and "Regional Sub-strategy for Research in Helse Sør-Øst " (Helse Sør-Øst, 2019).

Oslo University Hospital HF strategy 2019-2022 states: "securely and safely make health data available and use them to increase quality and safety in patient treatment, research, and education" (Oslo University Hospital), but the strategy is overarching and does not specify how this should be done. In the OUS Research Strategy 2021-2015 (Oslo University Hospital, Chapter "Specific Main Goals," Section 3: Develop opportunities for data management, data analysis, and data sharing), the following points are listed:

a) Work towards an overarching plan for the use of health data in research.

b) Facilitate open research and develop systems for data sharing that safeguard privacy.

c) Facilitate the development and use of high-performance computing, including artificial intelligence, in both clinical and translational research, and as a tool for treatment.

d) Facilitate the automation of data flow between patient records and registers to the greatest extent possible.

e) Contribute to the achievement of national quality registers' goals for complete and representative data collection, analysis, feedback to users, as well as research and quality improvement.

f) Support researchers with practical, improved, and secure ICT systems for research, including solutions for data extraction and storage, as well as online platforms for national and international collaboration.

g) Implement electronic, dynamic patient consent.

It's worth noting that none of these strategies describe how these actions will be implemented or financed.

In the "Action Plan for Patient Safety, Quality Improvement, and Work Environment" (e-handbook ID 142626), two essential measures for internal quality registers are described:

- Data from quality registers should be more actively used by clinics for risk assessment, management, and business improvement.
- Develop technical, structural, and administrative solutions so that quality registers provide a more comprehensive overview of the quality of delivered services and contribute to targeted quality improvement.

There is ongoing work from the Director's Staff - Patient Safety, Quality, and Collaboration, under the name "Registerløftet OUS," with the purpose of formulating a strategy for governance, financing, optimal utilization, and further development of quality registers in OUS. Simultaneously, the Cancer Clinic is working on the development of its registers. Currently, there is no formalized collaboration or coordination of these initiatives, but contacts have been established.

## Function of Internal Medical Quality Registers

A medical quality register is a health registry where results from healthcare for a defined patient group are continuously documented based on individual treatment courses (Ministry of Health and Care Services, 2019, Regulation on Medical Quality Registers, Chapter 1 §1-2). The regulation aims to facilitate that

medical quality registers, through statistics, analyses, and research, form the basis for quality improvement in healthcare. Health information from registers can also be used for planning, management, and preparedness. The prerequisite is that the collection and processing of health information in medical quality registers are carried out in an ethically responsible manner, safeguard individual privacy, and are for the benefit of individuals and society.

Currently, Neuroclinic's quality registers are used to varying degrees. Some registers are used extensively for research on activity and treatment, while others are used minimally. To the knowledge of this working group, local registers are used little for planning, management, and preparedness. To the extent that registers are used for quality improvement in the departments, it is somewhat unsystematic, and the use of registers for this purpose is not very visible to clinic management.

The desired situation is an appropriate number of internal registers that operate stably, the clinic has a good overview, and the registers are actively used in quality improvement and research. Furthermore, there is a desire to enable data harvesting from clinical systems to reduce manual plotting time, double registration, and the number of patient questionnaires. If all registers are under a common structure, it will provide a better basis for introducing structured data, facilitating data sharing with other institutions.

## Digital Infrastructure

The Neuroclinic aims to be future-oriented and adopt new digital infrastructure early, actively participating in the development of new infrastructure, always in line with OUS guidelines for ICT security.

Currently, only Medinsight is approved as a register solution. Data is manually entered into Medinsight (usually by reading records in DIPS or plotting from paper forms), which is time-consuming. There has been progress in recent years in importing data from Nettskjema, but the only current solution for Nettskjema is through the IT solution Services for Sensitive Data (TSD) developed and operated by the University of Oslo.

**DIPS/DIPS Arena:**

There is ongoing work through a working group in Helse Sør-Øst – Regional Data and Analysis Platform (RDAP), which will examine the extraction of data from all our systems. It is uncertain whether RDAP is relevant for OUS because the Clinical Data Warehouse (KDVH) is considered better.

DIPS Arena is scheduled to be implemented at OUS in March 2023, replacing DIPS Classic, which may provide opportunities in the long term for collecting structured data for clinics, research, and quality assurance. However, it will take some time before this is in place. The Department of Technology and e-health (ATE) is working on this.

**Clinical Data Warehouse (KDVH):**

Clinical Data Warehouse is a quality register and a repository for secondary use of data. This register receives its data from several of the hospital's source systems, including DIPS, Metavision, and several laboratory systems. When all this data is collected, it provides significant opportunities to quality-assure, optimize, and analyze treatment across many patients. KDVH's purpose is to make it possible to compile and analyze data from the electronic patient record, lab, pathology, radiology, and more. It is also possible to extract data for quality registers and research studies.

**Framework Agreement for Digital Home Monitoring Tools:**

From 2023, there is a plan to have a framework agreement for tool vendors of digital home monitoring that all health trusts can use. The procurement was initiated by HSØ but was stopped and restarted in April this year so that the other Regional Health Authorities could participate in the procurement. After this, the schedule was adjusted to fit the procurement of the process and task platform. Dialogue meetings with the vendors were held in week 39. Parallel framework agreements with several vendors are planned, providing health trusts the opportunity to acquire solutions through simplified procurement processes/calls on the framework agreement.

The establishment of framework agreements for digital home monitoring aims to ensure that all health trusts have the opportunity to use solutions for digital home monitoring developed by one trust. This approach allows for regional benefits from the work done by individual health trusts. It will also enable the setting of common regional requirements for architecture and information security.

## Data Transfer – Input from Medinsight

Everything that becomes available in KDVH can be imported into Medinsight, including structured data from DIPS Arena.

There are efforts to provide Medinsight with an API (Application Programming Interface) in 2023 that can communicate with various approved external solutions (tool vendors under the framework agreement), such as TSD/Nettskjema, Checkware, Norsk Helsenett/Helsenorge. However, it's important to note that there is a cost associated with performing the work to connect to these various possibilities.

There are also possibilities for solutions to collect data in the context of, for example, home monitoring, but this presupposes that someone pays to have it approved and tested.

## Input from Neuroclinic's User Council

(Represented by Jørn Sibeko and Helene Wangberg):
"Thank you for a draft with a lot of good content. Increased use of medical quality registers is a good and important measure for service improvement and good patient pathways. It is also in line with national political priorities and health strategies. I am pleased that the Neuroclinic takes a future-oriented perspective here and contributes to the development of new digital infrastructure in this context. Although this strategy is about local quality registers, I believe it is essential for the clinic to also consider establishing its own registers in relation to national needs and possibly similar registers at other hospitals. The same applies to the development of new infrastructure. Some patients have pathways that take them across health trusts and regions, and for a good understanding of their interactions with the healthcare system, standardization across administrative boundaries and possible establishment of national quality registers may be useful. This can also be crucial for health service research, where comparisons between hospitals or diagnoses may be made. Especially in areas where the clinic has national treatment

responsibilities, I believe it is important to also take a national perspective and consider initiating broader collaborations."
Jørn Sibeko (Epilepsy Association)

"It is important that the improvement of the quality of patient treatment is also measured in patient satisfaction. User surveys are conducted, and there are several measurable feedback points that can be further worked on to increase patient satisfaction."
Helene Wangberg (User Representative from MS Research Group and Representative in NevroNett)

## Neuroscientific Register and Biobank

The concept of the Neuroscientific Register and Biobank (Nevrovit) is an umbrella register with a common infrastructure for collecting data and biological material. Sub-registries are diagnosis or disease-specific, as illustrated in Figure 1.

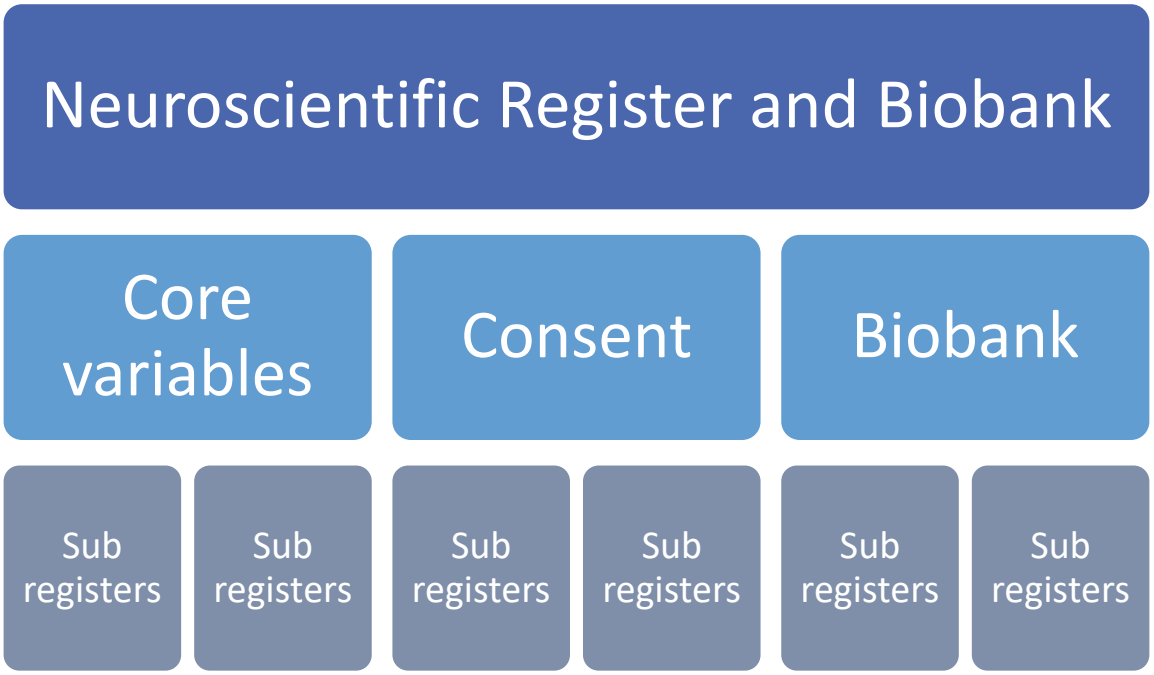


*Figure 1: Structure in Neuroscientific Register and Biobank*

More information in this website:

https://oslo-universitetssykehus.no/avdelinger/nevroklinikken/forskning-og-utvikling-nevroklinikken/nevrovitenskapelig-register-og-forskningsbiobank

## Process for Establishing a Registry in the Neuroscientific Register and Biobank

The process for establishing a new sub-registry is linearly guided. The deciding authority on behalf of OUS and the director is given to the Professional Council. The Professional Council consists of: Chair of the Professional Council (Clinic Director, can be delegated to the research leader in the clinic), department heads in the Neuro Clinic, the person in charge of the registry, and biobank. The Reference Group has an advisory function for the Professional Council and consists of the research leader in the clinic (group leader), contact persons for sub-registries, department heads (or person with delegated responsibility) in departments without sub-registries, the person in charge of the registry, the person in charge of the biobank, and a user representative. Necessary approvals from the Data Protection Officer (DPO), the Regional Ethics Committee (REC), or other authorities are a prerequisite. Employees in the Research and Development (R&D) department assist with all formalities in setting up sub-registries, including correspondence with the DPO.

Articles of association and procedures are available in the E-manual in the folder for the Neuro Clinic's R&D department: link to the E-manual folder.

## Support Function of the R&D Department

The R&D department currently has two registry coordinator positions, each at 50%, funded by external, temporary funds. The coordinators offer support in establishing a new registry and biobank. Specifically, this means guidance regarding information about formal requirements for establishing the registry, as well as applying to necessary authorities. They assist in dialogue with Medinsight, help design the database, create web forms, and engage in contact and dialogue with TSD and Research Support. Additionally, the coordinators keep track of the use and progress of registries and prepare monthly reports that are publicly available. The coordinators are not involved in the daily operation of the registries, i.e., data registration, cleaning, and quality controls of the sub-registries.

The coordinator function is an essential prerequisite and must be highlighted in the budget.

## Consent and Core Variables

The Neuroscientific Register is an internal quality registry without consent requirements but with the possibility to collect consent for research and storage of biological material. The registry has a few variables that are overarching and common to all sub-registries.

## Internal Data Sharing Between Sub-Registries

A common umbrella registry provides many opportunities for combining variables and thus sharing and comparing data.

## Control over Own Sub-Registry

Extraction of data for project purposes and publication is regulated by the articles of association of the Neuroscientific Register and Biobank. The professional community that has collected data has the first right to use data for publication. Employees in the R&D department assist with data extraction and ensure that overarching requirements to keep track of the use of registry data are met.

# Action Plan

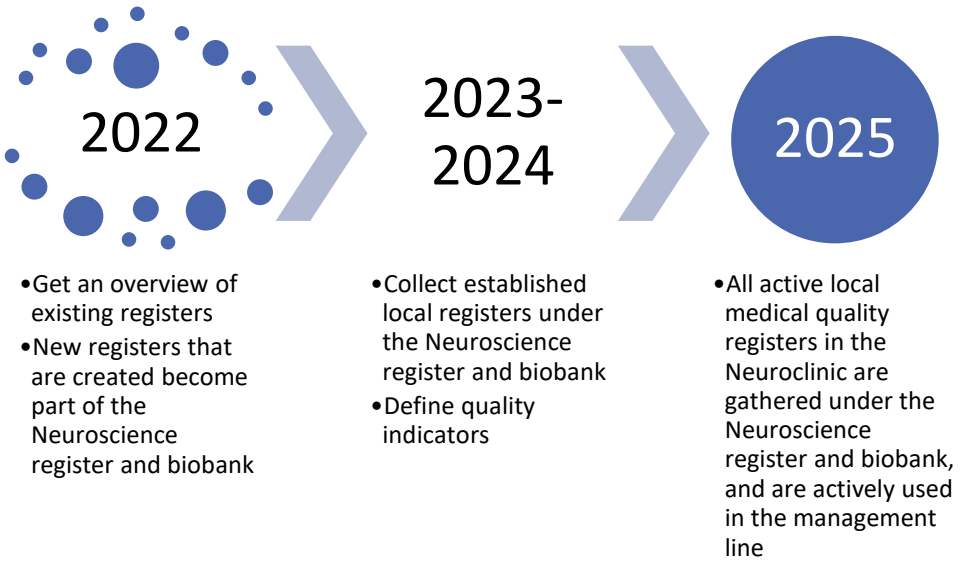


*Figure 2: Proposed process until 2025*

## Measures to achieve the sub-goals – Action plan:

### Sub-Goal 1 - Utilization of Data

- Data from quality registries shall be used in the management/evaluation of operations and professional leadership
    - Defined quality indicators for each (sub)registry

| Goal | Action | Who | Timeframe |
|---|---|---|---|
| **Clarify expectations and needs** | Clinic management and department leaders must clearly state in writing what they expect and need from quality registries and the registries' annual reports. | Clinic manager and department leadersNVR staff and Research and Development, dialogue with professional groups, central staff, and the Cancer Clinic | By april 1st, 2023 |

| | | | |
|---|---|---|---|
| **Annual reports from all quality registries in NVR** | Develop a template for the annual report<br><br>The report must include data from the registry's quality indicators (structure/process/result), | NVR stab og FoU, dialog med faggruppene, sentral stab og Kreftklinikken<br>NVR staff and Research and Development, dialogue with professional groups, central staff, and the Cancer Clinic | Template ready by June 1, 2023 |
| **Utilization of data** | Plan for how to use employees in educational programs, with a particular focus on interdisciplinary quality improvement projects (e.g., nurses in further education in collaboration with resident doctors) | NVR staff, department leaders, section leaders, and responsible for sub-registers | Annually in week 40, in connection with the following year's action plans and budgets |
| **Patient-reported outcome measures (PROM) and satisfaction (PREM) in the quality registries** | PROM: EQ-5D is one of the core variables in Nevrovit and should be implemented in registries that follow up with patients.<br>PREM: Investigate which forms are relevant.<br>Ultimately replace the current user survey sent via SMS. | NVR staff, Nevrovit, and responsible for sub-registers | Ongoing |

## Subgoal 2 – Operation of registries

- Clear framework for the operation of the registry and biobank incorporated into clinical operations

| Goal | Action | Who | Timeframe |
|---|---|---|---|
| **Determine the time spent on the operation of the registries to calculate work hours and make this visible in the budget and job descriptions.** | Determine the time spent on the operation of the registries to calculate work hours and make this visible in the budget and job descriptions.<br><br>Specifics: Calculate the time spent in all registries, e.g., over a four- | Responsible for the sub-register<br>Followed up by NVR staff | By June 1st, 2023 |

| | | | |
|---|---|---|---|
| **Easily accessible support and guidance for the operation and use of data.** | week period. Identify how many hours per week are spent on data plotting, issuing forms, additional consultation time, data cleaning, etc., and specify who performs these tasks (consultants, secretaries, nurses, fellows, others). | | |
| **Lett tilgjengelig støtte og veiledning for drift og bruk av data** | Skrive arbeidsbeskrivelse for koordinatorene i Nevrovit. Nødvendig stilling og drift må inn i budsjettet. Formidle i fagmiljøene hva koordinatorene bistår med | FoU | Innen 1. april 2023 |
| **Involve the office serviceInvestigate opportunities for medical secretaries to enter core variables and whether this is eventually included in the job description.** | Investigate opportunities for medical secretaries to enter core variables and whether this is eventually included in the job description. | NVR staff | Ongoing |
| **Monthly report on new patients in the registries** | Continue the report from Nevrovit.<br><br>Identify an indicator that can be monitored over time and is relevant to clinic management. | Nevrovit<br><br>NVR staff | Ongoing<br><br>Spring 2023 |
| **Biobank** | Dialogue and collaboration with the biobank unit at KLM (Clinic for Laboratory Medicine) | FoU | Ongoing |
| **Protocols for operation** | Develop a template for the procedure for the operation and quality assurance of each sub-registry.<br>Each sub-registry should have such a protocol available. | Research and Development and NVR staff<br><br>Nevrovit | Fall 2023<br><br>2024 |

## Subgoal 3 – Structure of registries

- To achieve a good structure:
    - Existing and new internal quality registries in the Neuro Clinic should be included in the Neuroscientific Registry and Biobank (Nevrovit)
    - Common variables and general consent (where possible/appropriate).
    - Coordination and linking with national registries.

| Goal | Action | Who | Timeframe |
|---|---|---|---|
| **Updated overview of active registries in NVR** | Systematic review of the quality registries under the Neuro Clinic | NVR staff in collaboration with Medinsight, departmental leaders, and responsible for sub-registries | By June 1, 2023 |
| **«New start»** | Evaluate:<br>(i) which registries should be continued<br>(ii) which should be terminated<br>(iii) should registries be established for new patient groups | Departmental leaders and responsible for sub-registries<br>Followed up by NVR staff | By December 1, 2023 |
| **Organization and structure of registries in NVR** | All quality registries established in NVR shall now be included in Nevrovit<br>Establish separate steering groups for sub-registries | Departmental leaders, responsible for sub-registries, and Nevrovit | From January 1, 2023 |
| | Integrate active registries into the Neuroscientific Registry and Biobank | Nevrovit and responsible for sub-registries, in collaboration with Medinsight | Start in 2024 |
| **Coordination and linking with national registries** | Establish contact and dialogue with key players, such as central administration, Cancer Clinic, and registry leaders in relevant national registries | Research and Development (FoU) and NVR staff, responsible for sub-registries | Ongoing |

## Subgoal 4 - Digital Platform and Development

- To be a driver for the development of future-proof digital infrastructure, with a digital platform accessible to both patients, clinicians, and researchers.

| Goal | Activity | Who | Timeframe |
|---|---|---|---|
| **Establishing a synchronized development plan with key partners** | Collaborate with Medinsight, Research Support, central OUS staff, Cancer Clinic, OUS at Home, other national registries, Section National Quality Registries HSØ. | NVR staff and Nevrovit / Research and Development (FoU) | Ongoing |
| **Electronic data transfer** | Plan and carry out pilots, e.g., from Dips Arena to Medinsight via KDVH, collection of PROMS/PREMS from new platforms.FoU, NVR staff, and Medinsight, Technology and Innovation Clinic? | FoU, NVR stab og Medinsight, Teknologi og innovasjonsklinikken? FoU, NVR staff, and Medinsight, Technology and Innovation Clinic? | Earliest start in 2024 |
| **Competence building** | Prioritize the establishment of expertise in the use and analysis of registry data, with a particular focus on quality improvement and health services research. Building will involve courses and further education, collaboration with external parties (universities, other health institutions, commercial entities). | Everyone | Ongoing |

# Economy

There are expenses associated with the establishment and operation of registries, as well as data analysis, where the cost is primarily related to salary/allocated time. However, as we develop a better digital structure, establish effective communication routines with the Privacy Protection Officer (PVO), have coordinators in the Neuro Clinic (under the Research and Development department), and hopefully achieve efficient data harvesting from other clinical systems, it will reduce the need for manual data plotting.

If the registries are actively used, it will be possible to identify strengths and weaknesses in patient treatment, such as infections, the effectiveness of medication/surgical treatment, or patient pathways. This can lead to significant savings for the hospital in the long run, as we will be able to develop more appropriate and personalized treatment pathways. Analyses from registry data will generate new knowledge, be a crucial contribution to improving patient care and operations, and have the potential for innovation projects.

In summary, the potential benefits of the clinic's registries will depend on the high quality of the registries. This requires an investment in registries where resource usage is mapped and recognized, and the financial framework is adapted accordingly. This is described in detail in sub-goal 2 of this strategy, and it is a critical point for the successful implementation of this strategy and action plan.

# References


Direktoratet for e-helse. (2021, 13. oktober 2021). Helsedataservice. Hentet fra https://www.ehelse.no/programmer/helsedataprogrammet/helsedataservice

Direktoratet for e-helse. (2022a). Direktoratet for e-helse vurderer konsekvenser av et felles europeisk helsedataområde (EHDS). Hentet fra https://www.ehelse.no/aktuelt/direktoratet-for-e-helse-vurderer-konsekvenser-av-felles-europeisk-helsedataomrade-ehds

Direktoratet for e-helse. (2022b). E-helsetrender: Utviklingstrekk 2022. Hentet fra https://www.ehelse.no/publikasjoner/e-helsetrender-utviklingstrekk-2022

European Commission. European Health Data Space. Hentet fra https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en

Helse og omsorgsdepartementet. (2017a). *Nasjonal hjernehelsestrateegi (2018-2024)*. Oslo,.

Helse og omsorgsdepartementet. (2017b). *St.meld. nr. 6 (2017-2018) Kvalitet og pasientsikkerhet 2016*. Oslo,.

Helse og omsorgsdepartementet. (2019). Forskrift om medisinske kvalitetsregistre, FOR-2019-06-21-789. Hentet fra https://lovdata.no/dokument/SF/forskrift/2019-06-21-789?q=kvalitetsregistre

Helse Sør-Øst. (2019). Regionale planer og strategier. Hentet fra https://helse-sorost.no/om-oss/vart-oppdrag/hva-gjor-vi/regionale-planer-og-strategier#forskning-og-innovasjon

Helsedirektoratet. (2022a, 04. mai 2022). 1. Ansvar, roller og styrende dokumenter. Hentet fra https://www.helsedirektoratet.no/veiledere/godkjenning-av-medisinske-kvalitetsregistre-for-nasjonal-status/ansvar-roller-og-styrende-dokumenter

Helsedirektoratet. (2022b). Nasjonal e-helse strategi. Hentet fra https://www.ehelse.no/strategi/nasjonal-e-helsestrategi

Nærings- og firskridepartementet. (2019). *Meld. St. 18 (2018–2019) Helsenæringen — Sammen om verdiskaping og bedre tjenester*. Oslo,. Hentet fra https://www.regjeringen.no/no/dokumenter/meld.-st.-18-20182019/id2639253/?ch=1

Oslo universitetssykehus. (04. januar 2021). Forskningsstrategi 2021-2025. Vår forskning skal gi ny kunnskap - til beste for pasientene. Hentet fra https://ehandboken.ous-hf.no/api/File/GetFile?entityId=159430

Oslo universitetssykehus. Strategi 2019-2022 - Oslo universitetssykehus HF. Hentet fra https://ehandboken.ous-hf.no/document/44757