



## CLINICAL TRIALS & TEST FACILITIES

### OBSTETRICS AND GYNECOLOGY OSLO UNIVERSITY HOSPITAL

Oslo



One of the largest Women's Clinics in the Nordics with more than 9 000 deliveries and 4 400 surgeries annually (>1400 cesarean sections)



Experienced clinical trial unit and testbed for pharma and medtech research



Internationally renowned state of the art surgical wards



Registry with real world data and biobank facilities for obstetrics and gynecology



Ambitious strategy for industry sponsored clinical trials and med tech testing

For more detailed information:

- Research & Development @ Kvinneklivikken
- Clinical Trials Unit @ Kvinneklivikken

## NATIONAL ASSETS

- National Action Plan for Clinical Trials (2021-2025) aiming to double the number of new clinical trials per year making clinical trials an integral part of the patient treatment
- Government-backed initiatives for clinical trials and medical innovation
- Easy to recruit patients due to a positive attitude towards research in healthcare
- Unique national ID numbers give continuous information of every patient's location and survival
- Ecologically valid research
- Medical Birth Registry of Norway: population-based data on all births since 1967

## ECOSYSTEM AND NETWORK

- Established network for inclusion of patients from other regions of Norway
- Strong innovation infrastructure with professional TTO and the renowned clusters Norway Health Tech and the Life Science Cluster
- Close collaboration with several dedicated test sites at the hospital such as the Clinical Trial Unit for children, Clinical Trial Unit for gynecologic cancer and the Oslo Innovation Center making it possible to follow children from before conception until adolescence
- Established relationship with relevant Norwegian patient organizations

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#### CLINICAL TRIALS UNIT/TEST BED

- Experienced study nurses and project coordinators serving all units
  - Established procedures for fast feasibility response
  - One point of contact for the clinic: [Kliniskestudier.kvinneklippen@ous-hf.no](mailto:Kliniskestudier.kvinneklippen@ous-hf.no)
  - In-house lab facilities for lab sampling, processing, storage and shipment
  - Engagement for and involvement in testing of digital tools for patient care
  - Strong expertise and competence in running recent clinical trials in collaboration with industry
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#### REGISTRIES AND BIOBANKS

- Oslo Pregnancy Biobank:
  - Prospective research registry including more than 1000 pregnancies, since 2001
  - Consists of maternal and fetal data, and biological samples including maternal and fetal blood, amniotic fluid, placental and decidual tissue and biopsies from the mother during cesarean section. Maternal follow-up at 1-8 years postpartum (>450) with biological and clinical data
- Preeclampsia, endothelial dysfunction and cardiovascular risk in women – The 4 Vessel Biobank:
  - Blood samples obtained from the ongoing placental circulation
  - Two maternal and two fetal vessels
  - Preeclampsia and healthy pregnancies
  - Placental samples, placental homogenates and adipose tissue
- PREPPeD term/postterm biobank:
  - Prospective research registry including more than 1000 pregnancies, since 2016
  - Consists of maternal and fetal data, and maternal blood samples prior to delivery, as well as placental samples for a subset
- National treatment unit and OUS Quality Registry for women with cardiac disease in pregnancy:
  - Prospective registry including more than 1000 pregnancies among women with heart disease since 2013
- Norwegian Female Incontinence Register (NKIR) (OUS-based register, 99% coverage in 2017)
- Close collaboration with National Norwegian Gynecologic Endoscopy Register (NGER)
- Close collaboration with the Medical Birth Registry of Norway.
- Very large reproductive medicine clinical biobank including semen, donor semen, eggs, embryos, and ovarian tissue

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### REPRODUCTIVE MEDICINE

- Largest academic fertility clinic in the Nordics, with 1700 fresh and 1200 thaw cycles per year
  - Extensive laboratory facilities carrying out standard IVF techniques, advanced analysis (sperm morphology, flow cytometry, FISH, immunofluorescence) and treatments (sperm donation, timelapse microscopy, artificial oocyte activation, fertility preservation, ovarian tissue cryopreservation and transplantation)
  - Currently implementing mouse oocyte activation test (MOAT) and preimplantation genetic testing (PGT)
  - Strong expertise and competence in running recent clinical trials in collaboration with industry (Merck KGaA, Ferring Pharmaceuticals) and researcher-initiated studies.
  - Research group carrying out fundamental developmental biology research, human embryo research, translational research, clinical and epidemiological studies
  - Inventors of the technology behind the IVD OptimOva® and the startup IVFfit AS
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### SURGERY

- 4 400 surgeries annually (>1400 cesarean sections)
  - State of the art operating rooms
  - Operating facilities dedicated to obstetrics and gynecology
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### PATIENT & PUBLIC INVOLVEMENT

- Close collaboration with private gynecological consultants
- Well established processes for patient involvement in research
- Established relationships with relevant Norwegian patient organizations

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### CONTACT FOR COLLABORATION AND CLINICAL TRIALS

**General enquires** Womens clinic: [kliniskestudier.kvinneklubben@ous-hf.no](mailto:kliniskestudier.kvinneklubben@ous-hf.no)

**Agreements** Inven2: [kliniskestudier@inven2.com](mailto:kliniskestudier@inven2.com)

#### Direct contact point for specific therapeutic areas

- Research Centre for Obstetrics and Gynaecology (Anne Cathrine Staff, [uxnnaf@ous-hf.no](mailto:uxnnaf@ous-hf.no))
  - Mother-Fetus Interactions (Trond Michelsen, [trmi1@ous-hf.no](mailto:trmi1@ous-hf.no))
  - Reproductive Medicine group (Peter Zoltan Fedorcsak, [pfedorcs@ous-hf.no](mailto:pfedorcs@ous-hf.no))
  - Norwegian Research Centre for Women's Health (Siri Vangen, [Siri.Vangen@ous-hf.no](mailto:Siri.Vangen@ous-hf.no))
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#### For more information see:

- Research at the Division of Obstetrics and Gynaecology
  - Division of Obstetrics and Gynecology
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Please copy "[kliniskestudier.kvinneklubben@ous-hf.no](mailto:kliniskestudier.kvinneklubben@ous-hf.no)" in all your direct correspondence