

NEWSLETTER



Project bachelor at the Gynecological Department, Women's Clinic	2
Regulatory input from Norway in Brussels	3
Annual Report 2023 from Center for Medical Devices, Technology and Innovation	5
Strengthening the IT Competence	5

Project bachelor at the Gynecological Department, Women's Clinic

Over several years, the Center for Innovation, Medical Equipment and Technology (formerly FOR) has assisted the nursing education at NTNU in establishing contact with various professional communities at the hospital for the

completion of project bachelors. An important supporter and contributor has been the Women's Clinic, which has shown great commitment and interest every year. Focus on information for patients who have undergone miscarriage has been a consistent theme. Ingvild Brenna, who is a professional development nurse at the Women's Clinic, says that this has concretely provided value, in that i.a. information collected through bachelor theses has led to improvements in the department's information booklet for these patients.



Some of the team who have facilitated the bachelor theses, for example: Ingvild Brenna (vocational development nurse), Guro Vikås (nurse), Nora Bruvold Valfridsen (nurse), Mariell Melsbø-Nilsen (nurse), Rita Berdal (section manager) and Camilla Reinjfjell (section manager)

The students have no patient contact, and complete their bachelor's degree using qualitative methods, based on in-depth interviews with mainly nurses and occasionally doctors. Rita Berdal, section leader at the bedside post, says that these interviews initiate reflections and ideas with us about what we should focus on, and is happy that the students want to write about women's health, which is a neglected field in health research.

This year, the inpatient unit on the 6th floor has received six bachelor's candidates who have written about follow-up of sexual abuse and nurses' practices and attitudes towards patients with endometriosis. These are:



F.rom left: Alexander Rødsjø Lobo, Ingeborg Myrvang, Martine Øyen, Miriam Horn, Rikke Nervik, Tuva Berthelsen

Head of Department and Head of Center at the Center for Innovation, Medical Equipment and Technology, Jan Gunnar Skogås is very happy about the long-standing collaboration we have had with the nursing education at NTNU, where various issues are given as bachelor assignments.

Today's students are tomorrow's value creators. The health sector faces many challenges in the coming years, where innovation and entrepreneurship are not only for those with a special interest, but are important for developing today's health service both within specialist and primary health care. This is also needed if you want to start your own business. This year's students are wished the best of luck on their way forward!

Regulatory input from Norway in Brussels

NorTrial's center for medical devices has been in Brussels to talk about how hospitals and industry can best work together to ensure patients' access to tomorrow's medical



Sara Edvardsen (NorTrials) and Shelley Jambresic (Geistlich Pharma AG) during their presentation in Brussels on how hospitals and industry can best collaborate around research and development of medical devices

10-14 June, our own researcher and regulatory advisor, Sara Edvardsen, participated in the MedTech Summit 2024 in Brussels. Here, the large MedTech industry and European authorities gathered for five days to discuss opportunities and challenges around the new regulations for medical devices, which were introduced in 2021 (Regulation (EU) 2017/745 - MDR and Regulation (EU) 2017/746 - IVDR). With the intention of increasing patient safety, the new regulations now set higher requirements for testing and documentation of the safety

and performance of medical equipment. As is normal when new requirements are introduced, there is a certain unpredictability in what a medical device must go through in order to be approved for safe use on patients. The actors in Europe gathered during the MedTech Summit to share knowledge and make the regulatory course and development course more predictable for everyone. This in a desire to facilitate the flourishing of innovation, without creating risks for patient safety.

Unique to this year's MedTech Summit was that the hospitals were also represented, as Sara participated and presented on behalf of NorTrial's center for medical equipment and all Norwegian hospitals. The presentation was entitled Research-initiated studies: Your recipe for a successful hospital-industry collaboration, and was presented as an informative and encouraging dialogue between hospital and industry. Shelley Jambresic from Switzerland, who holds the role of Group Lead Science and Evaluation at the company Geistlich Pharma AG, stood to represent the industry perspective.

The presentation's message was well received, and created great excitement and discussions. Emphasis was placed on how industry and hospitals are mutually dependent on each other, in order to ensure access to state-of-the-art medical equipment for patient care. Clinicians at the hospital have a unique insight into the needs of hospitals and patients, and the industry has all the resources to develop medical equipment that meets this need. Close cooperation is therefore essential. The presentation also aimed to inform how industry can use researcher-initiated studies from the hospitals to monitor their medical equipment on the market, and ensure continuous improvement of the equipment's performance.

Briefly, the presentation covered the following topics:

- Advantages of researcher-initiated studies for both hospitals, patients and industry.
- How researchers go about applying to carry out clinical studies on medical devices, and why researchers are often dependent on establishing contact with industry.
- Requirements the industry places on researchers who wish to use their medical equipment in clinical studies.
- How to make it easier for hospitals and industry to come into contact with each other.
- Factors that ensure good cooperation and good communication between hospitals and industry.

With NorTrials' goal of strengthening collaboration between hospitals and industry, in order to best develop and provide access to new and better patient treatment, we consider it important that hospitals also engage in dialogue with industry and the authorities. The fact that the hospitals are now also building up regulatory expertise around medical equipment was seen as very positive by the other players who presented in Brussels. This helps to create a good understanding of each other's needs, and paves the way for even better cooperation in the future. All to the benefit of continuous improvement of patient care, and increased patient safety.

Head of department and Center Manager at NorTrial's Center for Medical Devices, Jan Gunnar Skogås, emphasizes the importance of regulatory competence, and that one spends a good amount of time at the start to familiarize oneself with the regulatory aspects, in order to save time and money later on. He himself says the following:

From experience, we now see after 2 years of operation: That many people do not know how broad the definition of medical equipment is, and that medical equipment is not the same as medicines. The Norwegian Med-Tech industry mainly consists of start-ups and those who have clinicians on the team from the start have the best conditions for success. Early contact with the clinical environment - understand/verify clinical needs. Further development of the idea and solution (service, workflow). Design of study protocol. Advice on financing for development and testing, and not least understanding the regulatory landscape and the requirements that are set, are important areas to focus on if you are to succeed!



Sara Edvardsen (NorTrials) and Shelley Jambresic (Geistlich Pharma AG), who have worked across borders from Norway and Switzerland, to put together this year's presentation for the MedTech Summit

More about the MedTech Summit

The regulatory conference took place this year over five days in Brussels, where a total of eight highly relevant topics were taken up for discussion.

- European regulations for medical devices
- Law and compliance with legislation for medical devices
- In vitro diagnostic medical equipment
- Biocompatibility for medical devices
- Clinical trials and evaluations, monitoring after medical devices have been placed on the market and safety monitoring
- Regulatory affairs in global markets
- Software and artificial intelligence as medical equipment
- Project management within medical equipment

For more information, see the MedTech Summit website <https://informaconnect.com/medtech-summit/>

Annual Report 2023 from Center for Medical Devices, Technology and Innovation

2023 has been an exciting year, a lot has happened on the activity front. New tasks have been assigned to us. It



Jan Gunnar Skogås Head of department Managing director Photo: St. Olavs Hospital

has also resulted in us changing the overall name of the business, where we previously used the name "Fremtidens Operating Room", we have now changed the name to; "Center for Medical Equipment, Technology and Innovation", a name that reflects the breadth of our field of activity. NorTrial's center for medical devices, which was established the year before, has had many inquiries from industry, the health industry and start-up companies, nationally and internationally. There have been a total of 43 different activities during the year. Clinical studies are central to the development of medical equipment. It gives patients access to new forms of treatment, it gives doctors and researchers new knowledge, and it gives the industry the opportunity to test the effect of medical equipment.

During the year, the National Research Center for Minimally Invasive and image-assisted diagnostics and treatment (MIDT) established, as a result of an evaluation of the national competence services, the Ministry of Health and Care Services (HOD) proposed to continue the activity in the national competence services for 3D ultrasound (USIGT), functional MRI (fMRI) and advanced laparoscopic surgery (NSALK) as a national research center that is added to St. Olav's hospital HF. The research center is being established to further develop and utilize the synergy effects of the accumulated knowledge, infrastructure and expertise of the three former national expertise services. The research center will carry out research, innovation and education in the fields of minimally invasive surgery/treatment, medical imaging, image analysis, and image-guided diagnostics and treatment/intervention. The new center will strengthen and further develop the environment's position nationally and internationally. During the year, we have also followed up and arranged for PhD scholars, master's students and bachelor's students who all carried out their tasks using the FOR infrastructure. We are very pleased with the increase in scope and activity. We wish you a good reading of our [Annual Report for 2023](#)

Strengthening the IT Competence



From September 2024, Gisle Borg Gjertsen is associated with the Center for Innovation, Medical Equipment and Technology. Gisle is educated in technology design at NTNU in Gjøvik and entrepreneurship and innovation at NMBU. Gisle started at Hemit in April 2024 as product manager, Hemit System development and has previously worked at Cegal as a software developer. In the centre, Gisle will fulfill a long-awaited role by assisting with his expertise in relevant projects as an advanced "liaison officer" to shorten the waiting time at Hemit, which will increase progress in several of our most important projects. Gisle is active with running, mountain biking and mountain skiing, and has his

own 3D printer which he uses for design and 3D modelling. Gisle is a grant that will drive several of our most important projects forward, not only with greater speed, but also with increased quality and innovation. We warmly welcome Gisle and look forward to the collaboration

Center for Medical Devices, Technology and Innovation



Norwegian National Research Center for Minimally Invasive and Image-Guided Diagnostics and Therapy

Future Operating Rooms



Operating Room of the Future

- Experimental surgery (preclinical)
- Training Electromedical equipment
- Live transfer from ORs
- Visualization lab (extended reality)




NorTrials | Medical Devices



www.nortrials.no

3D printing laboratory




NorMIT


Norwegian Centre for Minimally Invasive Image Guided Therapy and Medical Technologies

www.normit.no

Research and Innovation projects

On-going: Ablation of renal cancer (ACUS), NUL-Fat, Aviant, Posired, MIREIA, IDEAR, LungGuide, NavCAD, MEDITATE, Lung Cancer Cockpit, In-Motion, HumanIC

FOR Neurosurgery	FOR Energy lab
FOR Gastroscopy	FOR Virtual OR
FOR Cardiovascular	FOR Visualization
FOR ENT	
FOR Orthopedics	
FOR Gynecology	




Collaborative partners   Hospitals Universities Industry International

 **ST. OLAVS HOSPITAL**
TRONDHEIM UNIVERSITY HOSPITAL

NorMIT Infrastructure

Book at normit.no

Trondheim					Oslo		
							
							
							

Chief Editor: Jan Gunnar Skogås
Editorial assistance: Gunnar Gjeldnes

Receive the Newsletter
E-mail: gunnar.gjeldnes@stolav.no