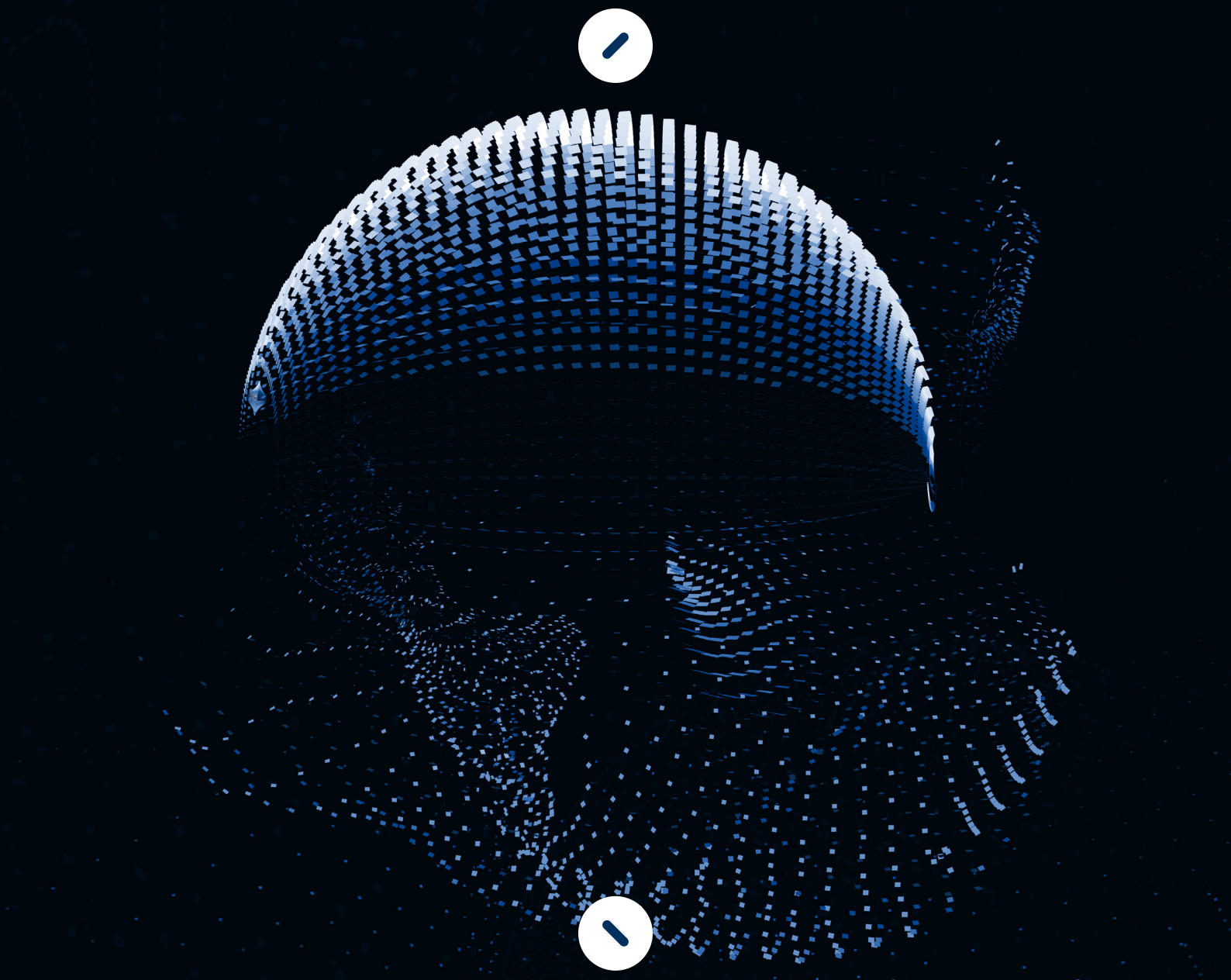
MATRIX - Norwegian Centre for Clinical Cancer Research

Annual Report 2022



MATRIX

Centre for Clinical Treatment Research

Presentation

MATRIX has an overall ambition to help patients with hard-to-treat cancers to live longer and with better quality of life

MATRIX Co-Funders:

The Research Council of Norway
The Norwegian Cancer Society

NORWEGIAN CANCER SOCIETY

The Research Council of Norway

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Greetings from the Director

Dear friends, colleagues and supporters of MATRIX,

It is a great pleasure to welcome you to the first MATRIX annual report. Thanks to the Research Council of Norway and the Norwegian Cancer Society, we have been given an opportunity to establish the Norwegian Centre for Clinical Cancer Research, and we are enthusiastic about the possibilities we now have been given. MATRIX officially opened in August 2022, and this report presents both our ambitions and research plans as well as some of the activities that have already taken place.

Precision medicine aims to offer patients more precise and targeted diagnostics and treatment, while avoiding treatment without effect. In the last couple of years, targeted work to implement precision cancer medicine at a national level in Norway has been performed, and a tailored ecosystem has been funded and built up since 2019 to be able to offer cancer patients systematic use of molecular diagnostics and precision medicine. MATRIX collaborates closely with and will continue to build on these initiatives. Recently, the Minister of Health launched the strategy for personalized medicine 2023-2030. The government's vision to make personalized medicine an integral part of prevention, diagnostics, treatment and follow-up in the public healthcare system is well in line with the ambitious visions and goals of MATRIX.

Thanks to medical advances, care rates have increased and more patients are now living longer with cancer than before. People with cancer risk substantial physical, psychological and social complications, and a more holistic approach that also takes mental and social needs of the patients into account, is therefore needed in cancer care. Studies have shown that involving patients directly in decisions, based on their own reports of symptoms and functions, are beneficial. It improves symptom control, quality of life, psychological distress, overall satisfaction and prolongs survival time. Tailor-made patient-centred treatments and prospective plans – also known as patient-centred care pathways – is asked for by patients, health care providers and recommended by health care authorities.

MATRIX Director Åslaug Helland. Photo: Per M. Didriksen, OUH

MATRIX consists of partners and study sites across all health regions in Norway, and altogether this national effort includes clinicians and researchers from fifteen hospitals with cancer departments as well as the University of Oslo and OsloMet. Establishment of MATRIX enables further development and testing of new, targeted treatment options for cancer patients across the country, and the aim is to contribute to more clinical trials also in earlier treatment lines than today. Trials in MATRIX should aim for patient benefit by focusing on precision cancer medicine, improving diagnostics, extend lifespans and / or improving

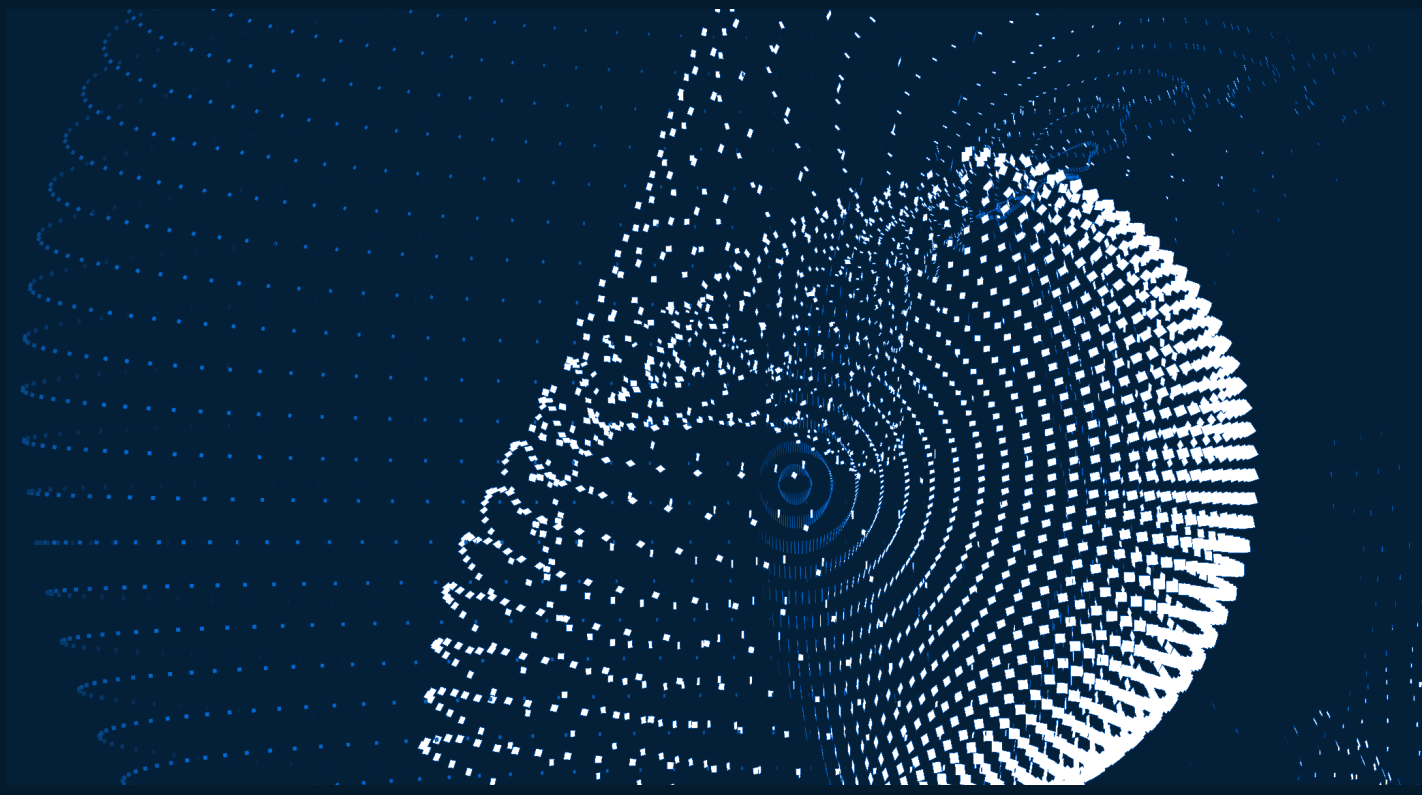
the quality of life. Another important aspect in MATRIX is the development and implementation of digital patient-centred care tools that secure treatment and follow-up tailored to the individual patient. The aim is that healthcare personnel will be able to more efficiently plan and adjust treatment plans so that the quality of treatment increases, and patients are well informed and included in the process.

In the recently launched strategy for personalized medicine 2023-2030, the government has highlighted three main goals: equal access to precision medicine for patients across the country, relevant expertise available in the health services and efficient and secure use and analysis of large-scale health data in health care, research and service development. MATRIX will through its five work packages described in more detail in the report, contribute to reach these goals within the field of precision cancer medicine. MATRIX has gathered experts from all over Norway to work together within several areas of cancer care, from developing next-generation diagnostics, increase the number of available clinical trials to developing and implementing new, digital solutions for patient-centred care.

The involvement of fifteen hospitals will result in a gradual competence building across Norway. Furthermore, MATRIX has established a support function, the Clinical Trial Engine that offers hands-on support to academic investigators around Norway. The aim is to lower the hurdles for initiating and conducting clinical trials, and thus, contribute to initiation of more decentralized clinical trials in the coming years. Finally, MATRIX will also develop new courses in clinical intervention studies to contribute to the training of the next-generation oncologists and raise the competence of all types of study personnel. A program is also planned in collaboration with the Health Innovation School.

We encourage researchers, industrial partners, patients and other interested parties to contact us to get more information and to discuss opportunities to shape the future of cancer treatment together.

Professor Åslaug Helland
Director, MATRIX



Section 1

MATRIX - A Brief Overview

About

Mission Statement

MATRIX, the Norwegian Centre for Clinical Cancer Research, is a national research centre with an over-all ambition to help patients with hard-to-treat cancers to live longer with better quality of life and to improve patient's involvement on decisions, "shared decision making". The Centre officially opened in August 2022 and will develop precision diagnostics, treatment and patient-centred care plans. Treatment will be adapted to molecular changes in tumours and to patient's preferences. Patient-centred care pathways will be developed, ensuring that the "patient's voice" is fully integrated into the entire course of treatment. MATRIX is collaborating closely with large ongoing national precision cancer medicine initiatives, national tumour groups, national initiatives in patient-centred care and the unique infrastructure for clinical trials to facilitate development and implementation of next-generation cancer care.

The Centre has partners and study sites across all health regions in Norway. Altogether, fifteen hospitals with cancer departments as well as the University of Oslo and OsloMet are partners in MATRIX.

MATRIX is one of four Centres for Clinical Treatment Research (FKB) in Norway. This funding scheme aims to establish clinical research environments, which, through outstanding research, contribute to improve outcome for Norwegian patients. The centres receive support for a total of eight years (5 + 3 years), and the primary research tasks for FKB centres are to perform clinical studies.

Photo: Thea Tønnesen, OUH

8
Years of Centre funding (2022 - 2030)

15
Hospitals across Norway included

>30
Research groups across Norway involved

750
Patients planned into clinical trials

10
PhD and reseacher positions funded directly by MATRIX

Impact

Focus on Clinical Cancer Treatment

Improved diagnostics, incl. pathology and radiology

MATRIX is developing new diagnostic methods in molecular profiling (-omics), drug sensitivity screening and immune system characterization as well as Artificial Intelligence (AI) tools for analysis of images and clinical real-world data. The Centre collaborates closely with the national network for precision diagnostics, InPreD. This enables systematic and rapid testing of the clinical benefit of diagnostic tools in new clinical trials.

More clinical studies and precise treatment

The Centre develops and tests new treatment strategies in clinical trials with an aim to contribute to an increased volume of precision cancer medicine, patient-centred care, including symptom and function improvements, as well as cell therapy studies and radiotherapy-studies, also including studies in earlier treatment lines. Patients from all of Norway should have the opportunity to participate in studies.

Patient follow-up and patient participation is central

There is a need for tools that ensure that the patient's needs and preferences are integrated into treatment decisions. MATRIX will develop and implement digital patient-centred care pathways, with evidence-based content that secures treatment and follow-up tailored to the individual patient.

Ambitions

Desired Outcomes

The Ministry of Health and Care has expressed a clear goal and wish that Norway should offer precision medicine to its citizens as part of an integrated line of treatment within the public health care system. The aim is to offer patients more precise and targeted diagnostics and treatment, while avoiding treatment without effect as well as involve patients in the decision-making processes.

MATRIX will make use of and build on already ongoing initiatives in Norway within precision cancer medicine and patient-centred care. Furthermore, MATRIX will collaborate with the ongoing EU-funded consortium: "MyPath – The Digital Solution to Patient-centred cancer care". The overall aim is to make Norway world leading in precision cancer research, treatment and care. Matrix plans to:

Build Competence and Experience

MATRIX seeks to build competence and experience with next-generation diagnostics and treatment by conducting a number of clinical trials. Patients will be recruited at hospitals all over the country.

Establish a systemic pipeline

MATRIX will establish a systemic pipeline for development of new diagnostic, treatment and digital solutions, testing in clinical trials and implementation in the health care system.

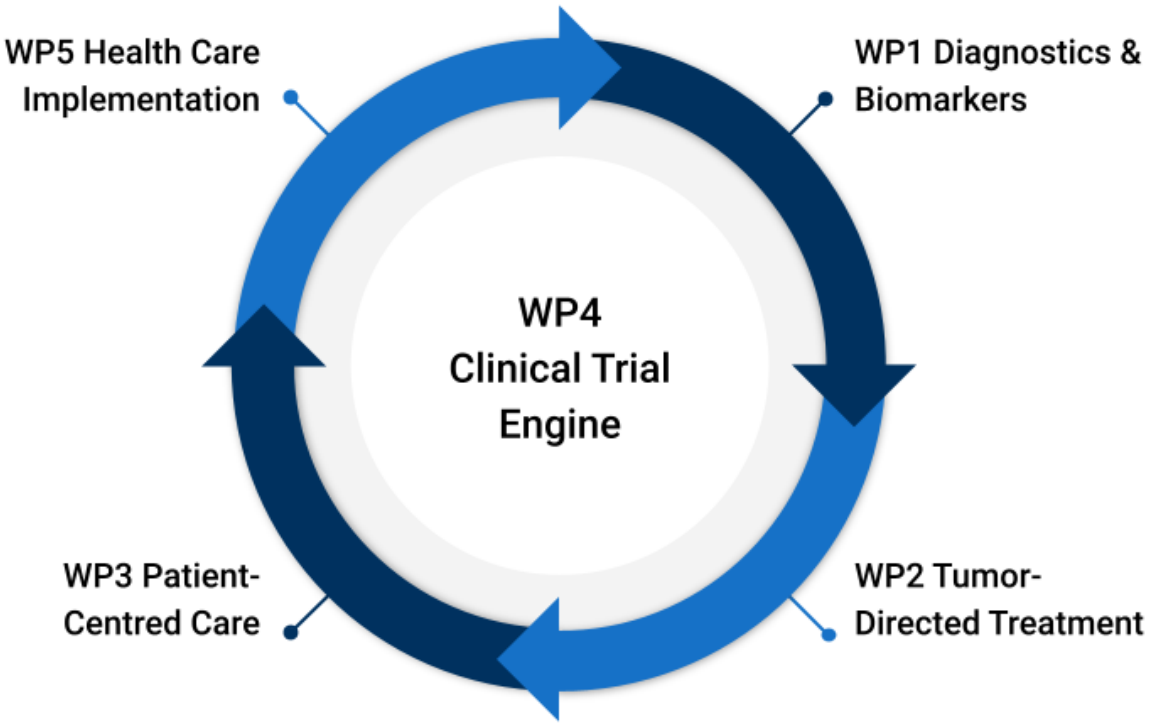
Facilitate Advanced Clinical Trials

MATRIX aims to facitilate advanced clinical trials by establishing a Clinical Trial Engine for handling regulatory, logistical and clinical needs. The Centre will also contribute to training of study personnel.

MATRIX Work Packages

A key element in modern cancer treatment is the possibility to guide patient treatment based on a detailed molecular characterization of each patient's disease – precision cancer medicine (PCM). These molecular properties may explain why patients with the same type and stage of cancer may respond differently to the same treatment. Based on our increased understanding of cancer, the goal is to offer patients more precise and targeted diagnostics and anticancer treatment, while avoiding ineffective treatment with potentially adverse effects on Quality-of-Life. An innovation for patient-centred care, digital patient-centres care pathways will be developed in collaboration between clinicians, patients, patient representatives and a computer science company.

Research taking place in MATRIX is divided into five work packages, which together will develop new personalized diagnostic and treatment options. Furthermore, patient-centred care pathways will be developed, ensuring that the "patient's voice" is fully integrated into the entire course of treatment.



WP1

Diagnostics & Biomarkers

There is great potential to improve the benefit of therapy for individual cancer patients by better patient selection through increased biological characterization of their disease, as well as by design of unique synergistic combination therapies that could give cure or overcome treatment resistance. The overall aim of WP1 is to predict treatment responses to advice optimal individualized single or poly-agent therapies for patients with hard-to-treat cancers. Deliverables include new methods, biomarkers and tools for patient stratification and follow-up.

This work package will utilize and develop the recently available technologies in InPreD, the national network for precision diagnostics, leading to implementation of next-generation diagnostics. Other-omics (including, but not limited to proteomics, flow cytometry and multiplex immunohistochemistry-based biomarkers), liquid biopsy assays as well as functional approaches such as cancer drug sensitivity screening and pharmacogenomic profiling, will be included. Furthermore, this work package will in collaboration with the CRAI Unit at OUH focus on new imaging (MRI and PET) technologies and methodologies such as multi-parametric scanning to gain decisive insight into resistance factors, such as tumour vasculature and metabolism. Including clinic-pathological and/or molecular factors and analysis by learning algorithms (machine and deep learning), is expected to aid the development of predictive/prognostic markers for treatment selection.

Work package leader Kjetil Taskén says “Work package 1 will work closely with the Norwegian Precision Medicine initiative to deliver new technologies that will facilitate the next generations of PCM trials using functional testing, imaging and modelling approaches to predict the optimal drug combinations that may elicit robust responses in individual patient”.

Photo: Lars Petter Devik, OUH

> ***We aim to deliver new technologies that will facilitate the next-generation of PCM trials using functional testing, imaging and modelling approaches.***

Kjetil Taskén, WP1 leader

WP1 - Work Package Leaders

Work package leader: Professor Kjetil Taskén, Oslo University Hospital
Work package co-leader: Professor Emiel Janssen, Stavanger University Hospital
Lead WP1a: Professor Hege Russnes, Oslo University Hospital
Lead WP1b: Kyrre E. Emblem, Oslo University Hospital

WP2

Tumor-Directed Treatment

Next-generation diagnostics, including drug sensitivity screening, patient characteristics and symptomatology, imaging and omics-data, will guide the use of new and old drugs, alone and in combinations in specified cohorts defined by tumour type and molecular profile of patients. MATRIX will facilitate the use of material and data across trials and connect clinical investigators with appropriate research groups and core facilities, allowing for use of cutting-edge-technology and expertise within immunology, genomics, proteomics, imaging and other areas. Furthermore, interventions targeting mechanisms for tumour resistance and escape during therapy will be assessed.

The aim of this work package is to increase the number of available clinical trials for patients with hard-to-treat cancers in Norway. We want to increase the number of patients included in studies, increase the number of national studies and include studies within cell therapy. An overarching goal is to increase survival by using precision cancer medicine, and we therefore want to move the precision medicine approach forward in earlier lines of treatment and not just in the final phase.

Work package leader Åslaug Helland says “We see great engagement from all centres participating, and we anticipate many investigator initiated clinical trials through the system the coming years”.

Photo: Thea Tønnesen, OUH

> ***We see great engagement from all centres participating, and we anticipate many investigator initiated clinical trials through the system the coming years.***

Åslaug Helland, WP2 leader

WP2 - Work Package Leaders

Work package leader: Professor Åslaug Helland, Oslo University Hospital
Work package co-leader: Professor Egil Blix, University Hospital North-Norway

WP3

Patient-Centred Care

Patient-centred care focuses on the patient with the disease or life after treatment has ended, and not exclusively on the specific cancer diagnosis. This aspect of cancer care applies to the entire treatment trajectory, from diagnostics, throughout treatment and beyond. The aim is to optimize and maintain quality of life, level of functioning and well-being in all phases of treatment, including survivorship care. Patient-centred care needs to complement tumour-directed treatment in order to improve current cancer treatment. This can only be achieved by tailoring the treatment and care to the individual patient. Thus, systematic information about the patient's symptoms, functions, needs and preferences must be collected from the patient. Patient Reported Outcome Measures (PROMs), information obtained directly from the patient with validated instruments, is the gold standard. However, systematic patient-centred care is still not part of routine clinical practice today.

The aim of WP3 is to develop digital patient-centred care pathways building on PROMs. Following iterative test-rounds and revisions, we will implement the pathways into routine clinical practice at centres participating in MATRIX. The digitalization and development will be conducted in collaboration with DNV Imatis, a provider of software and information technology within the healthcare industry.

The patient-centred care pathways provide patients and health care workers with a plan for individualized symptom management and care, based on patients' digital self-reports. This for example means that specific pathways for a patient with pain or nutritional problems will be generated automatically from the digital patient report. As such, the input will be used to advise on treatment and care decisions in consultations with the patient and family. Furthermore, the pathways will provide patients and health care workers with a plan for individual care and follow-up.

Direct communication between all involved is part of these pathways. Taken together, this represents a giant step forward in the provision of patient-centred cancer care. While WP3 operates on a national level, corresponding international solutions are being developed in the EU-project MyPath, also led by Stein Kaasa, OUH.

> ***Custom made digital patient-centred care pathways, implemented as an integrated part of routine cancer care, with an optimal use of health care providers, is ambitious, and it will improve the quality and efficiency of cancer care.***

Stein Kaasa, WP3 leader

WP3 - Work Package Leaders

Work package leader: Professor Stein Kaasa, Oslo University Hospital
Work package co-leader: Associate Professor Jo-Åsmund Lund, Ålesund Hospital

WP4

Clinical Trial Engine

There are several hurdles in initiating and conducting clinical trials. This is a particular challenge for academic investigators. As a result, academic trials often suffer from delayed start-up and slow patient enrolment. MATRIX is addressing this issue by establishing a Clinical Trial Engine, a joint asset with hands-on support to investigators across the country.

The Clinical Trial Engine will offer tailored services according to the needs, which may vary. In addition to make the start-up of clinical trials more efficient, we also aim to stimulate the establishment of more decentralized studies and thus in the long term, build up expertise nationally and establish a network for clinical studies in Norway.

A well-recognized obstacle for implementation of precision cancer medicine is access to employees with state-of-the-art knowledge and expertise within precision cancer medicine. There is therefore a need to raise the competence of all types of study personnel (e.g. doctors, study nurses and project coordinators). Work package 4 will in collaboration with OsloMet, develop new master courses in clinical intervention studies. Furthermore, a program in collaboration with the Health Innovation School at UiO is planned.

Work package leader Jon Amund Kyte says “We see that there is great demand for trial support and encourage investigators to contact MATRIX and to build knowhow among their study personnel through the master courses at OsloMet”.

> ***We encourage investigators to contact MATRIX and to build knowhow among their study personnel through the master courses at OsloMet.***

Amund Kyte, WP4 leader

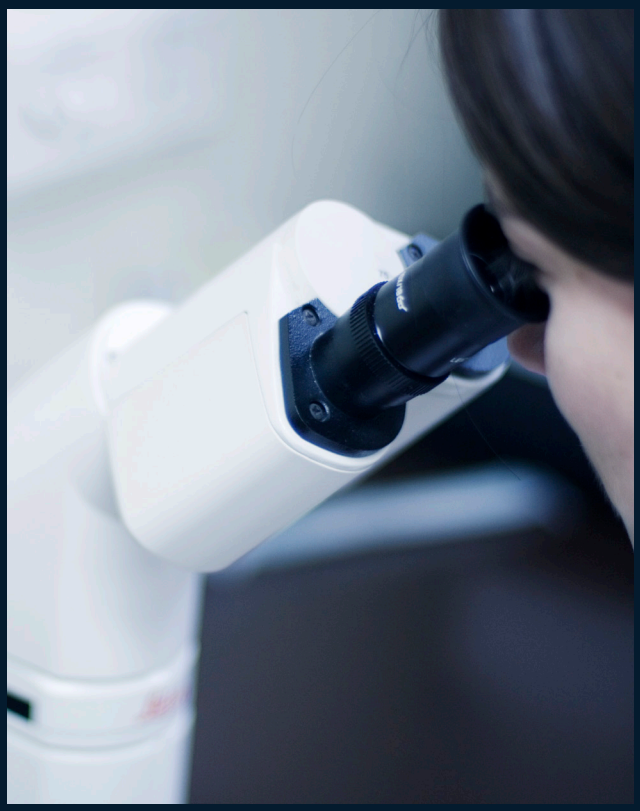


Photo: Per M. Didriksen, OUH

WP4 - Work Package Leaders

Work package leader: Jon Amund Kyte, Oslo University Hospital
Work package co-leader: Bjørnar Gilje, Stavanger University Hospital

WP5

Health Care Implementation

The work in this work package closely connects with the work of WP3. Research shows that patient-centred care with systematic use of PROMs improves the effect of anticancer treatment if provided alongside tumour-directed treatment. Furthermore, a series of randomized clinical controlled trials (RCTs) documents that patient-centred care optimizes performance status, level of functioning, symptom management, patient and caregiver satisfaction with care and facilitates the transfer of information between medical specialties and health care levels.

However, systematic patient-centred care is not an integrated part of routine clinical practice, despite the clear recommendations by important international stakeholders and organizations such as WHO, ASCO and ESMO to do so. National and international treatment guidelines explicitly recommend the collection and use of PROMs in treatment decisions. A prerequisite for this, and the aim of WP5, is that the methods for collection and use of PROMs are adapted to a clinical context, are easy to use for all end-users, and that real–time patient reported data can be accessed immediately when entered.

Work package 5 focuses on how patient-centred care with digital, individually adapted patient care pathways, can be implemented in the Norwegian healthcare system. This requires introduction of digital solutions at the hospital level that allow seamless transfer of clinical and patient-centred data to the working stations of the health care providers. WP5 will ensure that the patient-centred care pathways are available for and used in clinical practise. The implementation strategy in this work package is developed in close collaboration with work package 3.

A number of important preconditions apply: Contact with the local ICT departments must be established to ensure a user-friendly interface for all end-users as well as seamless transfer of real-time PROMs-data from the patient-data. Moreover, all procedures regarding transfer, storage, management and use of data must comply with Good Clinical Practice, confidentiality, legal and ethical requirements. Furthermore, standard operating procedures (SOPs) for the collection and storage of data must be developed to secure that the methods are GDPR compliant and aligned with the FAIR (Findable, Accessible, Interoperable and Reusable) principles. A collaboration with the Clinical Trial Unit at OUS will be established.

Hjermstad says “To succeed with the implementation, we will work together with WP3 in the iterative test-rounds of the pathways, and provide timely data that are necessary for adjustments of the pathways. WP5 will nominate designated personnel at the different centers as champions to anchor the implementation among clinical staff. This includes training of local personnel in data collection and handling”.

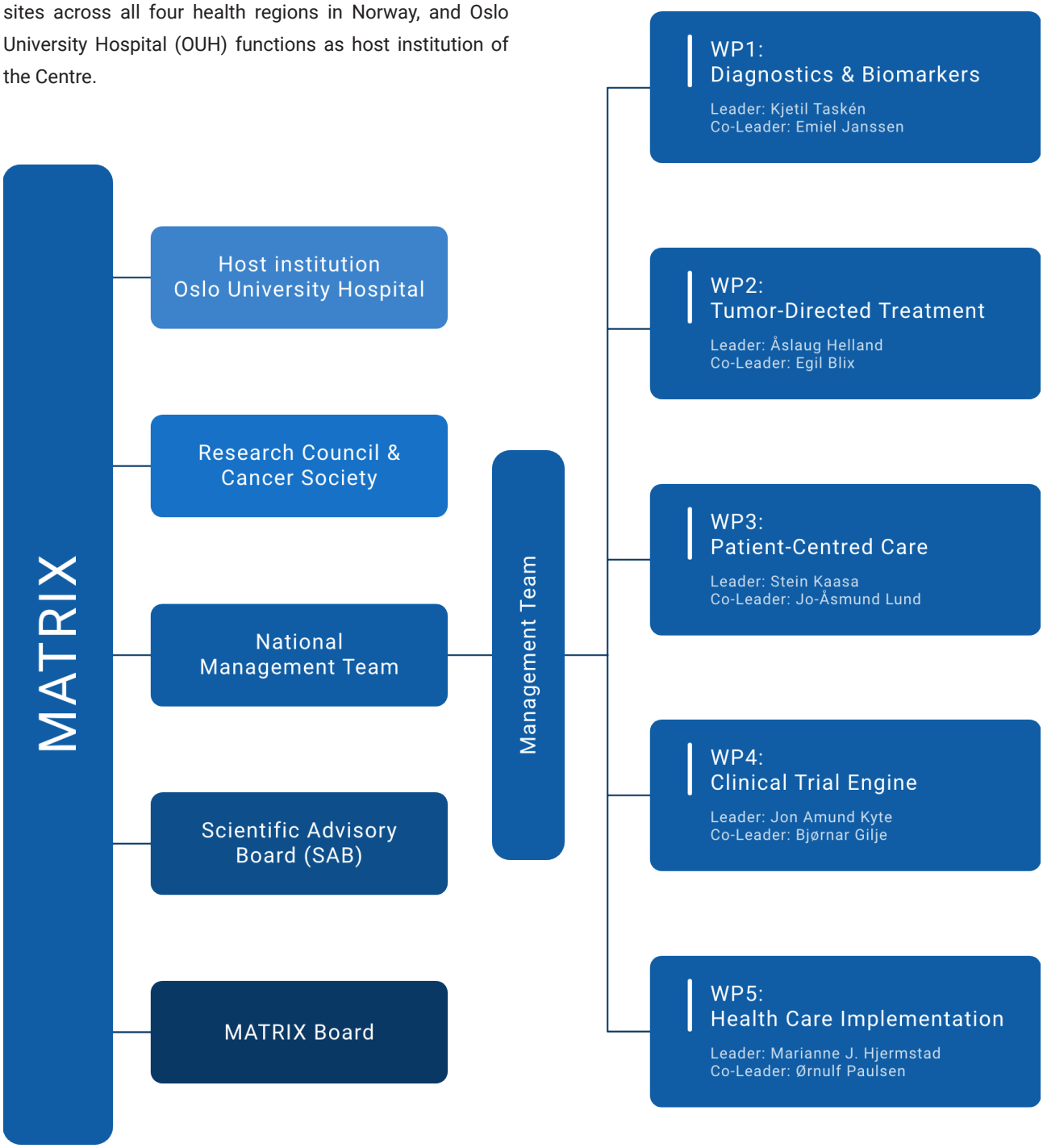
> ***We will work together with WP3 in the iterative test-rounds of the pathways, and provide timely data that are necessary for adjustments of the pathways.***
>
> Marianne J. Hjermstad, WP5 leader

WP5 - Work Package Leaders

Work package leader: Marianne J. Hjermstad, Oslo University Hospital
Work package co-leader: Ørnulf Paulsen, Telemark Hospital

Organizational Structure

The Norwegian Centre for Clinical Cancer Research is funded by the Research Council of Norway and the Norwegian Cancer Society. MATRIX has partners and study sites across all four health regions in Norway, and Oslo University Hospital (OUH) functions as host institution of the Centre.



Centre Management Team

MATRIX is coordinated and managed from OUH. The Centre Management Team takes care of the day-to-day running of MATRIX and consists of:

Director Åslaug Helland

MD, PhD, Professor, Research leader of Oslo University Hospital Comprehensive Cancer Centre & Head of IMPRESS-Norway

Deputy Director Stein Kaasa

MD, PhD, Professor, Head Department of Oncology, OUH

Professor Kjetil Taskén

MD, PhD, Head of Institute for Cancer Research, OUH

Jon Amund Kyte

MD, PhD, Head Department of Clinical Cancer Research, OUH

Elisa Bjørgo

PhD, Administrative Manager MATRIX

Extended National Management Team

The Extended National Management Team coordinates activities in the five work packages in MATRIX and ensures national participation and engagement. The members of this team represent all four health regions in Norway. Among the tasks of the national management team is assessment of trial proposals and approving initiation of new clinical trials within the Centre.

The National Management Team currently consist of:

- Åslaug Helland, Oslo University Hospital
- Stein Kaasa, Oslo University Hospital
- Kjetil Taskén, Oslo University Hospital
- Jon Amund Kyte, Oslo University Hospital
- Hege G. Russnes, Oslo University Hospital
- Kyrre E. Emblem, Oslo University Hospital
- Marianne J. Hjermstad, Oslo University Hospital
- Egil Blix, University Hospital North-Norway
- Åsmund Flobak, St. Olav University Hospital
- Line Bjørge, Haukeland University Hospital
- Bjørnar Gilje, Stavanger University Hospital
- Emiel Janssen, Stavanger University Hospital
- Jo-Åsmund Lund, Ålesund Hospital
- Ørnulf Paulsen, Telemark Hospital

MATRIX-site: St.Olavs Hosptial (OUH), Trondheim. Photo: Geir O. Johansen

MATRIX Board

The Board is in collaboration with the Centre Management, responsible for the Centre's overall coordination and progress. Furthermore, the Board must ensure that the interactions between the project management and collaboration partners works well.

The chair of the MATRIX Board is Sigbjørn Smeland, Head of the Divison of Cancer Medicine at Oslo University Hospital. All consortium participants can appoint one member each to the Board. In addition, relevant patient organizations are also represented. Furthermore, the Centre director and deputy director participate in board meetings.

Scientific Advisory Board

The main mission of the MATRIX Scientific Advisory Board (SAB) is to offer academic and strategic advice as well as benchmark the performance of the Centre internationally. The SAB consists of internationally renowned clinicians and researchers with expertise in precision medicine and cancer research. MATRIX will appoint 5-6 international members to the SAB in 2023.

Consortium Participants

MATRIX consists of altogether seventeen consortium participants, including hospitals that represent all the four health regions in Norway in addition to the University of Oslo and Oslo Metropolitan University.

Our national clinical network consists of fifteen hospitals with cancer departments that are all partners in Matrix and are located all over the country. The participation of hospitals in all health regions will facilitate that Norwegian patients get the opportunity to participate in studies as close to their own homes as possible.

Helse Nord:

University Hospital of North Norway
Nordland Hospital

Helse Midt-Norge:

St. Olav University Hosptial
Levanger Hospital
Ålesund Hospital

Helse Vest:

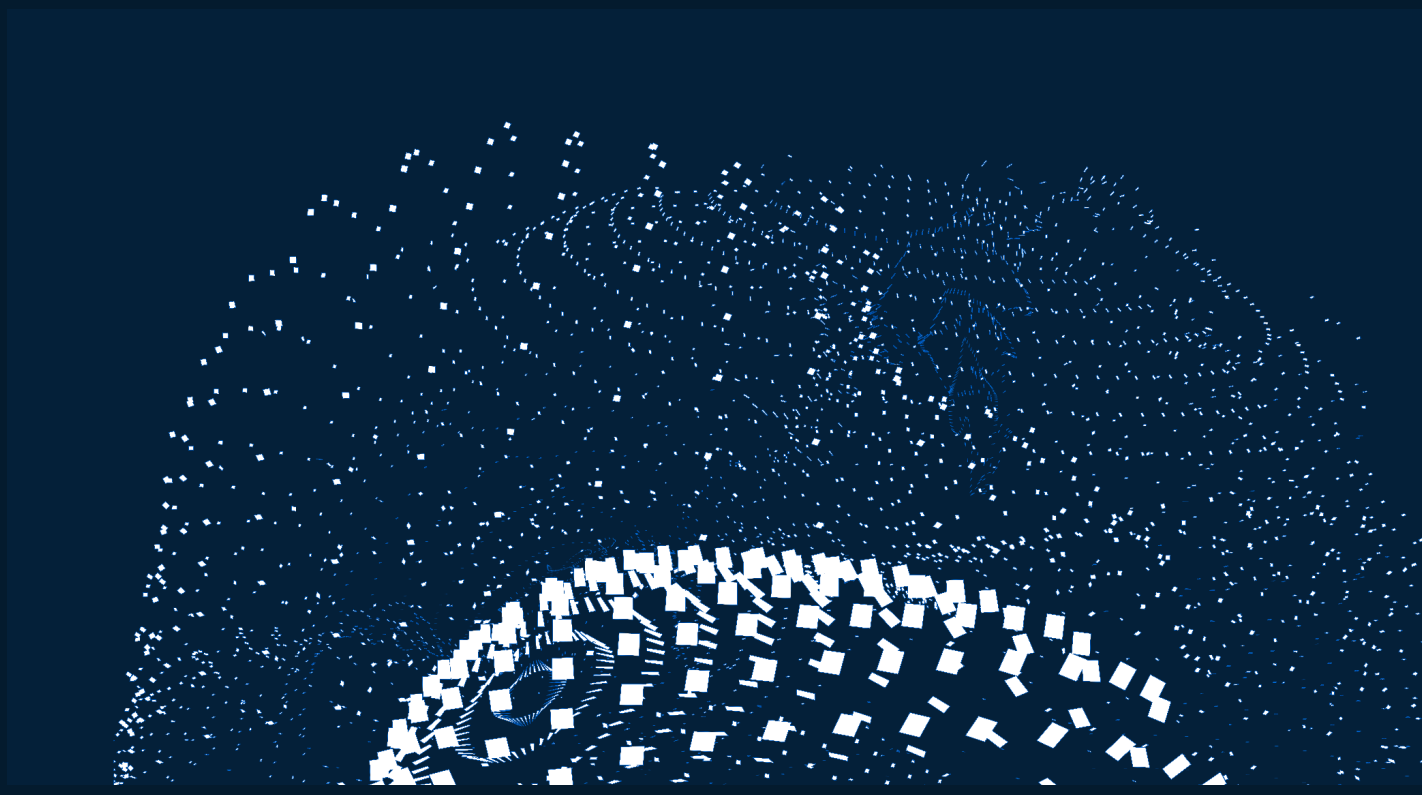
Haukeland University Hospital
Stavanger University Hospital
Førde Hospital
Haugesund Hospital

Helse Sør-Øst:

Oslo University Hospital
(Management & Coordination)
Innlandet Hospital
Østfold Hospital
Telemark Hospital
Vestfold Hospital
Sørlandet Hospital

Universities:

University of Oslo
OsloMet



Section 2

MATRIX - Highlights 2022

From left: Anne Kjersti Fahlvik (RCN), Ingrid Stenstadvold Ross (Norwegian Cancer Society), Åslaug Helland & Stein Kaasa. Photo: Kjetil Taskén, OUH

MATRIX Official Opening

The official opening of MATRIX took place on August 23-24. More than 70 participants from across Norway gathered at Gardermoen for this two-day kick-off event, both researchers and clinicians involved in MATRIX as well as stakeholders from the Research Council of Norway and the Norwegian Cancer Society. The main purpose of the event was to share detailed information about the Centre, get to know each other better as well as start planning activities in each of the five work packages.

In connection to the kick-off event, MATRIX in collaboration with the national network for precision diagnostics (InPreD) and the Centre for Precision Cancer Medicine (SEPREK), OUH organized a full day national course entitled “Extended molecular analyzes in advanced cancer. How and when is it useful to use large gene panel analyses?” Altogether, this hybrid course gathered 130 participants.

Photo: Lars Petter Devik, OUH

Clinical Trials

Research Centres for Clinical Treatment (FKBs) are to carry out frontline research to improve treatment for Norwegian patients. One of MATRIX's primary research tasks is therefore to conduct clinical trials open for patients with hard-to-treat cancers. Our national clinical network consists of fifteen hospitals with cancer departments that represent all the four health regions in Norway.

Principal investigators from MATRIX partner institutions can contact the Centre to register new trials or ask for support from the Clinical Trial Engine via an electronic registration form opened in the fall 2022. Potential new trials connected to MATRIX must aim for patient benefit, either by offering precision cancer medicine, improved diagnostics or because it will extend the expected lifespan or improve the quality of life of the patients. Furthermore, trials connected to MATRIX must have a Norwegian sponsor. The extended national management team have monthly meetings to assess trial proposals and approve initiation of new clinical trials within MATRIX.

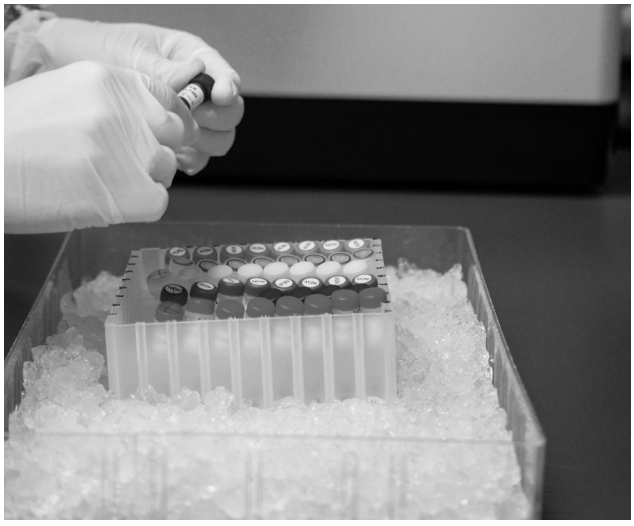


Photo: Lars Petter Devik, OUH

It is important that patients throughout Norway are included in the clinical trials, and MATRIX therefore aims to identify principal investigators locally and have study sites around Norway. In the fall 2022, MATRIX has decided to support two clinical trials:

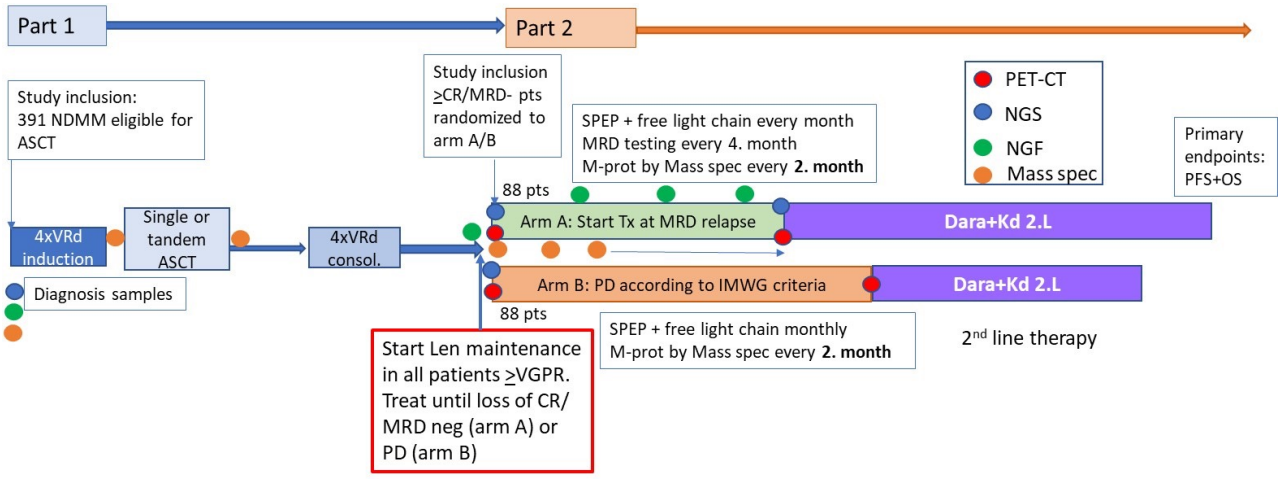


Illustration of the study design REMNANT by Anne-Marie Rasmussen, OUH

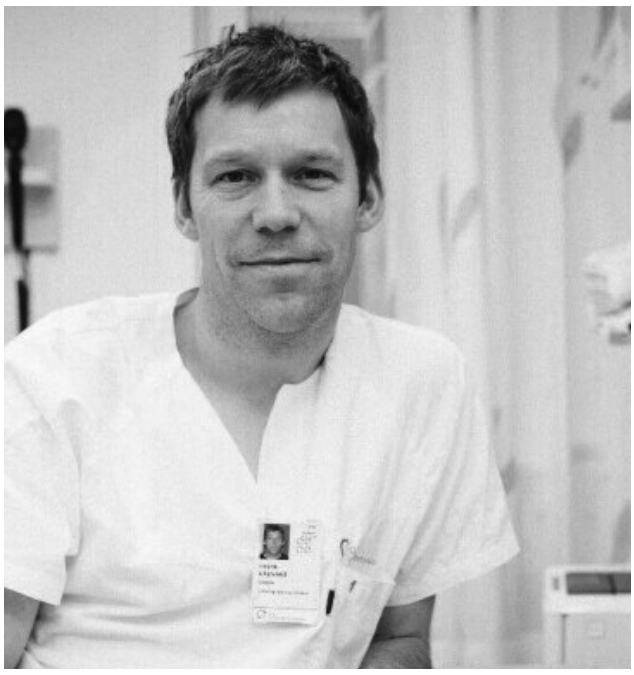
REMNANT

REMNANT is a national phase 2/3 trial for multiple myeloma patients. In addition, one hospital in Lithuania is participating in the study. The trial involves thirteen of the hospitals that are partners in MATRIX, and 400 newly diagnosed myeloma patients are planned included in the trial over a 4 years period (2020 – 2024). The study will follow patients until they progress on second line treatment which means 10-12 years from enrolment started. REMNANT, led by researchers from the Oslo Myeloma Centre at OUH, include newly diagnosed myeloma patients. Patients receive standard first-line treatment in Part 1 of the study. Those patients, who show a deep response to treatment measured by the absence of minimal residual disease (MRD), subsequently move on to the phase 3 part of the study. These patients are randomized to receive relapse treatment according to current treatment guidelines for myeloma , or to receive treatment in the event of earlier and minor signs of recurrence (become MRD+). The aim of the study is to discover whether very early relapse treatment affects the long-term prognosis.

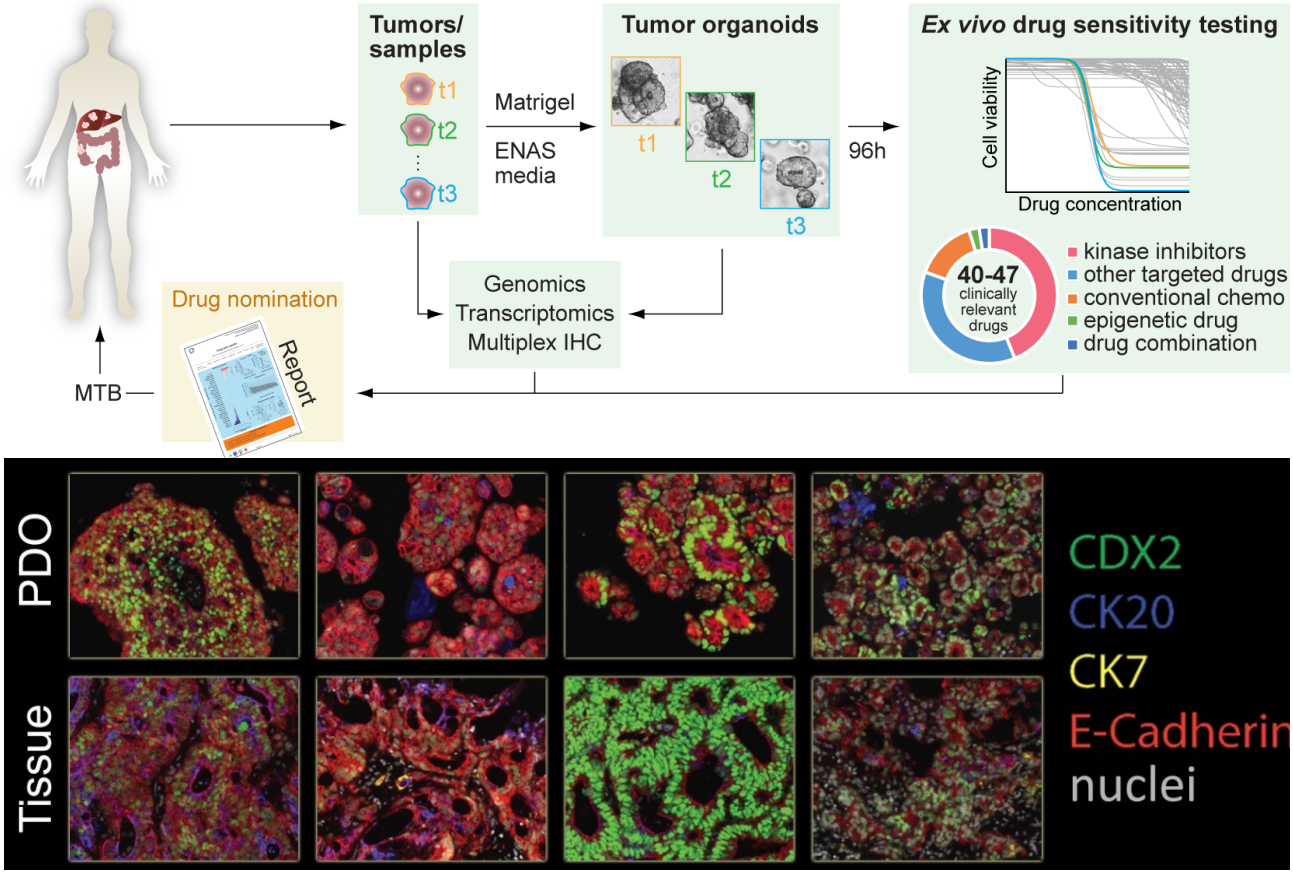
MATRIX supports inclusion of 50 additional patients in this study with a per-patient contribution to the MATRIX hospitals where the patients are treated.

PI of the study, Fredrik Schjesvold, says ”We anticipate that the REMNANT study will answer the question whether we should start relapse treatment earlier than we do today and how this will affect the outcome. As of today, 265 patients have been included in the Part 1 (phase 2) and 71 patients are now enrolled in Part 2 (phase III) where they will be followed for relapse (arm B) or become MRD+ (arm A). Data from this study may change international as well as national guidelines for when to start relapse treatment. No other study in the myeloma community are comparing starting relapse treatment early vs later”.

> ***We anticipate that the REMNANT study will answer the question whether we should start relapse treatment earlier than we do today and how this will affect the outcome***
>
> PI Fredrik Schjesvold



PI for the REMNANT study and Head of Oslo Myeloma Center at OUH Fredrik Schjesvold. Photo: Øystein Horgmo, UiO.



TOP: Illustration of the EVIDENT workflow. BOTTOM: Morphological and protein expression similarities between CRC liver metastases and corresponding organoids from four patients. Credits: PI Ragnhild A. Lothe, Genetics Group, Institute for Cancer Research (IRC), OUH

EVIDENT

EVIDENT is an open-label, single arm interventional phase 2 study of *ex vivo* drug sensitivity testing in metastatic colorectal cancer at Oslo University Hospital. Based on a combination of cancer molecular profiling and drug sensitivity testing of personal *ex vivo* cancer models (tumor organoids), we will expand the oncologic treatment repertoire and improve the selection of treatments to individual patients (Figure a). The study is conducted in the context of tumor heterogeneity and more than two metastatic tumors are cultured and investigated per patient. The trial is headed by Tormod K. Guren (Dept. Oncology) and Ragnhild A. Lothe (Inst. Cancer Research). Patient inclusion started in 2022 and will continue until the end of 2025.

A crucial aspect of this study is the experimental *ex vivo* diagnostics, involving culturing of cancer cells from tumor tissues under conditions fostering formation of 3D organoids that resemble the architecture of the patient's tumor (Figure b). The organoids are subsequently exposed to many different drugs or drug combinations at several concentrations each, providing robust read-outs of drug sensitivities. These pharmacological data are complemented with multi-level molecular profiling of the organoids and corresponding tumor tissue, including for all known biomarkers of treatment response. A combined pharmacogenomics profile of all tumor samples and organoids per patient is presented in a report to the molecular tumor board.

The molecular tumor board provides recommendations for *ex vivo*-guided treatment in the third line. The study has approval to intervene with 23 of the drugs in the screen, most of which are experimental treatments for metastatic colorectal cancer. Treatment nomination criteria include comparisons with a large reference of *ex vivo* drug sensitivities from an established living biobank of metastatic colorectal cancers. Only drugs with outlier sensitivity relative to this reference are nominated. In addition, evaluation of multiple samples from each patient reduces the risk of nominating drugs with heterogeneous activities across lesions and tumor subclones. This design puts EVIDENT at the international forefront of functional precision oncology research.

MATRIX supports EVIDENT with a per-patient contribution for *ex vivo* diagnostics of up to 150 patients and for experimental treatment of up to 20 patients.

Professor Ragnhild Lothe, PI of the experimental diagnostics, says: «Only a small proportion of colorectal cancers have clinically "actionable" biomarkers, and even in the biomarker-selected populations, only a third of the patients typically respond to the treatment. The functional approach implemented in EVIDENT has potential to improve the benefit of precision oncology in patients with colorectal cancer, and represents a next-generation of trial designs. We are pleased to be supported by MATRIX and to see interest in the study across Norway. Patients from other hospitals and health regions have already been included on an ad hoc basis, but we hope to set up a larger national study if EVIDENT can support a clinical benefit of this functional approach. We also want to transfer the know-how and expand the pharmacogenomics platform to other indications. We are therefore happy to collaborate with Kjetil Taskén's group and Dept. Gynecology on ovarian cancer».

> ***The functional approach implemented in EVIDENT has potential to improve the benefit of precision oncology in patients with colorectal cancer, and represents a next-generation of trial designs.***
>
> PI Ragnhild Lothe

Two researchers that have been instrumental in the establishment of the functional oncology platform during the last five years are Associate professor Anita Sveen in computational oncology and research scientist Kushtrim Kryeziu in preclinical functional oncology.

Read more about the EVIDENT study:

- Forskningen gir Oliver Håp - Kreftforeningen
- Nå kan vi kopiere kreftsvulster i laboratoriet og se hvilken behandling som funker best - Aftenposten

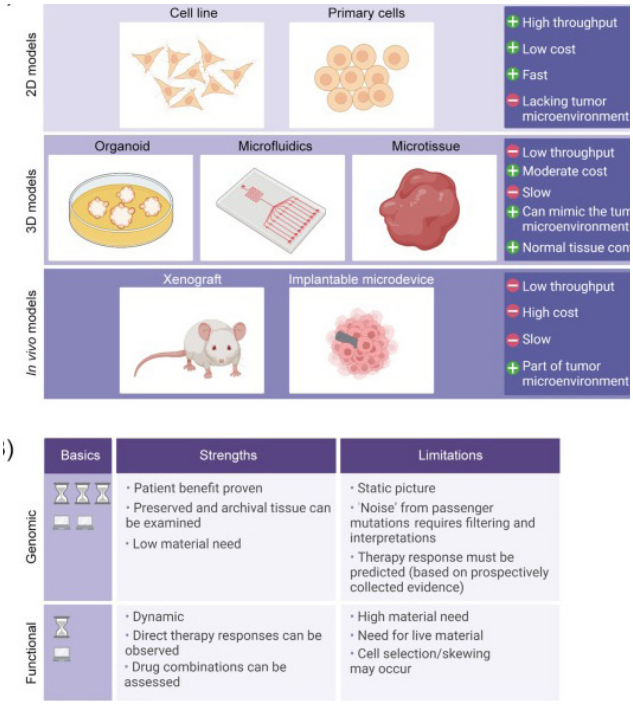
Researcher Kushtrim Kryeziu, Genetics Group, ICR, OUH.

Associate Professor Anita Sveen, Genetics Group, ICR, OUH.

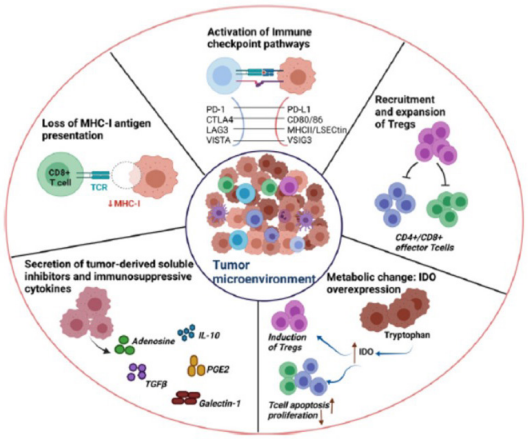
MATRIX Scientific Publications

Cancer researchers involved in MATRIX publish data from their projects in renowned journals every year. In 2022, examples include a description of the precision cancer medicine implementation initiative for Norway published in Nature Medicine in May and publication of data from the ALICE trial, led by Jon Amund Kyte, in Nature Medicine in December.

Although MATRIX opened in August 2022, the first two publications affiliated with the Centre, were published already in the fall:



Ex vivo and *in vivo* models for functional precision medicine. Figure from the publication.



Overview of tumor immune evasion mechanisms focusing on T cell-tumor interaction. Figure from the publication.

The first MATRIX publication entitled *"Functional precision cancer medicine: drug sensitivity screening enabled by cell culture models"* resulted from a collaboration between researchers at St. Olav's Hospital in Trondheim and at Oslo University Hospital:

Flobak Å, Skånland SS, Hovig E, Taskén K and Russnes H Trends Pharmacol. Sci., DOI: 10.1016/j.tips.2022.08.009

A MATRIX-affiliated review entitled *"Immunoregulatory signal networks and tumor immune evasion mechanisms: insights into therapeutic targets and agents in clinical development"* was published in October 2022:

Wei Q & Taskén K, Biochem J., DOI: 10.1042/BCJ20210233

Institute for Cancer Research, Oslo University Hospital. Photo: Thea Tønnesen, OUH

Funding Successes

There is a clear expectation that research environments in MATRIX should be able to attract additional funding from both national and international sources.

The Norwegian Cancer Society in November 2022 announced that 186 million NOK are allocated to 25 new projects from 2023. Five of the funded projects (4 at OUH and 1 at Stavanger University Hospital) were awarded 39 million NOK and will be led by research environments involved in MATRIX.

KLINBEFORSK, the national program for clinical treatment research in the specialist health service, is another important funding source for research environments in MATRIX. In 2022, Jon Amund Kyte, leader of work package 4 in MATRIX, was awarded 20 million NOK for a project entitled “CAR-T cell therapy targeting Ewing Sarcoma”. This study is well in line with the Centre’s aim to extend the lives and improve the quality of life of patients with hard-to-treat cancers, and the study will have a broad national involvement. Kyte and his team members have developed a specific CAR that targets the protein STEAP1. This protein is expressed in about 90% of all prostate cancers and subsets of other cancers, including non-small cell lung cancer, bladder cancer, Ewing sarcoma, breast cancer, pancreatic cancer, glioblastoma, and ovarian cancer. Moreover, STEAP1 is highly expressed in metastatic disease, and the STEAP1 CAR-T therefore offers hope for a potent therapy for patients without other effective treatment options. This project, now funded by KLINBEFORSK, focuses on cell therapy for patients with Ewing sarcoma, a rare form of cancer that most often occurs in the skeleton. Ewing sarcoma occurs most often in children and young adults (5-25 years).

MATRIX-affiliated researchers have also been successful in EU-calls in 2022 and the projects below are connected to MATRIX and have been initiated in 2022 or are in the process starting up:

MyPath, funded over EU's Horizon Europe programme, officially started 1 September 2022. This 5-year project is coordinated by Stein Kaasa, deputy director of MATRIX, and 6.5 million Euro have been earmarked to develop and implement innovative patient-centred care pathways in a digital solution. The aim is that these solutions will be applicable to all cancer patients irrespective of treatment intention and stage of disease. MyPath collaborates closely with work packages 3 and 5 in MATRIX.

PCM4EU, Personalised Cancer Medicine for all EU citizens, is a project under the Europe's Beating Cancer Plan by EU4Health that officially started 1 January 2023. The project is about facilitating implementation of molecular cancer diagnostics for precision oncology such as DRUP-like clinical trials and has been awarded 3 million Euros over two years. PCM4EU is coordinated by Hans Gelderblom at the Leiden University Medical Centre (LUMC), the Netherlands, and several MATRIX-affiliated PIs at Oslo University Hospital have key roles, including Kjetil Taskén, Åslaug Helland, Hege Russnes and Eivind Hovig.

PRIME-ROSE, Precision Cancer Medicine Repurposing System Using Pragmatic Clinical Trials, is a new project with a planned start-up in July 2023. This 5-year project is awarded 6 million Euros by EU's Horizon Europe Mission on Cancer and will be coordinated by Kjetil Taskén, Oslo University Hospital.

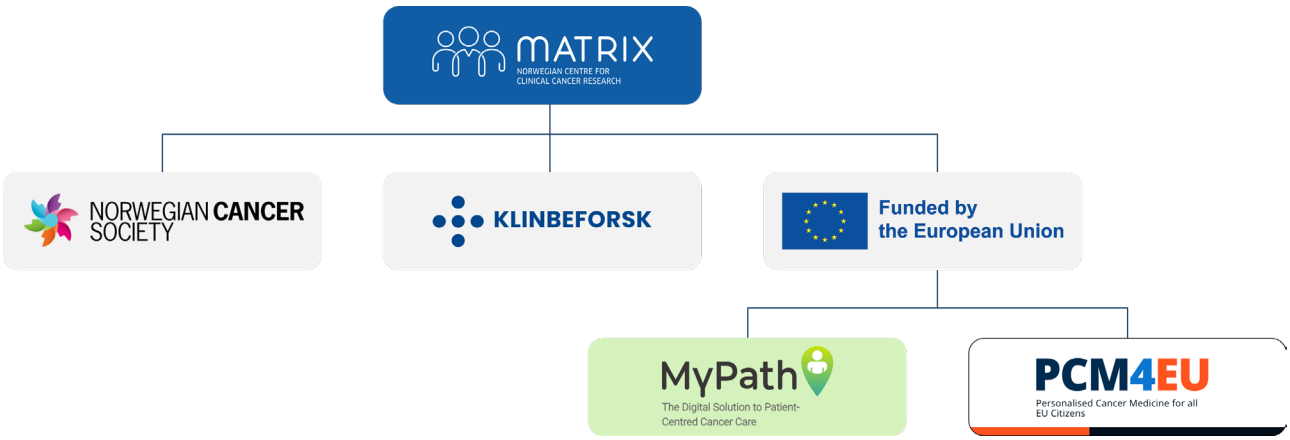
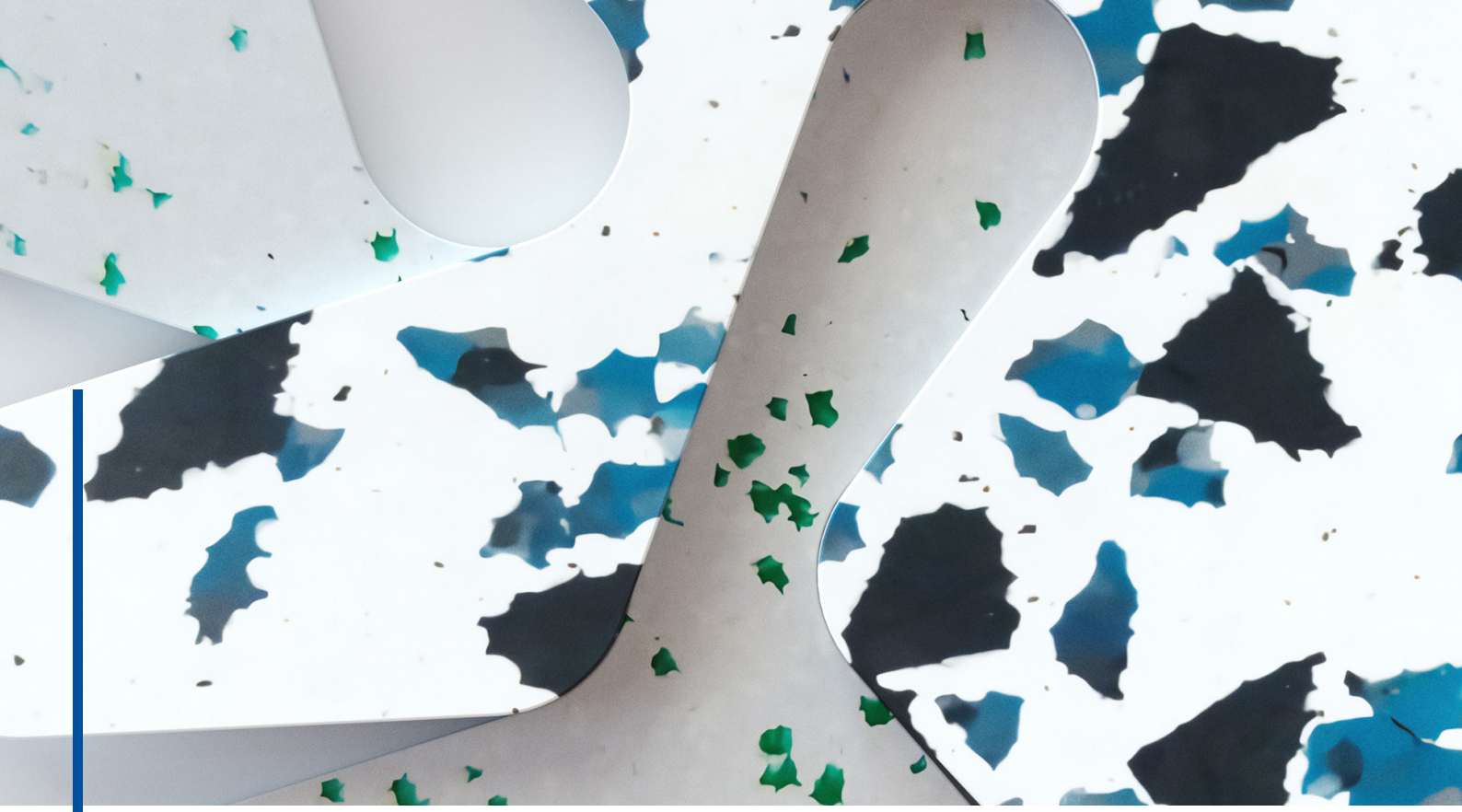


Illustration: Funding sources for new projects in 2022 secured by MATRIX-affiliated researches.



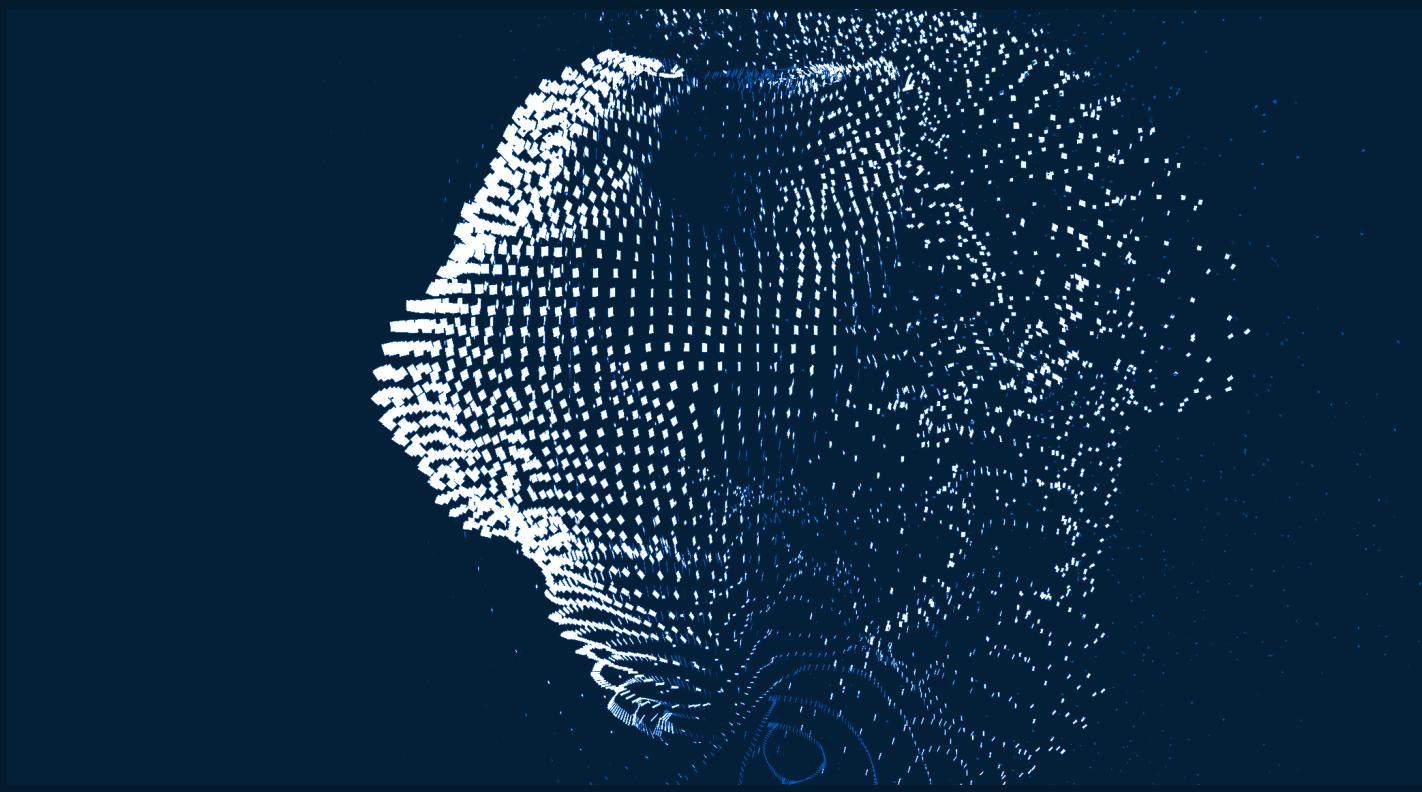
Centres for Clinical Treatment Research. Photo: Resarch Council of Norway (RCN)

FKB Forum

In 2022, three new Research Centres for Clinical Treatment (FKBs) were established and Norway now have four such Centres:

- Neuro-SysMed, a Centre for clinical treatment research on neurological diseases
- REMEDY, Research Centre for treatment in rheumatology and musculoskeletal diseases
- NorHead, Norwegian Centre for Headache Research
- MATRIX, Norwegian Centre for Clinical Cancer Research

MATRIX together with the Research Council of Norway on February 6 2023 organized the first meeting point for these four Centres. The event took place in the premises of the Research Council, and during this one-day event, each Centre presented their set-up and research plans. Furthermore, several topics of joint interest was discussed, including how to best incorporate user participation in our work, establishment of Scientific Advisory Boards and how the four Centres can collaborate in the coming years.



Section 3

International Collaboration

International Collaboration

MATRIX-site: Oslo University Hospital (OUH), Radium Hospital. Photo: Helse Sør-Øst

All MATRIX work package leaders already have well-established international networks and are all part of larger international consortia. MATRIX is part of a newly built Norwegian ecosystem within the field of precision cancer medicine (PCM) that includes InPreD, IMPRESS-Norway and CONNECT. Our research environments also collaborate closely with PCM environments abroad, in particular in the Netherlands (DRUP), Finland (FINPROVE), Sweden (MEGALiT) and Denmark (ProTarget). Furthermore, good, international networks have been built up over years also within patient-centred care. Some of the most important international collaborations are highlighted below.

Dutch-Nordic Alliance for Precision Cancer Medicine: The Nordic countries have all established national clinical precision cancer trials modelled on the successful DRUP trial in the Netherlands. In November 2021, a Memorandum of Understanding was signed by the leaders of the DRUP and the Nordic Precision Medicine Trial Network (ProTarget in Denmark, MEGALiT in Sweden, IMPRESS-Norway, and FIN-PROVE in Finland). Together, the partners collaborate to harmonize study designs, define similar clinical endpoints and share data. Study cohorts are opened in parallel in all the Nordic trials, and opened cohorts will be shared in a collaborative database, including open and closed DRUP-cohorts. This collaboration allows for more rapid gathering of evidence on very rare combinations of diagnosis, mutation, and treatment.

Nordic Trial Alliance: The Nordic Trial Alliance (NTA) aims to enhance Nordic cooperation on clinical trials. MATRIX-affiliated researchers have in collaboration with colleagues in Finland, Sweden and Denmarck received NTA funding to strengthen the precision cancer medicine collaboration within the Nordic region.

Precision Cancer Medicine for Europe: The PCM4EU project is funded under the Europe's Beating Cancer Plan by EU4Health and officially opened in January 2023. The project, coordinated from the Netherlands, is about

facilitating implementation of molecular cancer diagnostics for precision oncology such as DRUP-like clinical trials, and is thus building on the already established collaboration between the Netherlands and the Nordic countries. The planned work is divided into six work packages (WPs). WP2 is about mapping and facilitating use of molecular cancer diagnostics, and WP3 is about precision oncology and promoting and help starting more national DRUP-like clinical trials in European countries. WP4 is focusing on implementing precision oncology and standards for use in diagnostics and molecular tumour boards (MTBs) in European countries. Furthermore, WP5 is about equitable and cross-border access, whereas WP6 is focusing on training of the next generation of oncologists. PCM4EU has also incorporated a patient engagement strategy to ensure access to molecular-based clinical trials and will build a data aggregation platform. Partners from altogether 15 countries collaborate in this project, and MATRIX-affiliated researchers lead three of the work packages (Hege Russnes (WP2), Åslaug Helland (WP3) and Kjetil Taskén (WP4)). Furthermore, another EU-project (PRIME-ROSE, Precision Cancer Medicine Repurposing System Using Pragmatic Clinical Trials) coordinated by Kjetil Taskén, is currently finalizing contract negotiations and will open before the summer 2023.

MyPath: This 5-year project funded by EU's Horizon Europe programme, aims to develop a novel digital solution, MyPath, consisting of electronic patient-centred care pathways custom-made for each individual patient, including real-time communication of symptoms and care preferences. The solution will be implemented systematically in cancer care by investigating, improving, and adapting to organisational contexts of cancer centres across Europe. MyPath is coordinated by MATRIX deputy director Stein Kaasa and includes 15 partners from research, clinics, SMEs and Non-Governmental Organisations from altogether eight European countries. The international work planned in MyPath is tightly connected to the national tasks planned for WP3 and 5 in MATRIX.

European Palliative Care Research Centre (PCR): PCR is a European research centre consisting of 18 international and 8 national collaborating centres that plans and conducts international multicentre studies within palliative care, focusing on pain, cachexia and health care services. Stein Kaasa, OUH, is the director of the PRC.

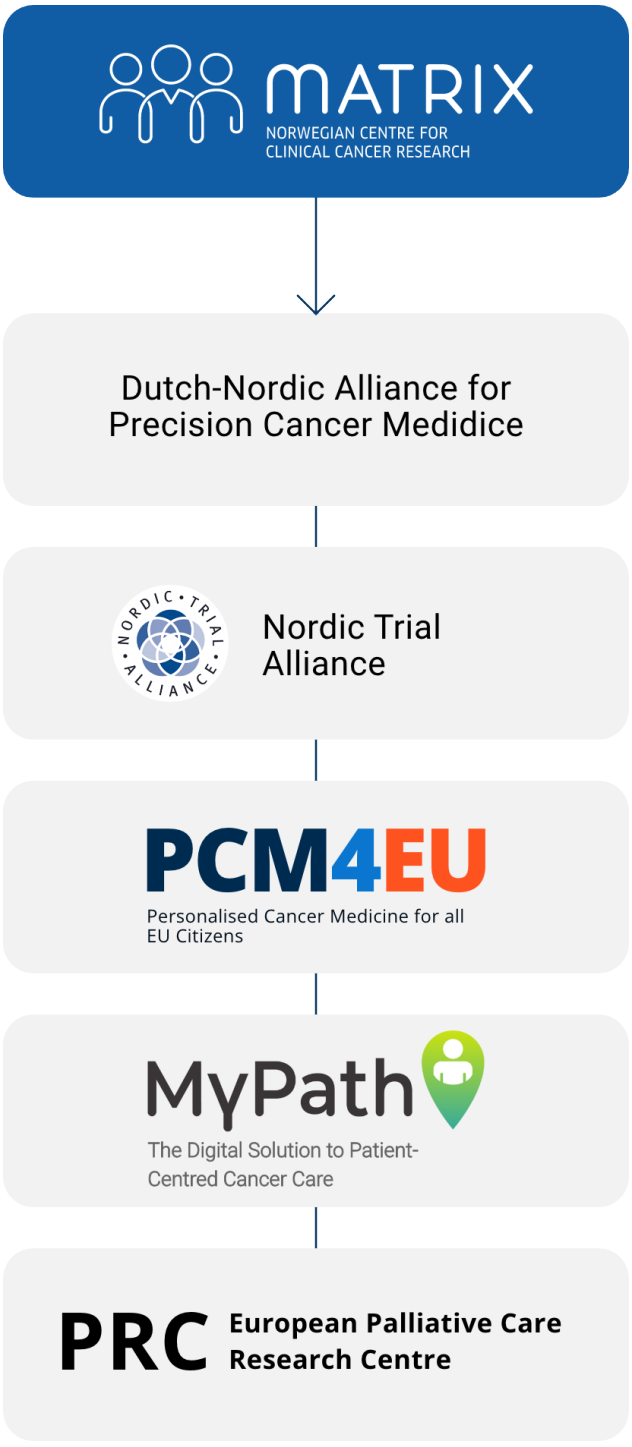
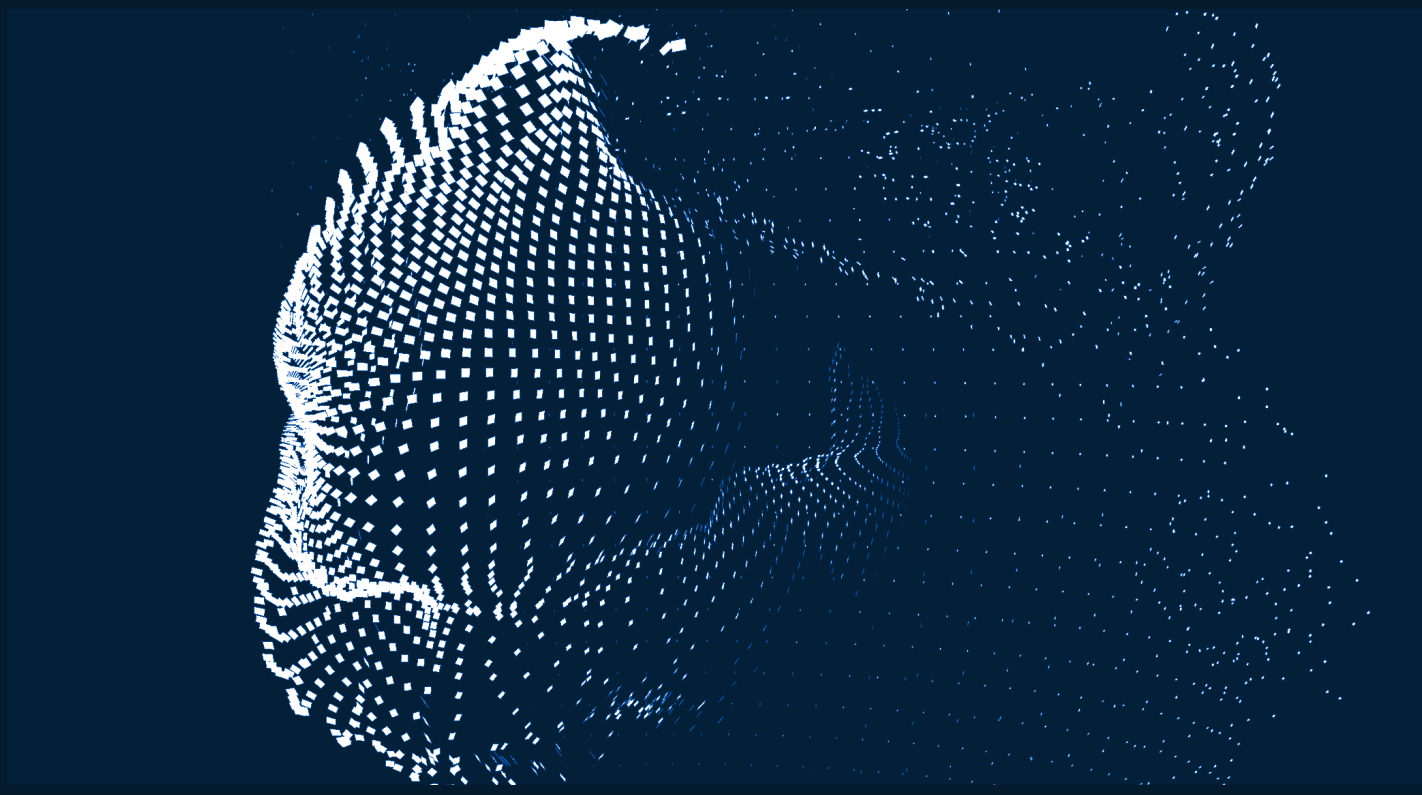


Illustration: Ongoing European Collaborations

Photo: Thea Tønnesen, OUH



Section 4

MATRIX Recruitment

Recruitment

New MATRIX Staff

MATRIX consists of research environments at 17 partner institutions across Norway, and the affiliated research groups are already operative. In particular, PhD students and postdocs affiliated with MATRIX groups (funded elsewhere) and involved in clinical trials, are already included in MATRIX activities and such involvement is planned throughout the project period. In addition, ten PhD and researcher positions are directly funded by MATRIX to make sure specific tasks can be fulfilled.

Since the opening of MATRIX in August 2022, the following have been recruited:

- Elisa Bjørgo, Administrative Manager
- Sigrid Skånland, Functional Precision Cancer Researcher, OUH (WP1)
- Alen Brkic, WP3 & WP5 Researcher
- Qian Wei, Precision Immune-Oncology Researcher, OUH (WP1)
- Martin Røvang, Software Developer / Researcher (WP1)

Elisa Bjørgo

Elisa joined MATRIX in August 2022 as administrative manager. She was recruited from Centre for Molecular Medicine Norway (NCMM), the Norwegian node in the Nordic EMBL Partnership for molecular medicine, where she worked both as Head of Office and as Head of Section for research strategy, communication and international relations. In addition to a broad administrative background, Elisa has a PhD from the University in Bergen and worked 10 years as a researcher at the University of Oslo before joining NCMM.

Sigrid Skånland

Sigrid joined MATRIX in January 2023 and is hired as a researcher in functional precision cancer medicine at OUH. Sigrid has a PhD from the University of Oslo, followed by an EMBO fellowship at the Goethe University School of Medicine in Frankfurt, Germany. In recent years, she has been a project leader at OUH, focusing on the development of functional precision medicine for hematologic malignancies. In the fall 2022, Sigrid spent six months at the Sloan Kettering Cancer Centre in New York as a guest researcher before returning to Oslo and joining MATRIX.

Alen Brkic

Alen joined MATRIX and OUH in January 2023 as a researcher connected to work packages 3 and 5. Alen is a medical doctor, has a master degree in public health, and plans to defend his PhD thesis in June 2023. Alen was externally funded by Sørlandet Hospital, Kristiansand, while conducting a PhD in Medicine and Health Sciences at NTNU, Trondheim.

Qian Wei

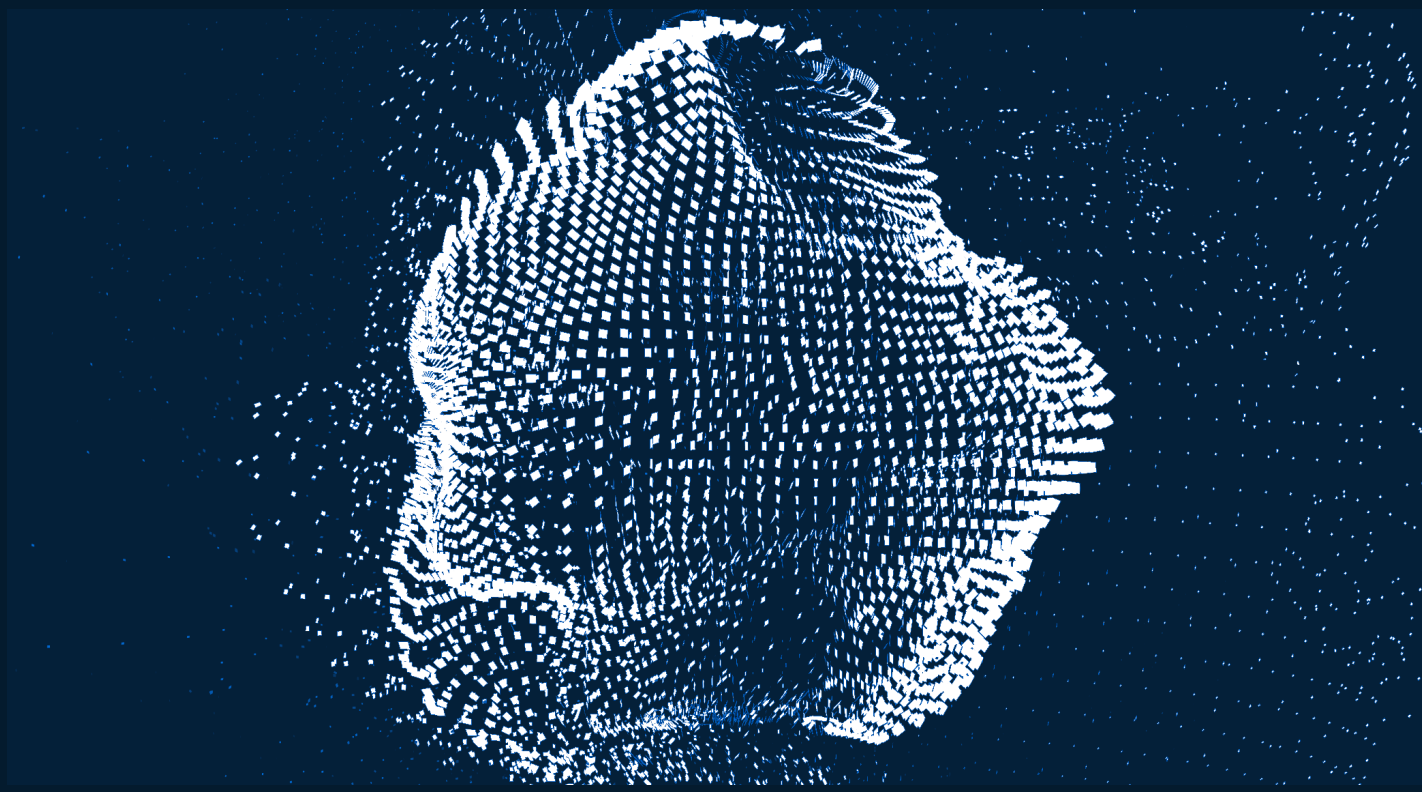
Qian joined MATRIX in February 2023 as a researcher in precision immune-oncology at OUH. Qian has a PhD from the University Academy of Sciences in China followed by postdoc positions at the University of Oslo and OUH. She has a strong background in tumour molecular biology

Martin Røvang

Martin joined MATRIX and OUH in March 2023 as a software developer / researcher and will be joining the team working on developing new imaging (MRI and PET) technologies and methodologies in work package 1. Martin has a master degree in deep learning and has solid experience in machine learning and medical imaging.

In 2023, MATRIX plans to recruit researchers also at Stavanger University Hospital, St. Olavs Hospital in Trondheim and at the University Hospital North-Norway in Tromsø. Furthermore, MATRIX is in collaboration with the Faculty of Health Sciences at OsloMet in the process of recruiting a Professor in a 20% position at OsloMet. The recruited person will contribute to develop new Master courses for clinical study personnel.

Photo: Lars P. Devik, OUH



Section 5

Communication & Dissemination

Dissemination Activities 2022

MATRIX in November 2022 launched newly built Centre webpages and is also using LinkedIn and Twitter (@fkbmatrix) to share regular updates.

Researchers affiliated to MATRIX regularly give presentations at national and international conferences and participate in panel debates, podcasts and other forums for discussion and dissemination related to new research findings, precision cancer medicine initiatives in Norway and clinical trials among others. Furthermore, mass media show an interest in MATRIX-related research and several press items were published in 2022. A selection of 2022 press items are listed below:

- NorTrials samlet klinikere og industri under ESMO, Dagens Medisin, 09.09.2022
- Impress-studien: Over halvparten har fått tilbud om ny behandling, Dagens Medisin 10.09.2022
- Starter storstilt journalprosjekt, Dagens Medisin, 11.10.2022
- Lungekreft: «Hvor lenge har jeg igjen å leve?», Dagbladet, 06.12.2022
- Oppløftende prøvemetode mot brystkreft: - Ville ikke stått her uten den, NRK, 09.12.2022
- Avslører blodets hemmeligheter, NRK, 28.12.2022

IMPRESS-OPPDATERING: – Per 1. august 2022 hadde 472 pasienter blitt inkludert for molekylærprofilering i InPreD. Av disse var 428 pasienter svart ut og samtykket for screening til Impress-studien. Av de 428 pasientene ble det funnet et legemiddel til 101 pasienter (24 prosent), og disse ble inkludert i Impress-studien, sier Kjetil Taskén. Her avbildet foran Marseille-auditoriet tar han skal holde muntlig presentasjon lørdag 10. september.
Foto: Lars Brock Nilsen

Impress-studien: Over halvparten har fått tilbud om ny behandling

Kjetil Taskén, leder for Institutt for kreftforskning ved Oslo universitetssykehus, holder lørdag muntlig presentasjon om data fra InPred-, Impress- og Connect-initiativene på ESMO-kongressen i Paris.

Lars Brock Nilsen

SIKTER HØYT: Stein Kaasa og Tonje Lundeby legger listen høyt for prosjektet med å utvikle en digital journal for kreftpasienter. Her er begge avbildet på kreftkongressen ESMO 2022 i Paris hvor de presenterte prosjektet og møtte mulige fremtidige samarbeidspartnere.
Foto:

Starter storstilt journalprosjekt

OUS-forskere har som målsetting at hele Europa om få år skal benytte seg av en ny digital journalløsning for kreftpasienter med pasienten i fokus.

Julie Kalveland

NorTrials samlet klinikere og industri under ESMO

Fredag møttes kreftforskere og internasjonale representanter fra legemiddelfirmaer i den norske ambassaden i kjærlighetens by.

Julie Kalveland / Lars Brock Nilsen redaksjonen@dagensmedisin.no

PUBLISERT Fredag 09. september 2022 - 22:01

Oppløftende prøvemetode mot brystkreft: Ville ikke stått her uten den

En ny metode for behandling av aggressiv brystkreft gir håp for flere pasienter. Norske forskere får internasjonal oppmerksomhet for funnene.

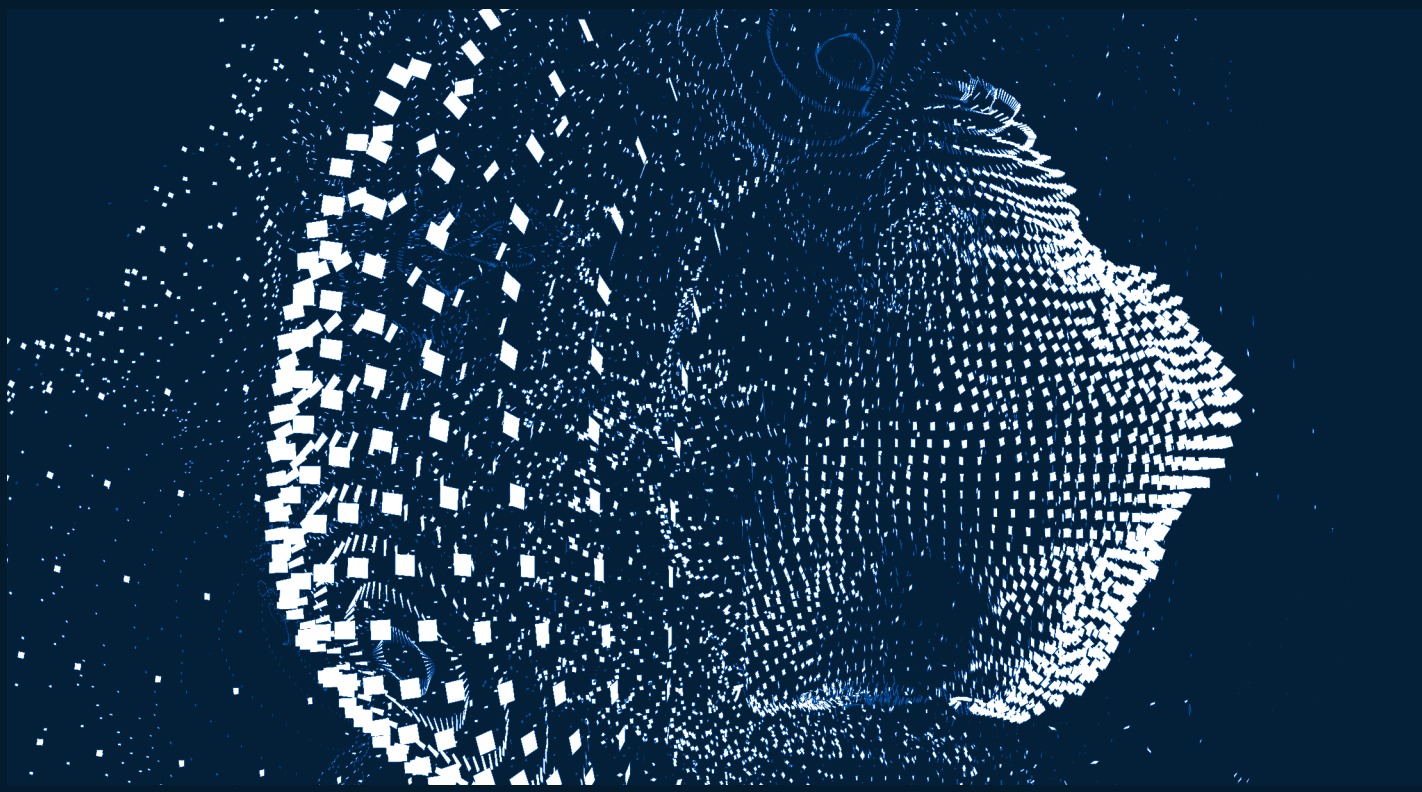
Avslører blodets hemmeligheter

Med ny teknologi har forskerne funnet ørsmå spor fra kreftceller i blodet. Det kan forlenge livet til pasienter med bukspyttkjertelkreft.

Åse Karin Hansen
Journalist

Vi rapporterer fra Ålgård og Stavanger

Publisert 28. des. 2022 kl. 19:58
Oppdatert 28. des. 2022 kl. 20:30



Section 6

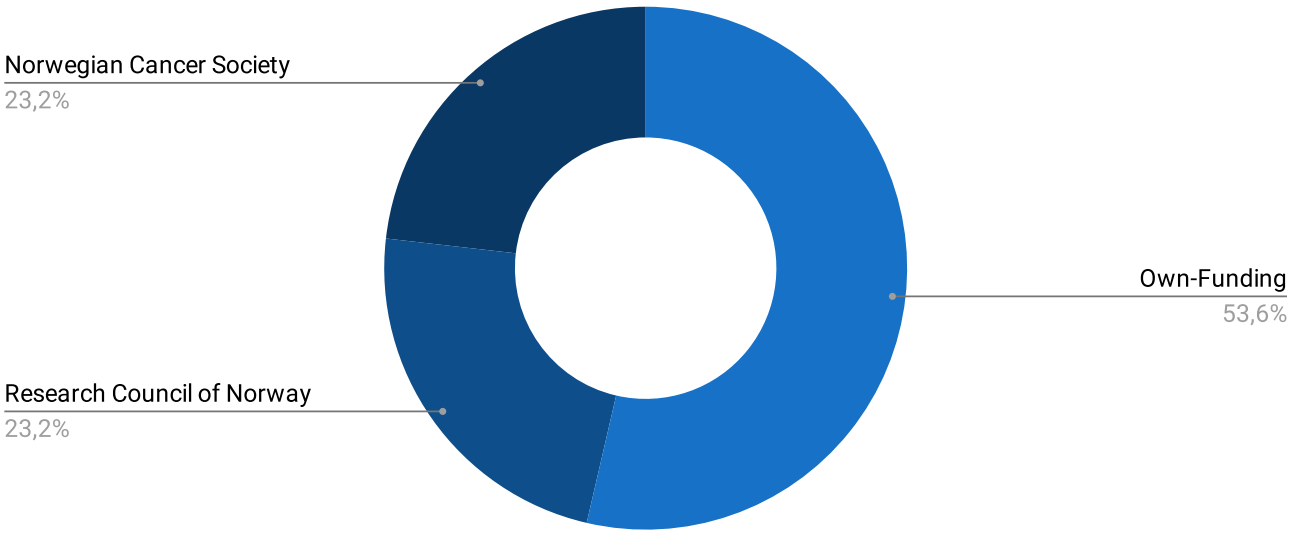
MATRIX Funding

Core Funding

MATRIX, co-funded by the Research Council of Norway (RCN) and the Norwegian Cancer Society (NCS), has been awarded 128 million NOK under the funding scheme for Centres for Clinical Treatment Research (FKB). This funding is granted over an eight year-period (2022 – 2030), pending a successful midterm evaluation after the first five years. A prerequisite for the awarded funding as a Centres for Clinical Treatment Research is an own-contribution of at least 50%. MATRIX has budgeted with an own-funding of 54% over the next eight years.

MATRIX officially opened in August 2022, somewhat later than originally planned. This delay affected recruitment of staff and spending somewhat, but MATRIX plans to scale up in 2023. In 2022, MATRIX spent in total 11 MNOK, including own-funding. Of the 17 partners included in the Centre, seven partners had costs related to the project in 2022: Oslo University Hospital (OUH) spent 8.7 MNOK, Stavanger University Hospital spent 0.7 MNOK, St. Olav Hospital spent 0.4 MNOK, the University of Oslo spent 0.5 MNOK, Telemark Hospital and Ålesund Hospital both spent 0.2 MNOK, and the University Hospital North-Norway spent 0.1 MNOK.

Annual Core Funding



External Funding

There is a clear expectation that research environments in MATRIX should be able to attract additional funding from both national and international sources. In 2022, around 90 MNOK in the form of national and international grants to research groups affiliated with MATRIX, has been secured as additional external funding. National external funding includes 39 MNOK from the Norwegian Cancer Society, 20 MNOK from KLINBEFORSK and 9 MNOK from the South-Eastern Norway Regional Health Authority for projects that will be running in the coming years. In addition, MATRIX-affiliated researchers are involved in two new EU projects, both awarded in 2022. For the MyPath project, coordinated by MATRIX co-director Stein Kaasa, 14.5 MNOK of the grant goes to Oslo University Hospital (OUH). Furthermore, in the PCM4EU project about 3.5 MNOK goes to OUH.

NORWEGIAN CANCER SOCIETY

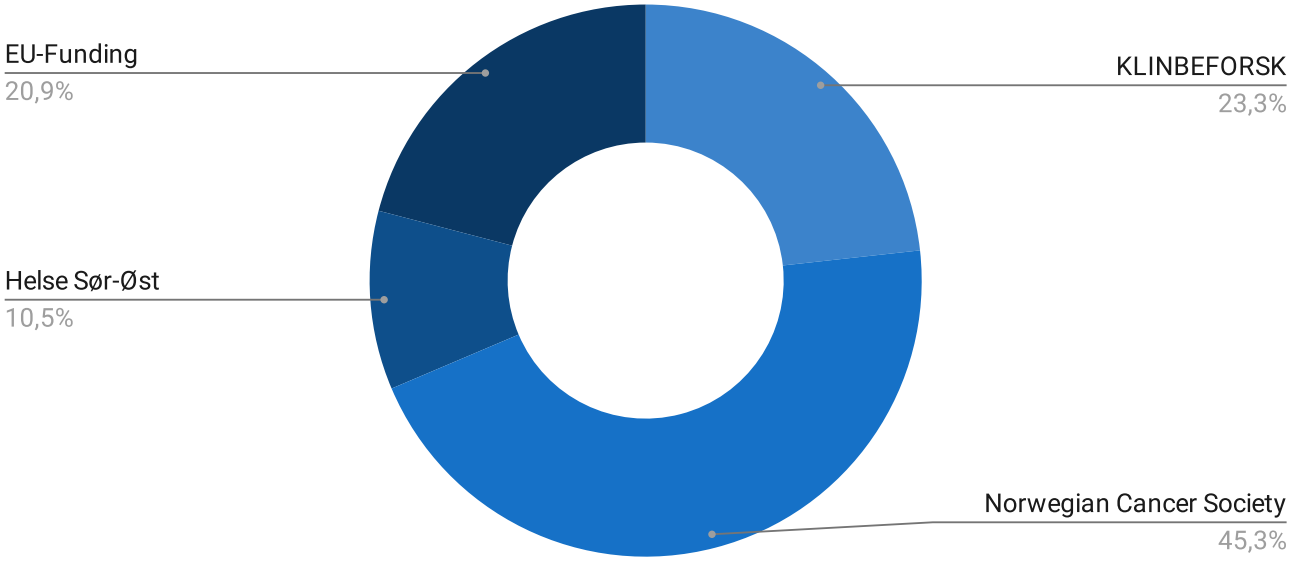
Funded by the European Union

KLINBEFORSK

HELSE SØR-ØST

MATRIX
NORWEGIAN CENTRE FOR CLINICAL CANCER RESEARCH

External Funding



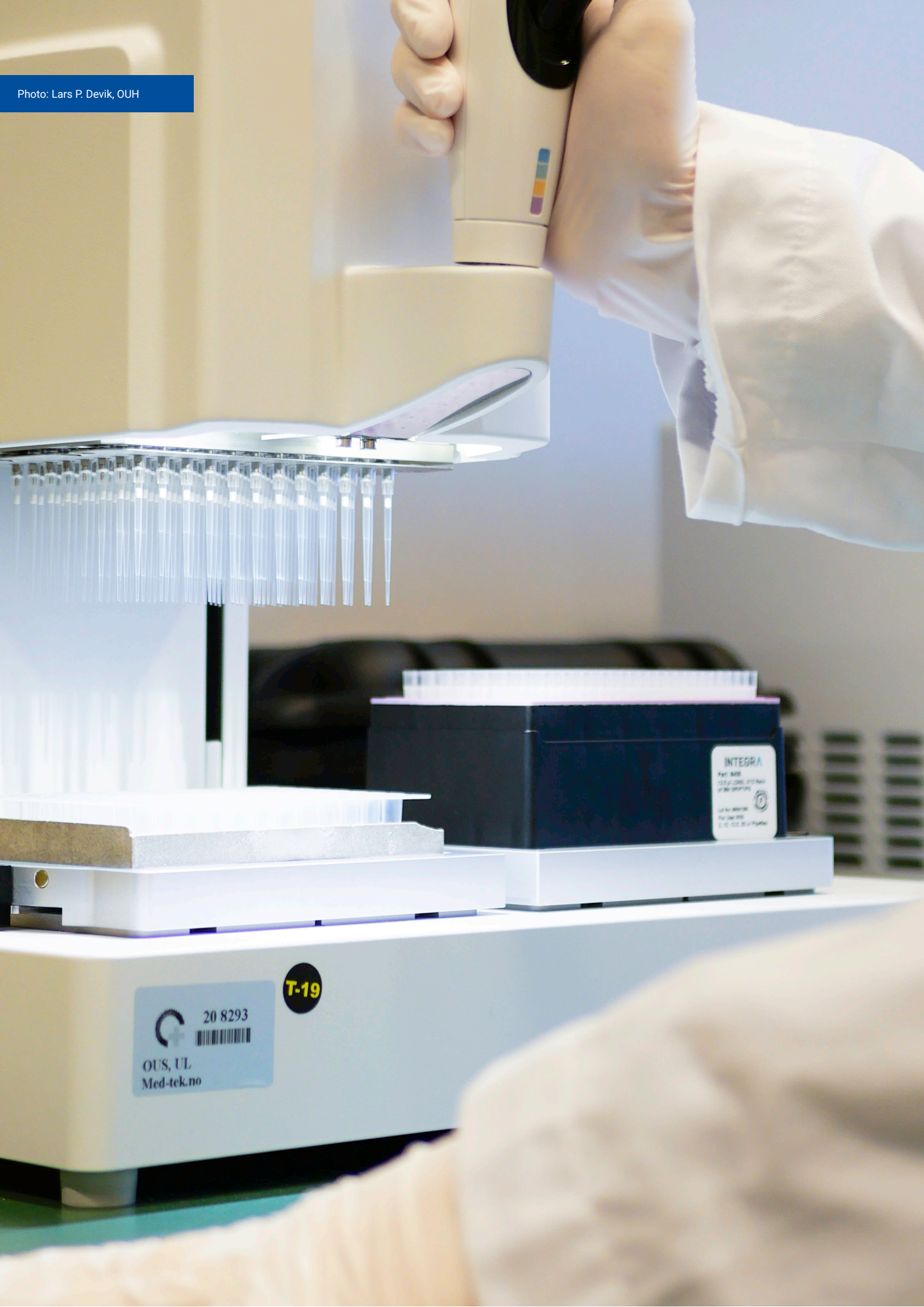
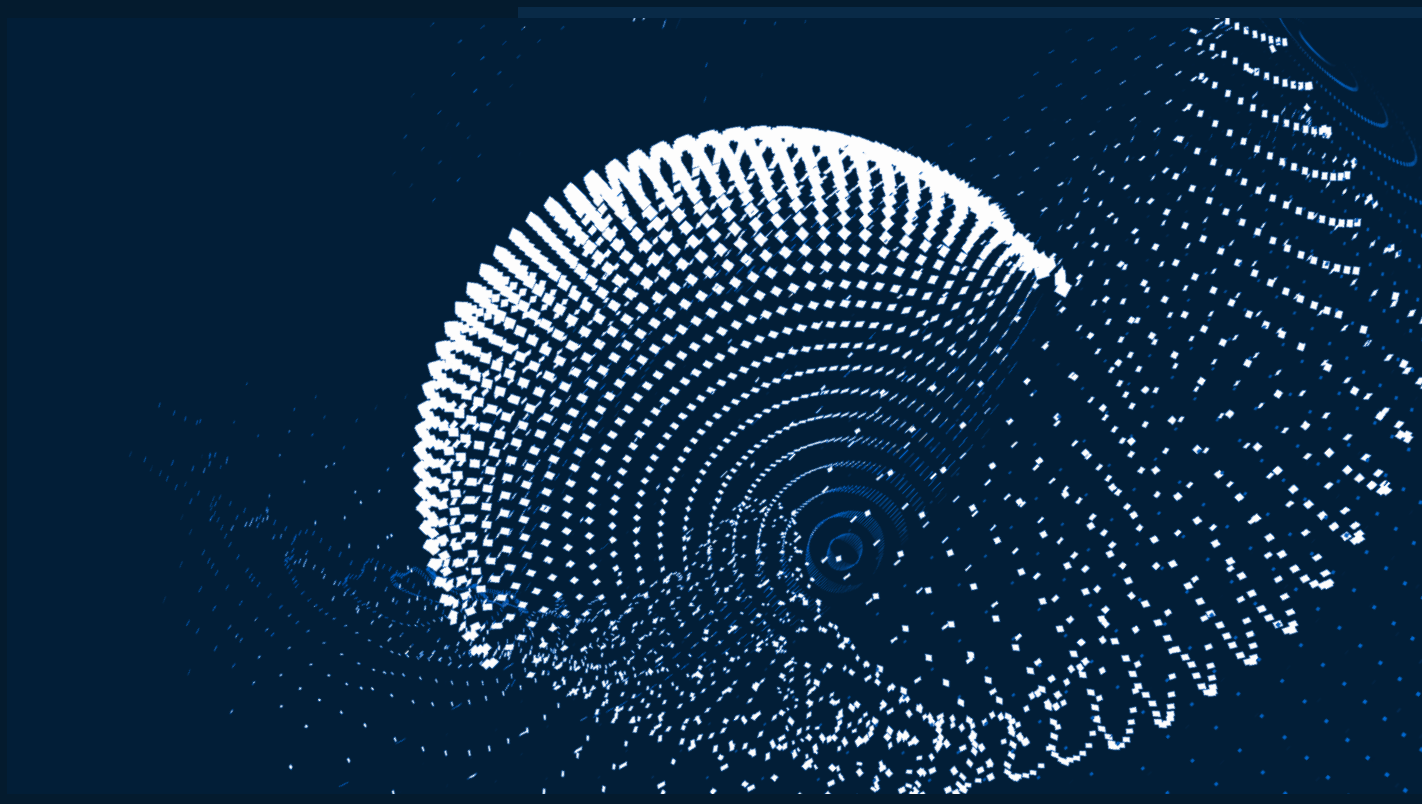


Photo: Lars P. Devik, OUH



Section 7

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Photo: Thea Tønnesen, OUH

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HELSE MØRE OG ROMSDAL

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UNIVERSITETSSYKEHUSET I TRONDHEIM

Helse Nord:

NORDLANDSSYKEHUSET
NORDLÁNDA SKIPPIJVIESSO

UNIVERSITETSSYKEHUSET NORD-NORGE
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Universities:

UiO : Universitetet i Oslo

OSLOMET

MATRIX - Norwegian Centre for Clinical Cancer Research

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Centre for Clinical Treatment Research