



# **Evaluation of Medicine and Health (EVALMEDHELSE) 2023-2024**

## **Self- assessment for administrative units**

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**Institution (name and short name): St. Olavs hospital, SOHO**

**Administrative unit (name and short name): St. Olavs hospital, SOHO**

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# 1.Strategy, resources and organisation

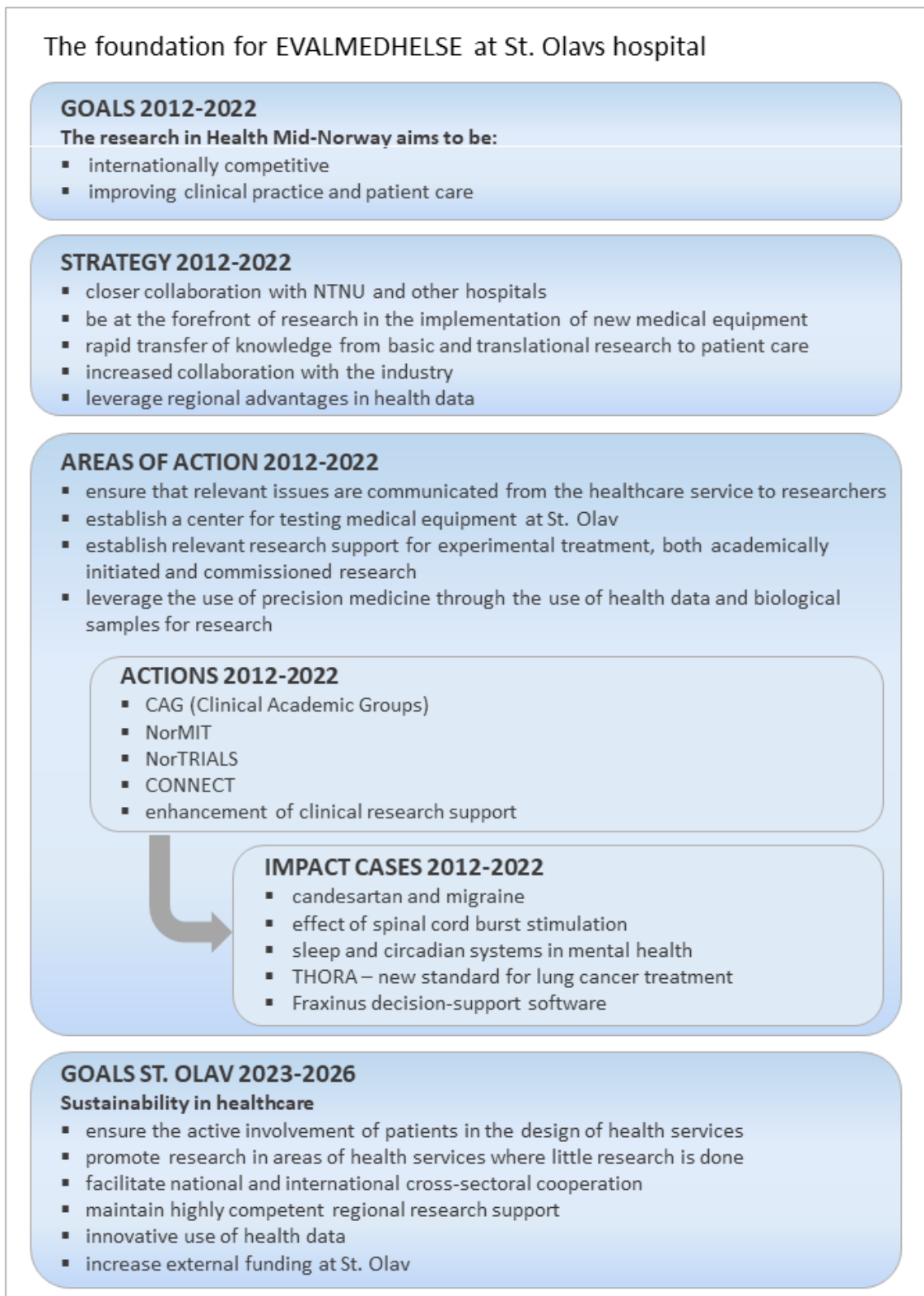


Figure 1: Report outline

## 1.1 Strategy

*Through this description, we will elaborate on how the organisation of research at St. Olav's Hospital in the period 2012-2022 is an instrument for achieving future goals set in the Regional Action Plan for Research 2023-2026.*

St. Olav's Hospital in Trondheim is Norway's fourth largest hospital, with a total of more than 12,000 employees (~8500 Full-time equivalents). The hospital has its roots in the New Trondheim Hospital, which was established as a local health care facility in 1902. In 2002, the ownership was formally taken over by the Norwegian state, leaving the administrative responsibility to the Central Norway Regional Health Authority (Central Norway RHA). This event also marked the start of a period of construction works, which lasted until 2013. During these years, the existing buildings were gradually replaced by a series of new, so-called "centres", into which the various medical wards and laboratories were transferred. At the same time, St. Olav's Hospital was formally recognized as a university hospital, and facilities for teaching and research were established in the appropriate clinical centres. Departments of the Norwegian University of Science and Technology were co-localized with the analogous clinical services. In this way, the "centre model" turns out to provide the perfect physical condition for close collaboration between personnel mainly involved in clinical medicine, research, innovation, and education, to their mutual advantage.

St. Olav's Hospital has defined its vision as "outstanding care", which can be translated into a goal of providing to all patients an excellent health service, which at any moment reflects the internationally recognized "state-of-the-art". However, excellent health service can only be developed and maintained if the whole organization accepts the necessity of constant critical assessment of existing practice and eagerness to search for improvement. In the years since St. Olav's Hospital gained the status as a university hospital, the idea that clinical research should be an integrated part of all clinical practice and that patient treatment should be continually revised based on new evidence has entered the mode of thinking. The main goal of all research and innovation is to provide excellent treatment through standardized patient pathways and optimal use of resources. The ensuing focus on innovation, in collaboration with academia and industry, and in particular the emphasis on digitalisation, underlies the recent acknowledgement by the Ministry of Health and Care Services (MHCS) that St. Olav's Hospital is the most innovative hospital in Norway. Moreover, we have even been ranked by Newsweek as 41st Best Smart Hospital in the world.

The goals are laid down in the strategy of emphasis on patient-oriented research, healthcare service research, global health research and innovations that contribute to increased quality, with a focus on patient safety and cost-effectiveness, and a holistic approach to patient care.

In order to realise the strategy, St. Olav's Hospital has the ambition to be a leader in testing and implementation of new medical technology, to evaluate a range of personalised experimental treatments in collaboration with industry partners, and to ensure rapid transfer of results from basic and translational research into clinical treatment. In this context, it is also important to aim at a sustainable health service, with a focus on avoiding the adoption and discontinuing the use of ineffective treatment. A main objective is to increase the number of patients who are offered participation in research. The Central Norway RHA being hitherto the only health region to have established a common medical record across the primary and specialist health services, St. Olav's Hospital is in a unique position to include patients across sectoral health services in a variety of clinical studies. Moreover, St. Olav's Hospital has the special advantage of being well integrated with NTNU, which is an excellent university for technological innovation and science. The described endeavour will contribute to health service improvement of huge societal and political impact, firmly

rooted in the principles of evidence-based medicine and paying due attention to the requirements of sustainability.

We ask to be evaluated on how our achievements in the period 2012-2022 constitute an appropriate foundation for a scientific contribution to an improved, sustainable health service in the next evaluation period 2023-2026.

The main activities in our action plan 2023-2026 are to

- follow up the National Action Plan for Clinical Trials
- ensure the active involvement of patients in the design of health services
- promote research in environments that are weak to ensure that the entire organization is engaged in research
- facilitate national and international cross-sectoral cooperation
- ensure that the research issues in the integrated university hospital are clinically relevant with a view to improve patient care
- build and maintain highly competent regional support service for research
- make innovative use of health data
- increase external funding at St. Olav

Furthermore, we specifically ask to what extent we are judged capable to:

- retain a leading position in trials of medical technology aiming at innovation and streamlining diagnostic and therapeutic procedures
- strengthen infrastructure and professional competence to attract and perform industry-funded and academically initiated trials of experimental drug treatment
- lead the practical implementation of new research-based knowledge to innovate the health service
- amplify and exploit our advantages of being the only hospital in Norway with an electronic "one patient-one record" solution

### Table 1. Administrative unit`s strategies

For each category present up to 5 documents which are most relevant for the administrative unit. We have also collected relevant documents and links available here: [Evaluation of medicine and health sciences - St. Olavs hospital HF \(stolav.no\)](#)

Research strategy		
No.	Title	Link
1	Regional research strategy HMN 2016-2020 (translated)	<a href="#">HMN strategy</a>
2	National strategy for clinical studies	<a href="#">National strategy for clinical studies</a>
3	Research Strategy 2015-2018 St. Olavs hospital	<a href="#">Strategy 2015-2018</a>
4	Development plan 2019-2035 St. Olavs hospital	<a href="#">Development plan 2019-2035</a>
Open science policy		
No.	Title	Link
1	Open science policy and execution in Norway	<a href="http://www.openscience.no/en">www.openscience.no/en</a>

## 1.2 Organisation of research

*Through this description, we will show how our organisation of research is an instrument for implementing our strategy.*

Research is one of four main tasks for St. Olav's Hospital. The CEO has overall responsibility for all activities at the hospital. Responsibility for research is in the hands of the Deputy Executive Director, while the operative tasks are handled by the Head of Research with executive authority.

St. Olav's Hospital has 17 medical clinics. The clinic is the administrative unit for both patient treatment and research projects with the chief of the clinic (CC) as the legally responsible person. Clinics with a substantial research portfolio can establish a research committee to handle practical questions regarding research. The research committee is led by an appointed manager and will either have delegated responsibility for research or may be assigned an advisory function. Projects involving several clinics and larger collaborative projects that require cooperation with other institutions, must be anchored with the vice administrative manager of the hospital in consultation with the relevant CCs.

Most research groups are integrated with NTNU, in the sense that the researchers have combined positions, in which case basic and translational research is normally carried out within the university part of their position. On the other hand, research involving patients is always organised within the administrative structure of the hospital. Support functions for clinical research are generally provided by the hospital, while NTNU takes care of the infrastructure for all other categories of research. Training of researchers, i.e. PhD education, is organized within a number of programmes at NTNU, whereas clinical trials and other research on living patients take place in hospital facilities and under the supervision and responsibility of St. Olavs Hospital. Specialization programmes for medical doctors is also administered by St. Olav's Hospital.

As a part of the integrated university hospital St. Olavs hospital and The Faculty of Medicine and Health Science have several meeting forums: A formal joint senior management meeting and a more informal joint research manager meeting, both twice per semester.

## ORGANIZATION

### St. Olavs hospital, Trondheim University Hospital

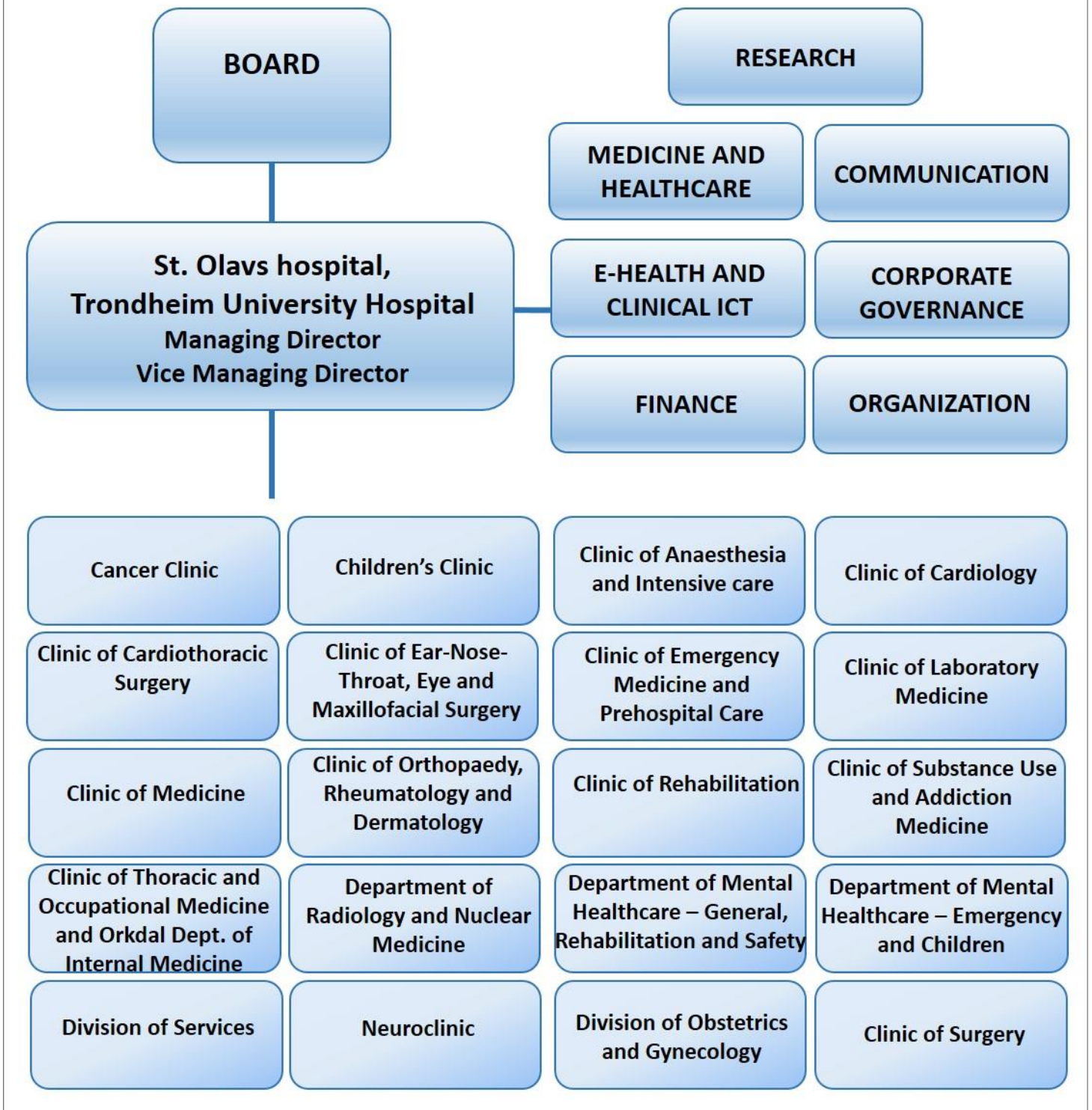


Figure 2: The main organisation chart for St. Olavs hospital

## **Facilities for trials with medical technology**

### NorMIT

Medical technology for diagnostics and therapy is a rapidly evolving field of intense research and innovation, with an extensive need for high end infrastructure. New, technology driven methods are expected to improve patient care in ways that can meet some of the challenges raised by the demographic changes brought about by increased longevity. However, the processes behind the development and approval of new medical technology are exceedingly complex, which entails the need for considerable creativity and painstaking research across several disciplines and sectors. In order to address the shortage in this field, St. Olavs Hospital has established, in collaboration with Oslo University hospital, a highly advanced research centre of minimally invasive therapy with hybrid imaging capabilities.

### NorTRIALS

NorTrials is a national partnership established with the intention of increasing the number of clinical trials in Norway. NorTRIALS contributes to a more efficient infrastructure and facilitated collaboration on industry-funded investigations. Six research centres have been selected as NorTrials centres, approved and adopted by the NorTrials board. The centres will serve as national contact points for industry sponsored trials, but also act as national network hubs within their specific areas. The aim is to recruit as many patients as possible and facilitate research in all public hospitals, so that patients will have the opportunity to participate in clinical trials regardless of where in the country they live. Use of medical devices is central to most diagnostics and treatment of patients in hospitals. Many hospitals engage in clinical trials comprising research, development and testing of medical devices and technology. The NorTRIALS centre of medical devices is located at St. Olav's Hospital.

### Relevant supporting clinical infrastructure

The Research department at St. Olav's Hospital offers a wide range of research support for clinical studies. The portfolio includes assistance with the application process, planning of project finances, monitoring of experimental treatment, data management, dealing with privacy issues, organization of registries and biobanks, study coordination and outpatient medical support. Advisory support with statistics is provided by academic experts of NTNU. St. Olav's Hospital has especially invested in research infrastructure for testing and development of medical equipment. Clinical biobanking facilities have proven especially crucial in time-critical situations, such as during the COVID pandemic. The research infrastructures at the hospital has a joint reference group consisting of active clinical researchers.

### Our flagship: one patient- one medical record

In the period 2015-2022, Central Norway RHA has undertaken a huge task of development and implementation of "Helseplattformen", which is a new, electronic health record (EHR) solution, based on an architecture delivered by the American company EPIC Systems. The EHR will function as a common record system for practically all health care in the region, i.e. for the hospitals and municipal health care, as well as for many general practitioners and specialist surgeries, under the slogan "one patient – one record".

An important part of this formidable innovation project is a web-based patient portal, which was developed in order to make clinical trials more accessible to patients, through digital consent and



seamless information sharing. This portal will make it possible to offer any patient, in primary care as well as in the hospital setting, the possibility to participate in a suitable clinical trial. It is to hope that this will increase the recruitment of participants in research, especially from the primary health service, which has been one of the main aims of the project. In the wake of the EHR project, work has been carried out during the period to establish a regional health data centre in Central Norway. This is a storage facility for structured data collected in the health care system, in a format suitable for use in research. This will make it possible to unleash the research potential of the vast amount of health-related data that reside in the medical records.



**Figure 3: The organisation of the Research department at St. Olavs hospital**

### **b) Synergistic effects**

Almost all professors with a specialty in medicine have combined positions, shared between university and hospital. Clinical research should be an integral part of all clinical treatment. Through the Clinical Academic Groups (CAG), St. Olav's Hospital and NTNU will stimulate professional interaction across sectors, with the aim of improving both health service and research.

St. Olav's Hospital has acknowledged that research competence is a value in itself. This has resulted in many clinicians doing their research in a field different from the one where they carry out patient care. In this way, knowledge flows across disciplines and fields of practice. This stimulates interdisciplinary learning and gives rise to new ideas and questions for research.

Researchers at St. Olav's Hospital can make use of all research infrastructure operated by NTNU, and all infrastructure at St. Olav's can be used by other research institutions in the region. For St. Olav's Hospital, the infrastructure within precision medicine is particularly important for precision diagnostics research

## 1.3 Research staff

The research staff at St. Olavs hospital should be divided into two categories: Those who are directly employed to perform and support research and those who are tasked to perform and support research as an integrated part of their ordinary work. We provide our official reported numbers for the former and provide some estimates for the latter. Our goal is to integrate research into ordinary clinical treatment, and our success in this endeavor means that a large part of our employed staff will support research at some point or another. This also means that St. Olavs hospital employs few researchers in temporary positions, and the major part of these will be hospital personnel with a permanent position on a temporary research leave.

**Table 2. Research staff**

	Position by category	No. of researcher per category	Share of women per category (%)	No. of temporary positions
<b>No. of Personell by position</b>	Senior physician *	284	47	
	Physician *	101	57	N/A (LIS by default)
	Psychologist *	23	57	
	Researchers and postdoc *	83	69	
	PhD-student */**	4	100	4 (by default)
	Study nurse *	15		
	Research coordinator *	12,5		
	Specialist nurse students ***	189		189 (by default)
	Laboratory staff, MSc ****	56		N/A
	Laboratory staff, BSc ****	385		N/A
	Research advisor	16		N/A

\*Reported directly as performing research or related tasks

\*\* PhD students are normally on leave and employed by the university

\*\*\*On paid leave, performs research as a part of master theses

\*\*\*\* Mainly diagnostic duties, performs research support to a varying degree

## 1.4 Researcher careers opportunities

a) Describe the structures and practices to support researcher careers and help early-career researchers to make their way into the profession.

Early-career research positions are generally available through competitive funding from the Joint Research Committee (FFU, joint between the hospital and the medical faculty) or the Liaison Committee between the Central Norway Regional Health Authority (RHA) and the Norwegian University of Science and Technology (NTNU) ("Samarbeidsorganet", SO). This funding can be obtained by the early-career researcher him/herself through application, or applied for as an open position by a senior researcher/PI. These positions are in the form of PhD stipends, post.doc stipends or researcher stipends, typically for 2-4 years.

Employees at the hospital can apply for one of these positions and be granted a research leave from their position at the hospital. The research position can be situated at the hospital, the university or a combination. Clinical professions frequently obtain a 50% research leave, in order to keep up with clinical practice. Split positions between the hospital and the university are possible, 50/50, 50/70 or 100/20 (either way between the institutions) are the most common modes of split positions.

Permanent research positions will typically be situated at the university in the form of tenured profesorates. Clinical positions with dedicated time to research can be negotiated locally per clinic.

b) Describe how research time is distributed among staff including criteria for research leave/sabbaticals (forskningstermin/undervisningsfri).

The main objective of the National Action Plan for Clinical Trials is to make clinical research integrated into all patient treatment. An indicator that distinguishes research from ordinary hospital procedures is therefore not a good method of measuring how well the research is integrated. Experimental treatment, quality assurance of the health service and observational studies that provide knowledge about the value for patients, should be difficult to distinguish from the ordinary patient treatment. This means that research and health service innovation must be defined as part of ordinary clinical treatment.

St. Olav's Hospital has established indicators to assess the extent of research training and possibility to engage in research among the hospital's employees:

- **time employees spend doing research activity in their clinical position**
- **number of St. Olav's Hospital employees with part-time positions at NTNU**
- **number of combined positions with NTNU**
- **amount of time clinicians are free to do research projects through internal health trust funds or external financing**
- **senior medical consultant leave, which can be used for research**

Each of these indicators show increased values in the period 2012-2022.

c) Describe research mobility options.

Mobility stipends for researchers are available from the Liason committee (SO). Senior medical consultant leave works as a sabbatical, and can be taken anywhere.

## 1.5 Research funding

- a) Describe the funding sources of the administrative unit. Indicate the administrative unit's total yearly budget and the share of the unit's budget dedicated to research.

St. Olavs hospital funding comes from the Ministry of Health and Care and is channelled via the Middle Norway Regional Health Trust (HMN), an enterprise fully owned by the government. St. Olavs hospital is a separate enterprise owned by HMN. Funding for research is split, where some is specifically allocated in the yearly budget and some are free allocations that can be used as the hospital sees fit. A part of this allocation is used for the Joint Committee on Research (FFU), a part is used for infrastructure and a part is allocated for free use to the clinics based on research performance. HMN also allocates funds to the Liason Committee, and these funds are available through grant applications for all hospitals, universities and colleges in Middle Norway.

St. Olavs hospital has a yearly budget of 13 500 000 000 NOK, of which 1% is dedicated to research. Further funding is also dedicated to research-related national assignments, infrastructure and development. The total reported funds spent on R&D by St. Olavs hospital is 279 219 000 NOK (Table 3). It is important to note that parts of this funding (e.g. FFU grants) are also available to researchers employed by the university.

- b) Give an overview of the administrative unit's competitive national and/or international grants last five years (2018-2022).

Research Council – NorHead, Cut Covid. Head of infrastructures NorCRIN (until 2023) and NORMIT.  
KlinBeForsk – 6 clinical trials funded in the period, 3 more granted in 2023 with start 2024.  
EU – Grant Holder Institution for 1 COST action.

**Table 3. R&D funding sources**

Please indicate R&D funding sources for the administrative unit for the period 2018-2022 (average NOK per year, last five years).

<b>For Higher Education Institutions: Share of basic grant (grunnbevilgning) used for R&amp;D<sup>1</sup></b>	
<b>For Research Institutes and Health Trusts: Direct R&amp;D funding from Ministries (per ministry)</b>	
Name of ministry	NOK
Ministry of Health and Care	234 557 000

<b>National grants (bidragsinntekter) (NOK)</b>	
From the ministries and underlying directorates	7 171 000
From industry	
From public sector	835 000
Other national grants	25 483 000
<b>Total National grants</b>	<b>33 489 000</b>
<b>National contract research (oppdragsinntekter)<sup>2</sup> (NOK)</b>	
From the ministries and underlying directorates	
From industry	3 057 000
From public sector	
Other national contract research	6 800 000
<b>Total contract research</b>	<b>9 857 000</b>
<b>International grants (NOK)</b>	
From the European Union	571 000
From industry	
Other international grants	745 000
<b>Total international grants</b>	<b>1 316 000</b>
<b>Funding related to public management (forvaltningsoppgaver) or (if applicable) funding related to special hospital tasks, if any</b>	
<b>National competency centers</b>	
Total funding related to public management/special hospital tasks	38 135 000
<b>Total all R&amp;D budget items (except basic grant)</b>	<b>44 662 000</b>

<sup>1</sup> Shares may be calculated based on full time equivalents (FTE) allocated to research compared to total FTE in administrative unit

<sup>2</sup> For research institutes only research activities should be included from section 1.3 in the yearly reporting

## 1.6 Collaboration

*Through this description, we will show our networks and cooperation in medical technology, experimental treatment with pharmaceuticals and in health data management*

St. Olav's Hospital is strongly integrated with NTNU, and parts of the description below are therefore identical to NTNU's evaluation report. Together, the two organizations embody the integrated university hospital, an integration which manifests itself in physical co-location and organizational interaction. Thus, approximately 370 persons hold combined positions, being partly employed by the hospital and partly by the university. The need for coordination and collaboration is addressed in the composition of the formal governance bodies, through joint management meetings, co-location of management and various joint committees for common areas, education, and research. At a more overarching level, NTNU is represented in the hospital board by its rector, and the CEO of St. Olav's Hospital is leader of the faculty board.

Technical and administrative support for research is largely realized across organizational borders. As part of the specified assignments the university takes primary responsibility for basic research, whereas the hospital has a sharper focus on clinical research. Although research infrastructure serving clinical research is managed primarily by the hospital, and equipment for basic and translational research is the faculty's responsibility, all infrastructures are indiscriminately at disposition for researchers belonging to either organization. Some of the infrastructure, like MRI and gene sequencing equipment, serve both research and clinical use, thus decreasing cost and increasing sustainability.

The extent of the collaboration in the integrated university hospital model is most evident when looking at the research groups that has joined EVALMEDHELSE from St. Olavs hospital and from NTNU. 20 of the 28 research groups that are being evaluated are considered joint, with shared resources from both the hospital and the university:

**Table A.** Overview of research groups participating in EVALMEDHELSE at St Olavs hospital which is also part of the integrated university hospital/MH-faculty.

Department MH-faculty*	Participating research groups	Link webpage
IKOM	Obesity	<a href="https://www.ntnu.edu/ikom/obesity#/view/about">https://www.ntnu.edu/ikom/obesity#/view/about</a>
	Clinical Academic Group (CAG)-Precision medicine in Inflammatory Bowel Diseases (CAG-IBD)	<a href="https://www.ntnu.edu/cag-ibd/">https://www.ntnu.edu/cag-ibd/</a>
	Clinical Academic Group (CAG)-Multiple myeloma center	<a href="https://www.ntnu.edu/ikom/myeloma">https://www.ntnu.edu/ikom/myeloma</a>
	Children's and Women's health	<a href="https://www.ntnu.edu/ikom/childwomenhealth">https://www.ntnu.edu/ikom/childwomenhealth</a>
	Biological Research in Addiction and Clinical Toxicology - BRAC	<a href="https://www.ntnu.no/ikom/bract#/view/about">https://www.ntnu.no/ikom/bract#/view/about</a>
IPH	Trondheim sleep and chronobiology research group	<a href="https://www.ntnu.edu/iph/sacr#/view/about">https://www.ntnu.edu/iph/sacr#/view/about</a>
	Warning Signs and treatment of acute suicide risk in psychiatric crises	<a href="https://www.stolav.no/fag-og-forskning/forskning/forskningsprosjekter/life-crisis-and-suicide-risk/#integration-with-the-hospital">https://www.stolav.no/fag-og-forskning/forskning/forskningsprosjekter/life-crisis-and-suicide-risk/#integration-with-the-hospital</a>

**Table B.** Overview of the research groups participating in EVALMEDHELSE at the MH-faculty that is a part of the integrated university hospital

Dep	Participating research groups	Link webpage	Part of IUH*
<b>IKOM</b>	Centre of Excellence in Molecular Inflammation Research - CEMIR	<a href="https://www.ntnu.edu/cemir/research">https://www.ntnu.edu/cemir/research</a>	Yes
	Research group for cancer and palliative care - CancerPalliative	<a href="https://www.ntnu.edu/ikom/cancerpalliative">https://www.ntnu.edu/ikom/cancerpalliative</a>	Yes
	Unit of Laboratory medicine - Labmed	<a href="https://www.ntnu.edu/ikom/labmed">https://www.ntnu.edu/ikom/labmed</a>	Yes
	NTNU Low Birth Weight in a Lifetime Perspective - LBWL	<a href="https://www.ntnu.edu/ikom/research">https://www.ntnu.edu/ikom/research</a>	Yes
	Women's health and PCOS – Womens Health	<a href="https://www.ntnu.edu/ikom/pcos#/view/about">https://www.ntnu.edu/ikom/pcos#/view/about</a>	Yes
<b>INB</b>	Norwegian Centre for Headache Research - NorHEAD	<a href="https://www.ntnu.edu/norhead">https://www.ntnu.edu/norhead</a>	Yes
	Geriatrics, Movement and Stroke - GeMS	<a href="https://www.ntnu.edu/inb/gems">https://www.ntnu.edu/inb/gems</a>	Yes
<b>IPH</b>	Regional Centre for Child and Youth - Mental Health and Child Welfare - RKBU	<a href="https://www.ntnu.edu/rkbu">https://www.ntnu.edu/rkbu</a>	Yes
	HUNT Center for Molecular and Clinical Epidemiology - HUNT MCR	<a href="http://www.ntnu.edu/hunt/mce">www.ntnu.edu/hunt/mce</a>	Yes
<b>ISB</b>	Anesthesia and Emergency Medicine unit	<a href="https://www.ntnu.edu/isb/anaesthesia#/view/about">https://www.ntnu.edu/isb/anaesthesia#/view/about</a>	Yes
	MR Unit	<a href="https://www.ntnu.edu/isb/mr#/view/about">https://www.ntnu.edu/isb/mr#/view/about</a>	Yes
	Exercise, Circulation & Respiration - TSR	<a href="https://www.ntnu.edu/isb/exercise-respiration-circulation#/view/about">https://www.ntnu.edu/isb/exercise-respiration-circulation#/view/about</a>	Yes
	The Ultrasound Research Group - USRG	<a href="https://www.ntnu.edu/isb/ultrasound">https://www.ntnu.edu/isb/ultrasound</a>	Yes

\*IUH – The Integrated University Hospital

### Collaboration between St. Olavs hospital, the municipalities and NTNU

In 2020 the health community between St. Olavs hospital, the municipalities and the general practitioners in the catchment area to the hospital was established both on a political, strategical and operational level. This arrangement enables close collaboration in research, innovation and everyday practice between the hospital and its partners in the health community. This close collaboration between St. Olavs hospital and the municipalities is only in its sparse beginning, and has several opportunities. St. Olavs hospital and several of the nearby and largest municipalities, including Trondheim municipality, have acquired and started to use the shared electronic patient record «Helseplattformen» from Epic. Helseplattformen yields new opportunities to utilize and analyze patient data from different levels in the health system at different periods of time.

Recently, St. Olavs hospital and Trondheim municipality was awarded 7 MNOK from the Norwegian research council to an innovation project aimed at highlighting the challenges concerned with the increased need for health- and care services in the general population, especially the elderly frail

patients. More specifically, the project will by data analyses and simulation methods try to get an overview of the patient flux, capacities and coordination between the hospital and Trondheim municipality. This knowledge can lead to more effective use of resources and less waiting times for elderly frail patients. Moreover, the health community has also got funding financing a health service innovation project aimed at establishing a patient-centered interdisciplinary healthcare team with members from both the hospital and the nearby municipalities to support the transition from hospital admission to returning home from hospital stay for elderly frail patients. Eventually, both these innovation projects will lead to research projects evaluating patient outcomes as well as effects of intervention and treatment. Consequently, members from both the hospital, the municipalities and NTNU are planning to apply for a clinical academic group during fall 2024 aimed at addressing the question: «how to handle the elderly wave in the nearest future?». Knowledge from all these projects will be generalized and used to generate new research projects for other vulnerable patient groups needing interdisciplinary healthcare support, including patients with psychiatric illness and children with chronic diseases.

### Centre for Medical Devices, Technology and Innovation

The Centre for Medical Devices, Technology and Innovation is an interdisciplinary arena focusing on development and clinical use of medical technology. The centre offers an infrastructure that facilitates effective interdisciplinary collaboration between clinicians, technologists, researchers, and industry.

The Norwegian centre for minimally invasive Image guided Therapy and medical technologies (NorMIT), is an infrastructure designed to support research and innovation in medical technology, with particular emphasis on minimally invasive and image-guided treatment. NorMIT offers access to a wide range of modern operating theatres with advanced medical technology equipment to anyone with relevant research projects.

NorMIT was established in collaboration between the Future Operating Room (FOR) at St. Olav's Hospital and the Intervention Centre at Oslo University Hospital (OUS) with operating theatres physically located in both Trondheim and Oslo. The Centre for Medical Devices, Technology and Innovation conducts its own research, manages several small and large research and innovation projects, and operates some large national centres, such as NorMIT, NorTrials MU and the National Centre for Minimally Invasive and Image-Assisted Diagnostics and Therapy (MID).

NorMIT's aim is to contribute to better and safer treatment for patients with fewer complications and hospitalisation days, and cost-effective solutions for the health service and society. Researchers from all over the country benefit from the extensive equipment and advanced expertise in their commitment to develop tomorrow's diagnostic and therapeutic procedures, which is shown by the publication list.



## KLINBEFORSK

Clinical trials are carried out with the aim of building a knowledge base for prevention, diagnostics, treatment and rehabilitation, and patients are given the opportunity to receive new and experimental treatment. In order to meet the need for large clinical trials of high quality with predictable funding, the MHCS asked the health trusts (RHAs) to establish a national organ for clinical multicentre studies. The studies should respond to needs identified by patient organizations, health service providers, decision-makers, and the researchers themselves. This initiative resulted in the establishment of the Programme for Clinical Treatment Research in the Specialist Health Service (KLINBEFORSK).

The Ministry of Health Care created the funding scheme “KLINBEFORSK” in 2016. The mission of KlinBeForsk is to fund clinical studies that include patients from the specialty health service of Norway. Such studies are expensive by their nature, involving specialized personnel and equipment and with major regulatory compliance demands. KlinBeForsk is set up as a collaboration between all four regional health trusts and is administered by Helse Sør-Øst.

KlinBeForsk has an annual allocation of 150-200 million NOK. The annual call is in the springtime, and the funding is usually split 50/50 between targeted calls and free calls. The maximum grant sum is 20 mill NOK per application. The call is only available for researchers in the public hospital sector. All KlinBeForsk projects must have partners from all four regional health trusts. This is partly to foster collaboration between hospitals in Norway, but also to ensure that patients in all of Norway get access to the same treatment options.

In practice, all KlinBeForsk-funded projects are large national collaboration projects. A university hospital is usually sponsor, but many of the projects include smaller hospitals all across Norway. The clinical study should preferably be decentralized and performed locally. If the treatment option being investigated is too complicated to perform at all hospitals, the local hospitals can function as partners for recruiting, inclusion and follow-up.

St. Olavs hospital is currently the sponsor of eight clinical studies funded by KlinBeForsk.

## CONNECT

CONNECT is an initiative within Precision Cancer Medicine with the intention to ensure infrastructure and collaboration on diagnostics, clinical trials, implementation of advanced precision medicine and use of health data, e.g. for economic analysis. The goals of CONNECT are to give patients access to medicines they otherwise would not receive, increase the precision medicine experience of clinicians and researchers nationwide, generate data and insights important for analysing the outcomes and adopt health technology assessments and reimbursement schemes for these novel, personalized treatment concepts.

CONNECT is a collaborative effort between public and private entities aimed at advancing precision cancer medicine by collectively tackling significant challenges and testing innovative approaches to change current practices. As one of six university level hospitals, St. Olav’s hospital joined the CONNECT consortium as a founding partner when the consortium was established in December 2020. The consortium has increased from 22 founding partners to now 28 partners in total, including university hospitals, health regulatory entities, and private pharmaceutical companies. With our partnership in CONNECT St. Olav’s hospital is a visible stakeholder in the precision medicine ecosystem that is developing in Norway.

### NorCRIN

NorCRIN is a national research infrastructure body, whose primary objective is to strengthen and simplify collaboration in all categories of clinical research in Norway. A number of the work packages in NorCRIN focus on developing an infrastructure that aims to resolve and harmonise national tasks and challenges, as described in the assignment documents from the MHCS and the RHAs. This effort will lead to a more coordinated, transparent, and harmonised implementation of the procedures in all participating hospitals. In addition, a number of the measures will directly strengthen the competence of researchers and support staff and enable them to conduct high-quality clinical trials. Examples include procedures for planning, implementing and completing clinical trials; including data management, monitoring, GCP courses and GCP course templates.

### St. Olav's Hospital in Biobank Norway

Biobank Norway represents one of the world's largest resources within biobanking comprising both population-based and disease-specific clinical biobanks. In addition to biological material, biobanks in Norway comprise a vast array of longitudinal health data, on a scale that is unique in a global perspective and ideal for research and innovation projects within life sciences, including disease prevention and treatment. Norway has several hundreds of disease specific clinical biobanks. In the last decades, St. Olavs hospital has played a key role in clinical biobanking with focus on protocols for collections with broad consent, elaboration of national standards for collection of material and data, documentation, and strict quality measures. This has resulted in several nation-wide collections from large numbers of patients, containing fit-for-purpose material and data that meet the strict measures of new analytical technologies, such as multi-omics. St. Olav's Hospital has also been a driving force in the development of biobank databases and IT-platforms in clinical biobanking, with a focus on interoperability between the several biobank databases that exist nationwide.

St. Olavs hospital was the first hospital in Norway establishing a primary biobank-infrastructure, surpassing the "historical" project-based academic collections that were routine in Norway at that time. Internationally, biobank-infrastructures is presented as the future, with specialized personnel trained in all parts of the biobank field from collection, handling, storing and distribution of biological material and associated data, as much as the legal and economic aspects. Using such an infrastructure results in standardized and harmonized collections of material and data across borders. During the last decade, one focus area at St. Olavs hospital has been to build a logistic for research sampling in hospitals in the whole region.

In addition to the biobank unit, there has been a systematic work at the university hospital to build a research day care unit with trained study nurses, suitable areas, advanced medical patient monitoring device and the possibility to prepare and store biological samples. This infrastructure is further improved and has increased the activity by ambulatory assignments doing bedside research procedures at the patients *treating* department.

The implementation of these infrastructures that serve researchers with practical support has given results, and during the COVID-19 pandemic, HMN was one of the first regions in Norway to start collections of samples and data of hospitalized COVID-infected patients in the entire region, contributing to regional, national and international clinical research. This was possible because of an existing research logistic and a massive collaboration between these units, clinicians and researchers.

The research infrastructure that is built over years in our hospital is prepared to handle new activity in close collaboration with the clinic, such as an increasing number of clinical trials. The increased complexity of the protocols in clinical trials, require study personnel that can coordinate the patient flow, handle complex sample protocols, with dedicated time and suitable areas such as those in the research infrastructure at St. Olavs hospital. By offering this support, more clinicians can be able to run clinical trials in the years to come in our hospital.

#### St. Olav is part of the joint venture GEMINI

Gemini centre is a model for strategic research coordination between parallel research groups at NTNU, SINTEF, University of Oslo, St. Olav's Hospital and NTNU Social Research. The Gemini model requires planned and actively maintained collaboration between otherwise independent entities, with the aim of building larger and more robust professional communities of high quality that will be better equipped to seize and develop new opportunities. In this way, the partners aim to enhance competitiveness and create value for the community. The pillars of the model are a willingness to collaborate and a mutual understanding and respect for each other's roles and unique characteristics.

#### Clinical Academic Groups (CAG)

A CAG is a mutual obligation between employees of the health trusts and employees at universities/university colleges. The partners commit themselves to realising a common professional ambition to develop new knowledge with concrete effects for the health services. Through the Cooperative Body, the partner institutions support the realisation of this ambition. The initiative was established in 2019, and the following projects are currently ongoing:

- UNICAN CAG – UNite AI and CANcer
- ProstateCAG – Standardizing prostate cancer care
- CAG for Rare Genetic Diseases
- Multiple Myeloma in Central Norway
- The Translational Neuroscience CAG for Alzheimer's Disease
- Improved cardiac diagnostic imaging at the patients' point of care
- Precision medicine in inflammatory bowel disease (IBD)
- BREATHE CAG - Bridging REsearch and clinical practice for AsTHma and COPD
- SCN CAG - Sleep and Chronobiology Network

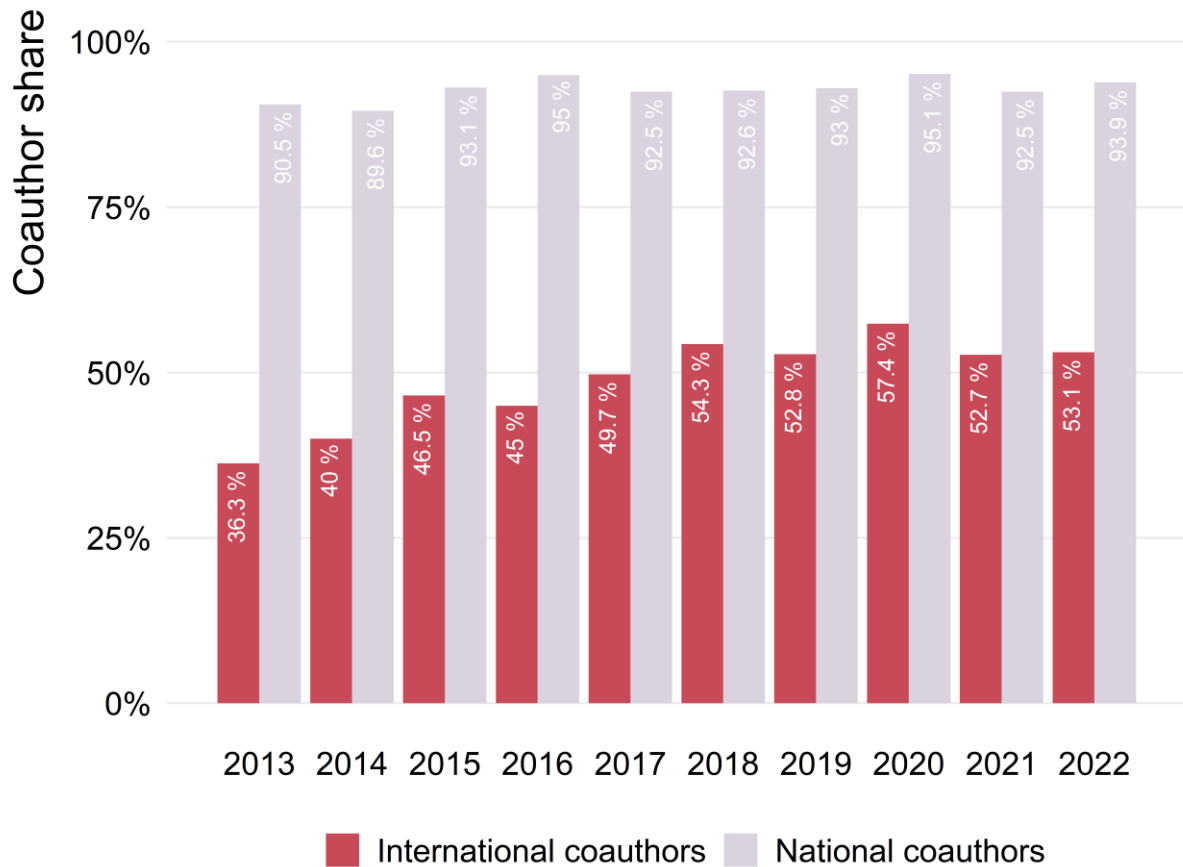
#### Outreach activities

St. Olav's Hospital participates in several international exchange agreements through the "Memorandum of Understanding", in close collaboration with NTNU, mainly concerning research. In connection with the introduction of "one patient – one medical record", an extensive collaboration has been initiated with Yale University, USA. Other research partners are:

- Kathmandu University and Dhulikhel Hospital, Nepal
- Karolinska Institutet, Sweden

Project collaborations and publications

Researchers from St. Olavs hospital have frequent collaborations on a project basis, typically with other Norwegian hospitals and universities as well as other European university hospitals. From 2012 to 2022 we have had a steady rate of copublication with national collaborators, and an increasing rate of copublication with international authors:



**Figure 4: National and international coauthorships**

Our top 10 national and international copublication institutions are:

<b>National copublishing institution</b>	<b>Co-publications</b>
Norwegian University of Science and Technology	1774
Oslo University Hospital	520
University of Oslo	505
University Hospital of North Norway	240
University of Bergen	231
Bergen Hospital Trust - Haukeland University Hospital	210
UiT The Arctic University of Norway	188
Nord Trondelag Hospital Trust	160
Stavanger Hospital Trust - Stavanger University Hospital	131
Møre og Romsdal Hospital Trust	115

<b>International copublishing institution</b>	<b>Co-publications</b>
Karolinska Institutet	176
Karolinska University Hospital	117
Copenhagen University Hospital	91
University Medical Center Rotterdam	88
University of Copenhagen	83
Umeå University	82
Radboud University Nijmegen Medical Centre	77
Medical University of Vienna	73
Sahlgrenska University Hospital	73
Aarhus University Hospital	71

**Table 4a. The main national collaborative constellations with the administrative unit****National collaborations**

<b>Collaboration with national institutions - 1</b>	
Name of main collaboration or collaborative project with the admin unit	<b>The integrated university hospital</b>
Name of partner institution(s)	<b>Norwegian university of science and technology</b>
Sector of partner/institution(s)/sectors involved	<b>Education and research. The main integration is with the Faculty of Medicine and Health Sciences with collaborations with several other faculties.</b>
Impacts and relevance of the collaboration	<b>Integration on several levels: Education, research, treatment, infrastructure. Shared ownership of building stock.</b>
<b>Collaboration with national institutions - 2</b>	
Name of main collaboration or collaborative project with the admin unit	<b>Collaboration between St. Olavs hospital, the municipalities and NTNU</b>
Name of partner institution(s)	<b>NTNU, Trondheim municipality, Melhus municipality, Orkland municipality with expansion options for several other municipalities</b>
Sector of partner/institution(s)/sectors involved	<b>Education and research, healthcare</b>
Impacts and relevance of the collaboration	<b>Collaboration on patient treatment and workflow, prevention and public health, and on the common electronic journal system for all patients.</b>
<b>Collaboration with national institutions - 3</b>	
Name of main collaboration or collaborative project with the admin unit	<b>Gemini centres</b>
Name of partner institution(s)	<b>SINTEF, NTNU, University of Oslo.</b>
Sector of partner/institution(s)/sectors involved	<b>Research institute, education and research, health trust.</b>
Impacts and relevance of the collaboration	<b>Closer cooperation between industry, basic research and clinical implementation through mutual commitment.</b>

<b>Collaboration with national institutions - 4</b>	
Name of main collaboration or collaborative project with the admin unit	<b>Hospitals in Middle Norway Health Region.</b>
Name of partner institution(s)	<b>Helse Møre og Romsdal and Helse Nord-Trøndelag.</b>
Sector of partner/institution(s)/sectors involved	<b>Health trusts, hospitals.</b>
Impacts and relevance of the collaboration	<b>Collaboration on treatment, education and research.</b>

**Table 4b. The main international collaborative constellations with the administrative unit**  
**International collaborations**

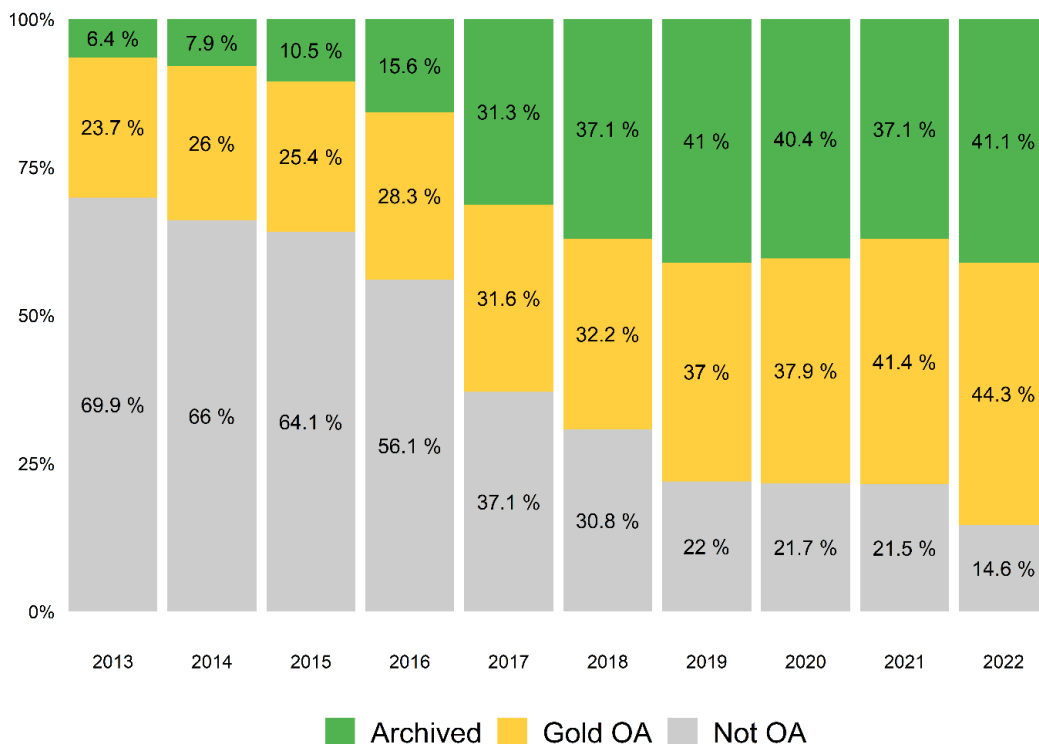
<b>Collaboration with international institutions - 1</b>	
Name of partner institution(s)	<b>Yale university</b>
Sector of partner/institution(s)/sectors involved	<b>Education and research, clinical services</b>
Impacts and relevance of the collaboration	<b>Medical research and cooperation on EPIC/Helseplattformen</b>
<b>Collaboration with international institutions - 2</b>	
Name of partner institution(s)	<b>Kathmandu University and Dhulikhel Hospital, Nepal</b>
Sector of partner/institution(s)/sectors involved	<b>Education and research, hospital</b>
Impacts and relevance of the collaboration	<b>Exchange of students and personnel, collaborations on health projects</b>
<b>Collaboration with international institutions - 3</b>	
Name of partner institution(s)	<b>Karolinska institutet</b>
Sector of partner/institution(s)/sectors involved	<b>Education and research, clinical services</b>
Impacts and relevance of the collaboration	<b>Exchange of students and personnel, project collaborations</b>

## 1.7 Open science policies

### a) Describe the institutional policies, approaches, and activities to the Open Science areas

St. Olav have a close cooperation with NTNU on library services. Through a collaboration agreement, the hospital has access to exactly the same functionality as university employees. This aligns St. Olav towards a plan where all publications should be published as open access. Data collection in any study from the hospital should abide to FAIR standards and user involvement is also a mandatory requirement for all studies carried out from the hospital. Clinical trials are held to GCP standards, and open-source software must abide to the Code of Conduct. The researchers are responsible for archiving their own publications in an open access database (NTNU Open).

There is currently no hard stops for missing open science in a project, but most projects are funded on a competitive basis, and lack of open science implementation will be unfavorable for competitiveness. The evolution of the use of open access is seen in figure xx, where the use of open access has increased from 30,1 % of total volume of publications to 85,4% of total volume of publications. This formidable increase have been aided by offering more open access possibilities such as self-archival and an increased number of open access journals, but also reflects a cultural change where open access is now the standard mode of publication for our researchers. Library service update online-resources on open science, offer online courses in making data management plans and give in-person advise and training in data management, licensing, archiving, FAIR data and privacy.



**Fig 5: Distribution of publications considered open access in the years 2013-2022.**



For user involvement, St. Olavs hospital follows a three-tiered system:

1. The user committee on the central level is tasked with user involvement in policy and strategic decisions regarding research, but will assist in recruiting user representatives in larger projects (e.g. research centres, international projects).
2. All clinics are tasked with creating a user panel for involvement in research relevant to the clinic. This level of involvement is for creating clinic strategies/action plans and direct involvement in research project.
3. Research groups will frequently have contact with patient interest groups and work with user involvement through these. Several of these patient interest groups have their own research funding (E.g. the Norwegian Cancer Society), or collaborate with national funding organisations to prioritise research (e.g. The Dam Foundation).

**b) Describe the most important contributions and impact of the administrative unit's researchers towards the different Open Science areas cf. 1.7a above.**

St. Olavs hospital has a special responsibility for patient involvement and patient safety in the integrated university hospital. Patient involvement is mediated through several user panels and good connections with patient organisations as described in section 1.7a and is now a natural part of any patient-centered research project. St. Olav also has a special responsibility for clinical trials in the region and for FAIR data in these studies. St. Olav follows the "Joint statement on public disclosure of results from clinical trials" from WHO. In addition, all studies with a minimum common data set are reported to Clinicaltrials.gov.

Adverse reactions are graded according to "Common Terminology Criteria for Adverse Events (CTCAE)". Openness about results and side effects is crucial for the trust of patients participating in such studies. St. Olavs therefore reports openly on adverse event (AE, serious adverse event (SAE) and suspected unexpected serious adverse reaction (SUSAR) Adverse reaction is done in accordance with Regulation (EU) No. 536/2014. SUSARs that occur during trials are reported as individual reports (reports for each patient). As a general rule, SUSAR is unblinded. In the case of industry collaboration (commissioned research), the sponsor also reports SUSARs for comparison talk and placebo. SUSARs are reported via the EudraVigilance (EVCTM) system. Annual Safety Reports are delivered annually through CTIS.

Studies that plan to include patients in Norway must also be registered in a national open access database. On this national website, patients can find information about current studies for their disease. Through the project "one patient-one medical record", digital consent to participate in clinical trials has been implemented, which significantly lowers the bureaucratic threshold for access to experimental treatment.

**c) Describe the institutional policy regarding ownership of research data, data management, and confidentiality.**

The handling of research data in clinical trials takes place in accordance with Good Clinical Practice (GCP). This international standard provides guidelines on data management, data quality and archiving. GCP is a scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects. St. Olav have a policy of research data that compliance with this standard provides public assurance that the rights, safety and wellbeing of trial subjects are protected and that clinical-trial data are credible. GCP

All of our researchers are encouraged to keep a statistical analysis plan (SAP) and a data management plan (DMP) for their projects. For clinical intervention trials the research department will assist in setting up SAPs and DMPs, and for clinical interventions to GCP standards this is a requirement.

## 1.8 SWOT analysis for administrative units

**Instructions:** Please complete a SWOT analysis for your administrative unit. Reflect on what are the major internal Strengths and Weaknesses as well as external Threats and Opportunities for your research and innovation activities/projects and research environment. Assess what the present Strengths enable in the future and what kinds of Threats are related to the Weaknesses. Consider your scientific expertise and achievements, funding, facilities, organisation and management.

<b>Internal</b>	<b>Strengths</b>	<b>Weaknesses</b>
<b>External</b>	<b>Opportunities</b>	<b>Threats</b>

<b>Internal Strengths</b>	<ul style="list-style-type: none"> <li>• close collaboration with NTNU with a value chain from basic research to RCTs</li> <li>• close cooperation between other hospitals in the region to include patients in multicenter studies</li> <li>• research infrastructure for clinical trials of high quality</li> <li>• outstanding infrastructure for testing medical devices on humans</li> <li>• “one patient- one medical journal” gives the hospital a national advantage in health data-driven research</li> <li>• unique culture of improvement in the hospital</li> </ul>
<b>Internal Weaknesses</b>	<ul style="list-style-type: none"> <li>• workload for health professionals increases due to a demand of dual proficiencies in clinical and research skills</li> <li>• weak on external financing</li> <li>• varying research culture, organisation and integration between different clinics</li> </ul>
<b>External Opportunities</b>	<ul style="list-style-type: none"> <li>• greater focus from funding authorities on RCTs with drugs and medical devices</li> <li>• increased focus on research-based innovation in healthcare area</li> <li>• NTNU has a nationally leading technology environment to support RCTs with medical devices</li> </ul>
<b>External Threats</b>	<ul style="list-style-type: none"> <li>• Lack of qualified personnel, it is difficult to recruit health personnel for research and research support</li> <li>• reporting indicators diverge between hospital and university, which makes co-reporting challenging</li> <li>• there is a very large research bureaucracy that must be overcome to offer experimental treatment</li> <li>• an increasing share of resources is spent on reporting</li> </ul>

## 2. Research production, quality and integrity

### 2.1 Research quality and integrity

a) Describe the scientific focus areas of the research conducted at the administrative unit, including the unit’s contribution to these areas.

The scientific activity of St. Olav’s Hospital is broad and encompasses basal, translational, and clinical sciences as well as technological and service-based innovation. This is evident in the diversity of the hospital’s 6 largest research fields by volume, as shown in figure 6.

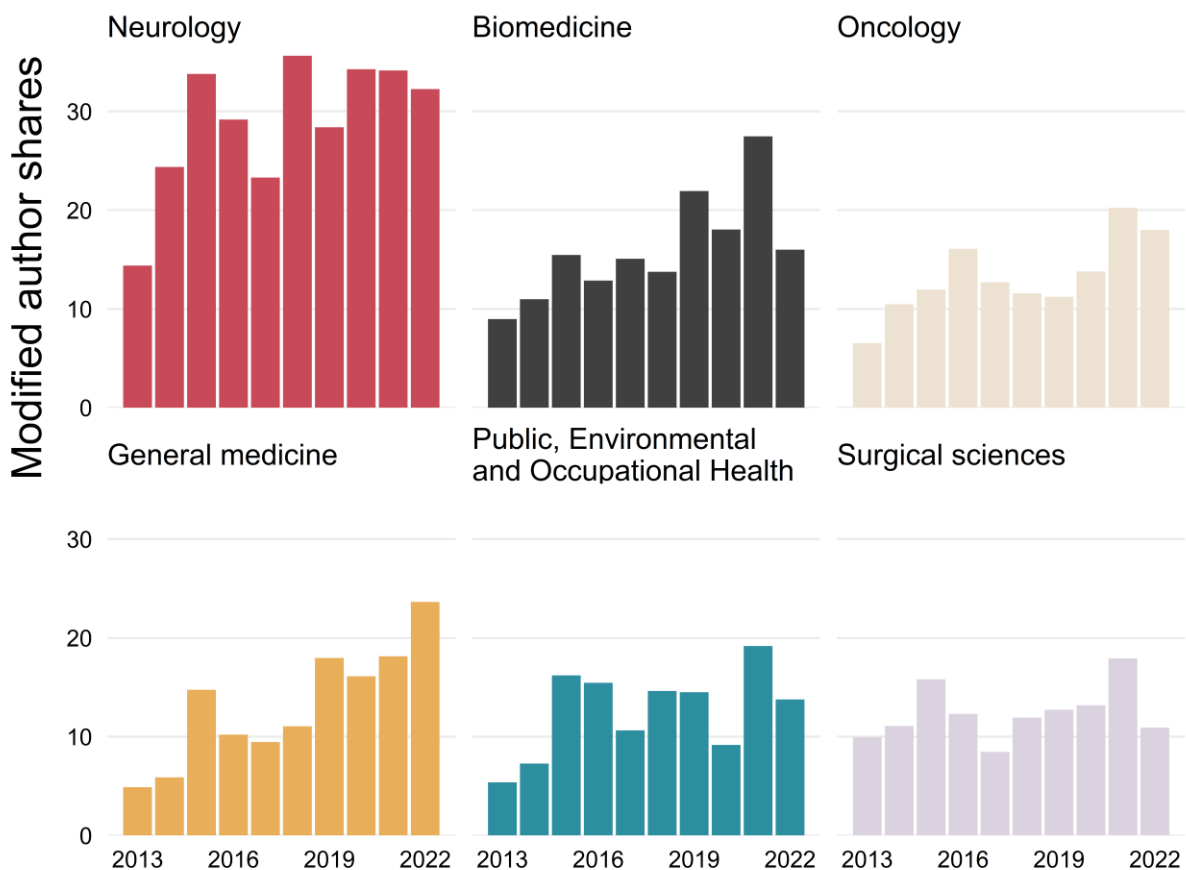


Figure 6: Top 6 publication fields for St. Olavs hospital.

Special focus has been on integrating clinical and basal sciences in cooperation with the NTNU. The research groups that are most successful in this respect can apply to obtain the status as a Clinical Academic Group (CAG). There are currently 9 active CAGs at the integrated university hospital:

- UNICAN CAG – UNite AI and CANcer
- ProstateCAG – Standardizing prostate cancer care
- CAG for Rare Genetic Diseases
- Multiple Myeloma in Central Norway
- The Translational Neuroscience CAG for Alzheimer's Disease
- Improved cardiac diagnostic imaging at the patients' point of care
- Precision medicine in inflammatory bowel disease (IBD)
- BREATHE CAG - Bridging REsearch and clinical practice for AsTHma and COPD
- SCN CAG - Sleep and Chronobiology Network

St. Olav's Hospital also hosts many smaller research and innovation groups, typically consisting of a smaller number of specialists with overlapping interests. Such groups are highly capable of doing evidence-based service innovations, and they regularly publish their work in renowned scientific publications. Typical impact of this work is incremental treatment improvements or evidence of effect or non-inferiority of treatments.

St. Olav's Hospital is, per its ambitions, the leading technological hospital in Norway and has placed special emphasis on development and implementation of new medical technology. A separate unit, "Fremtidens operasjonsrom" (FOR, now Centre for Medical Devices, Technology and Innovation") was established in 2005.

to enable the hospital to synergize with university and industry partners in testing and implementing the use of new technology. St. Olav's Hospital also houses the NorTrials unit for clinical studies involving medical equipment. This unit is organized under FOR and has a national mandate to increase the number of industry-initiated studies in cooperation with hospitals.

**b) Describe the administrative unit's policy for research integrity, including preventative measures when integrity is at risk, or violated.**

St. Olav's Hospital complies with the Helsinki Declaration and the Vancouver Convention in all research activity. Integrity violations are to be reported through the hospital quality assurance system EQS procedure #32327 and #15866. Reported integrity violations will be handled by the notification committee, consisting of the chief of human resources, the main Environment, Health, and Safety (EHS) representative, a legal representative and an EHS advisor. For research integrity violations, they will include the respective Head of Clinic as research owner/responsible. The research department will assist in inquiries as needed.

The research department is also responsible for internal revision of research procedures and research projects, and will each year inspect 10% of active research projects chosen randomly for compliance to laws, external and internal regulations, and research integrity.

New clinical researchers and PhD students in clinical disciplines are offered the course KL MED 8009 – Clinical Research. The course details important laws and regulations relevant to clinical research and teaches the basics of protocol writing, data collection and proper statistical methods.

## 2.2 Research infrastructures

### a) Participation in national infrastructure

NorCRIN – Norwegian clinical research infrastructure network. St. Olav’s Hospital was a leading developer of this network and was the host of the network from 2014-2021. The infrastructure works for harmonizing Norwegian research under Good Clinical Practice (GCP) and encourages Norwegian hospitals to cooperate for running clinical trials compliant to GCP

NorMIT – Norwegian centre for minimally invasive image guided therapy and medical technologies. This infrastructure is hosted by the St. Olav’s Hospital department FOR. This is a national infrastructure for testing new medical technologies, including devices and software. It also hosts NorTrials, the national node for industry-sponsored clinical trials of medical devices.

NorSeq – St. Olav’s Hospital is a partner in NorSeq, whose aim is to integrate nucleic acid sequencing into personalized medicine.

Biobank Norway – St. Olav’s Hospital has participated in Biobank Norway since Biobank Norway 1 2011. The official participation has been through the Central Norway RHA, while the operational participation has been taken care of by St. Olav’s Hospital, through Biobank1.

**Table 5. Participation in national infrastructure**

Areas in roadmap	Name of research infrastructure	Period (from year to year)	Description	Link to website
Biotechnology	NorSeq	2017-now	Infrastructure for nucleic acids sequencing in research and diagnostics	<a href="#">NorSeq</a>
Medicine and health	NorCRIN	2014-now	Infrastructure for performing clinical trials under Good Clinical Practice	<a href="#">NorCRIN</a>
	Biobank Norway	2014-now	Infrastructure for biobanking services	<a href="#">Biobank1</a>
	NorMIT	2014-now	Infrastructure for minimally invasive therapy and medical technology	<a href="#">NorMIT</a>
	Health Registries for Research	2014-2019	Infrastructure for health registries, including national medical quality registries	<a href="#">HRR</a>

### b) Not applicable

**c) Participation in European (ESFRI) infrastructures**

Describe the most important participation in European (ESFRI) infrastructures (Norske medlemskap i infrastrukturer i ESFRI roadmap) including as host institution(s).

St. Olav's Hospital has been an active partner in the European Clinical Research Infrastructure Network (ECRIN), as the main Norwegian contact point for ECRIN while St. Olav's Hospital hosted NorCRIN (from 2014-2021). During this time, the hospital has been active as a potential partner for clinical trials with ECRIN involvement and has sponsored several international clinical trials together with NTNU.

St. Olav's Hospital participates in BBMRI through Biobank1 and participates in Biobank Norway in cooperation with NTNU.

St. Olav's Hospital participates in EATRIS and ELIXIR through the cooperation with NTNU.

**Table 7. Participation in infrastructures on the ESFRI Roadmap**

<b>Biology and medicine (Life sciences)</b>			
<b>Name</b>	<b>ESFRI-project</b>	<b>Summary of participation</b>	<b>Period (from year to year)</b>
<a href="#">ELIXIR (EMBL)</a>	European infrastructure for biological information, supporting life science research and its translation to medicine, agriculture, bioindustries and society	Through cooperation with NTNU. Access to training, workshops and other services.	
<a href="#">BBMRI ERIC</a>	Biobanking and Biomolecular Resources Research Infrastructure	Through Biobank1 and Biobank Norway Samples from Biobank1 are included in BBMRI directory.	2011-now
<a href="#">EATRIS ERIC</a>	European Advanced Translational Research Infrastructure in Medicine	Through cooperation with NTNU.	
<a href="#">EU-OPENSREEN ERIC</a>	European Infrastructure of Open Screening Platforms for Chemical Biology	Through cooperation with SINTEF. Access to sample library.	
<a href="#">ECRIN ERIC</a>	European Clinical Research Infrastructures Network	Through ECRIN, national contact 2014-2019	2014-now
<a href="#">Euro-BioImaging ERIC</a>	Research Infrastructure for Imaging Technologies in Biological and Biomedical Sciences	Through NTNU	

**d) Access to research infrastructures**

Describe access to relevant national and/or international research infrastructures for your researchers. Considering both physical and digital infrastructure.

Employees are offered full access to the infrastructures in which the hospital is a partner.

In practice, access is mediated through the local branch of the infrastructure, either through the research department (Clinical trials, Biobanking) or core facilities (Mass spectrometry, NMR, nucleic acids sequencing, imaging) that are shared with NTNU. Infrastructures will charge eligible costs to the researcher/project but are operated on a not-for-profit basis. Internal funding to support the use of these infrastructures on a project basis is available at several levels: Clinic-wise, hospital or regional health trust. Advisory functions connected to the infrastructures are free of charge.

Personnel employed at St. Olav's Hospital has also been able to utilize other national infrastructures through the cooperation with NTNU: ELIXIR Norway, Network of Advanced Proteomics (NAPI), Norwegian Advanced Light Microscopy Imaging Network (NALMIN), The Norwegian NMR Platform (NNP), NORBRAIN – Norwegian brain initiative: a large-scale infrastructure for 21st century neuroscience, NORMOLIM – Norwegian Molecular Imaging Infrastructure – National node in Euro-Bioimaging, and PCRN – The Norwegian Primary Care Research Network.

**e) FAIR- principles**

Describe what is done at the unit to fulfil the FAIR-principles.

All clinical trials performed by St. Olav's Hospital are registered in a searchable, public database, typically [clinicaltrials.gov](https://clinicaltrials.gov) or Clinical Trial Information System. All research projects should have a Data Management Plan, where the FAIR principles should be addressed. Project data can be made accessible either through publication, through self-archival, or a combination. We recommend the DMP tool available from SIKT (Norwegian Agency for Shared Services in Education and Research) to all our researchers: <https://sikt.no/en/data-management-plan>.

As a majority of our projects collect data in special categories (e.g. health data), often from a vulnerable population (patients), we must balance the act of making data accessible and protecting the privacy rights of the study population. We always strive to create accessible, anonymous data sets from our studies whenever this is possible, but deleting the original data set is required for all projects using data or material from human subjects after a set time-period as demanded by ethical authorities or by law.



### 3. Diversity and equality

St. Olav's Hospital has joined the inclusive work agreement ("Inkluderende arbeidsliv, IA"). This is a tripartite agreement between the government, employers' organizations and trade unions in Norway to secure access to work for everyone and combat discrimination of any kind. Any perceived discrimination can be reported to union representatives or a chief protective officer (Hovedverneombud), and St. Olav's Hospital is bound by the agreement to officially accept and investigate such cases. As a part of this work, St. Olavs hospital publishes a Yearly statement on equality and discrimination as a part of reporting to the board of the hospital.

**Table 8. Administrative unit policy against discrimination**

Give a description of up to 5 documents that are the most relevant. If the administrative unit uses the strategies, policies, etc. of a larger institution, then these documents should be referred to.

No.	Name	Valid period	Link
1	Ethical guidelines for The Central Norway Regional Health Authority	Continuous	<a href="#">Ethical guidelines</a>
2	Yearly statement on discrimination and equality for St. Olavs hospital	2021-2022	<a href="#">Yearly statement</a>

## 4. Relevance to institutional and sectorial purposes

### 4.1 Sector specific impact

Describe whether the administrative unit has activities aimed at achieving sector-specific objectives or focusing on contributing to the knowledge base in general. Describe activities connected to sector-specific objectives, the rationale for participation and achieved and/or expected impacts. Please refer to chapter 2.4 in the [evaluation protocol](#).

- Alternatively, describe whether the activities of the administrative unit are aimed at contribution to the knowledge base in general. Describe the rationale for this approach and the impacts of the unit's work to the knowledge base.

As a university hospital, St. Olav's Hospital has an official obligation to orient its activity towards patient treatment and research, both by law and by decree from the government. We have summarized this in our vision: Outstanding treatment. The guiding points for our sector specific research impact can be summarized as:

To improve existing treatment and diagnostics  
To assure the quality of current treatment and diagnostics  
To develop new evidence-based treatment and diagnostics

The measurable impact of these will be the development of new or updated local and national guidelines on patient treatment and patient treatment trajectories. It should be noted that improvement also includes parameters such as increased efficiency and reduced costs.

This does not exclude research that does not directly influence on patient treatment. Basal research is also an obligation imposed on university hospitals in Norway, and performing basal research enables our personnel to reach a higher standard of knowledge in the basic disciplines underpinning clinical competence. The potential for translation of the new knowledge into improved treatment and better diagnostics is a core criterium for all internally funded basal science projects.

St. Olav's Hospital has taken a national leading role in development and implementation of new medical technologies. Our unit FOR pioneers the use of new technology in patient treatment and has 7 operating rooms as testbeds for new technology. Six operating theatres in different clinics are in de facto use for testing and implementation of new technologies in the treatment of patients. One of these operating rooms is used as a full-scale test bed for modelling workflow and environment. A main impact of this is that St. Olav's Hospital has been an early adopter of minimally invasive and computer-assisted surgery.

## 4.2 Research innovation and commercialisation

### a) Describe the administrative unit's practices for innovation and commercialisation.

NTNU Technology Transfer AS (TTO) was established in 2003 and is partly owned by Central Norway RHA. The purpose of TTO is to secure, manage, develop, market, and sell rights of use and property rights to knowledge, ideas, inventions, and other intangible values created by St. Olav's Hospital, and thus by Central Norway RHA. TTO is Central Norway RHA's strategic tool for generating benefit from research. At the most basic level, the aim is to enhance technology and increase knowledge. Commercialization is but a tool for achieving that aim. In this way, the research benefits society in the form of new products, new services, new industries and new jobs.

### b) Describe the motivation among the research staff in doing innovation and commercialisation activities.

The research staff is encouraged to look for innovation and commercialisation possibilities in their daily work. Basic services to facilitate innovation and research are provided for free by the research department and the TTO. There are several options for financial contribution to innovation and commercialisation. Thus, the Central Norway RHA has established a dedicated funding scheme for innovation, which has been active since 2016. For successful commercialisation projects the researcher will receive a percentage of the profit generated by the project by e.g. sales of patent rights.

Many of the innovation projects at the hospital are centred on improved practice in the health care service, which often has limited commercial potential. The unit Regional Centre for Healthcare Development (RSHU) has a special mandate to provide service and support for this type of innovation. Currently, two full-time employees fill this function. St. Olav's Hospital has introduced a practice of business cases, where each clinic can present improvement projects with a defined expected impact on patient treatment and hospital workflows. Most of these cases fall into the category technological or service innovation projects. After several years of this practice, these innovation projects are now an ingrained feature of continuous improvement in the hospital.

### c) Describe how innovation and commercialisation is supported at the administrative unit.

In addition to the local administrative support the innovation activities are supported by the staff at TTO on behalf of the university hospital. The core of the activity is to receive ideas, which are then evaluated by investigating ownership, maturity of the idea and marked interest and to develop and verify that the generated knowledge may be commercialized. A dedicated main contact point is available for the university hospitals' employees. In the years 2012-2022 a total of 94 ideas have been reported to the TTO, of which 15 priority patents and 9 successful technology transfers have been obtained.

**Table 9. Policies for innovation including IP policies, new patents, licenses, start-up/spin-off guidelines**

Describe up to 5 documents of the administrative unit's policies for innovation, including IP policies, new patents, licenses, start-up/spin-off guidelines, etc., that are the most relevant. If the administrative unit uses the strategies, policies, etc. of a larger institution, then present these documents.

No.	Name	Valid period	Link
1	Regional utviklingsplan HMN	2023-2026	<a href="https://www.helsemidt.no/49d50f/siteassets">https://www.helsemidt.no/49d50f/siteassets</a>
2	Utviklingsplan 2023 – 2026 St.Olavs Hospital	2023-2026	<a href="https://www.stolav.no/4948da/siteassets/om-">https://www.stolav.no/4948da/siteassets/om-</a>
3	Samarbeidsavtale HMN og NTNU TTO	2023-2024	<a href="https://www.ntnutto.no/wp-">https://www.ntnutto.no/wp-</a>
4	Tjenestekjøpsavtale HMN og NTNU TTO	2023-2024	

**Table 10. Administrative description of successful innovation and commercialisation results**

Please describe up to 10 successful innovation and commercialisation results at your administrative unit in the period 2012-2022.

No.	Name of innovation and commercial results	Link	Description of successful innovation and commercialisation result.
1	EIR – license DNV Imatis	<a href="https://mypath-cancercare.eu/partners/dnv-imatis/">https://mypath-cancercare.eu/partners/dnv-imatis/</a>	License with industry – launched under the name MyPath
2	Multiguide – license Palion Medical	<a href="https://www.linkedin.com/company/palionmedical/about/">https://www.linkedin.com/company/palionmedical/about/</a>	Patents filed – license with industry -
3	Shear – license DeSoutter Medical	<a href="https://www.de-soutter.com/">https://www.de-soutter.com/</a>	Patent filed – license with industry which target CE mark and marked launch 2024/2025
4	Doppler – license to Cimon Medical	<a href="https://cimonmedical.com/">https://cimonmedical.com/</a>	Patents filed - license with industry which target CE mark and marked launch 2024/2025
5	MI – insight, Cerebri and headache diary– license to Nordic Brain Tech	<a href="https://nordicbraintech.com/">https://nordicbraintech.com/</a>	Patents filed - license with industry which perform clinical trials and have a product launched.
6	Instapatch – license to Isansys	<a href="https://www.isansys.com/">https://www.isansys.com/</a>	License with industry which further develops and implements technology into existing solutions
7	Cryo – license to Keimon Medical		License with industry which further develops technology
8	Reboa trainer – license to Lærdal Medical	<a href="https://laerdal.com">https://laerdal.com</a>	Patents filed – license with industry -

## 4.5 Health trusts

**a) Reflect on how the administrative unit's clinical research, innovation and commercialisation contribute towards development, assessment and implementation of new diagnostic methods, treatment, and healthcare technologies.**

During the period of 2012-2022, the Norwegian healthcare system has developed a more focused patient-centric strategy for research. This has manifested as an indicator for clinical treatment studies. While in the early years the goal was "to increase the number of patients enrolled in a clinical study", there is now a specific target that the number of patients being enrolled in a clinical study should increase by at least 15% annually. St. Olav's Hospital has followed up this development by switching more resources to clinical studies, by increasing funding opportunities and administrative support.

Our integration with the university enables us to make use of novel concepts in basal science that are relevant for clinical treatment and diagnostics and provides our researchers with a strong scientific base of knowledge that is invaluable also for clinically oriented research. Our established cooperations with industry (e.g. the Gemini centers in partnership with SINTEF) and the national infrastructure NorMIT enable us to quickly adapt and implement new technologies for better and more effective treatments and diagnosis, while also being an attractive partner for clinical trials testing new technology.

St. Olav's Hospital is regularly either the host of or a participant in clinical studies that improve patient treatment and diagnostics. These regularly result in updates of local, national, and international guidelines for best clinical practice and changes in patient trajectories. Just as important are the studies that show non-inferiority of alternative treatments, and studies that show limited or no effect of treatments. Reducing the amount of non-effective treatments is a primary goal of the Norwegian health sector overall.

**b) Reflect on how research at the unit contributes towards the quality of relevant education programme at your institutions or beyond.**

Experienced researchers are often employed as both lecturers and clinicians. This means that theoretical lectures and practical lessons often will be held by the same personnel, with expert-level knowledge of their topics. This gives students access to a practice that is closely intertwined with research and secures that all lectures and lessons are grounded in up-to-date research. St. Olav's Hospital also has a policy of valuing research outside a specialists' field to foster interdisciplinary cooperation and knowledge.

**c) Describe the different opportunities for students on relevant educational programmes to become involved in research activities at the administrative unit, and the extent to which students use those opportunities.**

Medical students are in extensive praxis at the hospital during their education, and they are regularly encouraged to join research projects. All medical students are also required to perform a 3-month research assignment during their education, where they are offered residency in existing research groups at the hospital/university. There is a separate research program offered to medical students who want to delve more into research. Participation in this program will extend the study by a whole year. The aim of this program is that the graduates should have completed research training corresponding to one half of a PhD degree. The program is very popular, with a high number of applicants.

Students enrolled in relevant bachelor educations (e.g. nursing, laboratory technician) can write their final bachelor assignment attached to a research group and perform work which is relevant for their thesis.

Master students (e.g. psychology, biology, sports sciences etc.) can be attached to a research group upon admission and are encouraged to join a research project as early as possible during their education. The master thesis will regularly constitute part of a larger project which is later published in a scientific journal.

## 5.Relevance to society

Reflect on the administrative unit's contribution towards the Norwegian Long-term plan for research and higher education, societal challenges more widely, and the UN Sustainable Development Goals.

Reflect on the administrative unit's contribution towards the Norwegian Long-term plan for research and higher education, societal challenges more widely, and the UN Sustainable Development Goals.

Sustainability is one of the top priorities for research in the health sector. The earlier focus on translational research and novel treatments has now been shifted towards sustainability as a goal in itself. The healthcare sector is the largest employment sector in Norway, accounting for more than 10% of BNP spending. While Norway scores very high on the availability and quality of its health services, the situation is not sustainable if one takes into account the aging population and future demands of health services. There will not be more resources available to health services in the future, and there will be a shortage of health professionals with the necessary qualifications.

During the period of 2012-2022 one can see a clear shift in the priorities of research missions and funding for hospitals, with an increased focus on sustainability in the future health service. St. Olav's Hospital have approached this development in several ways:

- Focus on technological innovations that give effective treatment for less resources (e.g. minimally invasive surgery).
- Technological innovations that can relieve medical staff of administrative or time-consuming work.
- Studies on cost-effectiveness of treatment and studies to eliminate non-effective treatment
- The repurposing of commonly used drugs for new indications (e.g. Candesartan for migraine).
- Showing non-inferiority of less resource-demanding treatments.
- Implementing a shared electronic medical record to streamline treatment and care across the health services and expand the cooperation with local municipalities.
- Engaging and informing patients and next of kin about preventive measures and treatment options.
- Engaging and informing healthcare policy makers on preventive measures and treatment options
- Improving research data quality and prolonged storage of data for further study

### 5.1 Impact cases

Please use the attached template for impact cases. Each impact case should be submitted as an attachment (pdf) to the self-assessment.

**St. Olavs hospital Impact case #1 - candesartan and migraine**

**St. Olavs hospital Impact case #2 - effect of spinal cord burst stimulation**

**St. Olavs hospital Impact case #3 - sleep and circadian systems in mental health**

**St. Olavs hospital Impact case #4 - THORA – new standard for lung cancer treatment**

**St. Olavs hospital Impact case #5 - Fraxinus decision-support software**