

CV - Clinical Cancer Research Unit

The Norwegian Radium Hospital, Oslo University Hospital

Established 1995

Facilities & staff

- 2 senior physicians and 2 in part time position, 8 study nurses, 4 site project managers and 1 secretary.
 - Certified, trained and working according to GCP. Updated GCP training/ course every second year
 - Trained in emergency situations (physicians and study nurses) and in the management of safety events (e.g. immune-related)
 - Experienced in web based electronic data capture and easy access to a computer with web/internet high speed access
 - Resources to complete data entry and resolve queries 1- 5 working days after visit completion
 - Availability of workspace for Monitors to perform regular site visit activities including ability to access the electronic data capture website
 - Experienced in using RECIST 1.1 and irRC to evaluate tumour response
- Facilities for close patient surveillance, including equipment for continuous cardiac monitoring
 - Covering seven days a week with facilities for overnight stay (co-operation with in-patient ward)
- Close co-operation with Intensive Care Unit and 24-hour access to the hospital Emergency Response Team
- 24-hour facilities for standard blood sample analysis with expedited processing
- Fully equipped facilities for first-in-man studies
- 4 beds, available treatment chairs and 2 outpatient consulting rooms
- A laboratory which includes a (blood) sample preparation area containing equipment for processing and storage of study samples in compliance with GLP and GCP
 - Staff trained to collect, process and ship samples, completing tracking logs on an ongoing basis
- -20° C and -80° C freezers available with adequate space for the storage of study samples

Pharmacy

- Trained Pharmacists working according to GMP
 - Specialised in oncology
 - Dedicated to clinical trials

Quality

- Inspected by Norwegian Health Authority Inspectors in January 2008 without critical findings
- Site specific SOPs continuously revised
- Oslo University Hospital has one of the largest Radiotherapy departments in Northern Europe with 17 Linac's

Collaboration

- Pharmaceutical Industry - collaboration
BMS, Novartis, Bayer, Pfizer, Roche, MSD, Astra Zeneca, Abbot, Lytix, Ultimovacs, Targovax, Medigene, Abbvie
- Authorized by Novartis – Part of Oncology Translational Medicine (OTM) network
- Selected partner, 1 of 6 European BMS Immune-Oncology Centers of Excellence
- Cancer Centres in Europe and in the US
MD Anderson Cancer Center (part of the Global Academic Program)
- EORTC Network of Core Institutions (NOCI) for translational research
- Nordic Network for Early Cancer Trials (Nordic-NECT)
- Member of Nordic Trial Alliance
- "In house developed- trials" in collaboration with Institute for Cancer Research:
 - Section for Immunotherapy
 - Dept. of Cellular Therapy
 - Dept. of Tumor Biology

Tumor biopsy collection

- Ability to collect sequential biopsies at required time-points with an established process for taking tumor biopsies from either deep or superficial lesions
- Ability to process the samples immediately (formalin, transfer medium, snap frozen), fixation
- Biobank for various tumor types

Molecular and biochemical analyses

- Routine laboratory assessments including biomarkers
- Immunohistochemistry and immunological assays
- Receptor expression and functional receptor analyses
- Protein analyses (ELISA, RIA and immunohistochemical investigations)
- MicroRNA gene analyses
- Gene profiling with individually designed panels dependent of target and pathway

PET and NMR (functional) imaging

- Senior technicians and radiologist dedicated to the clinical studies
- Access to 1 PET-CT scanners (Siemens biograf 16)
- Access to MRI (GE lightspeed VCT 64, 1.5 tesla) and CT scanner (GE Discovery 450) with slice CT scans, dynamic CT, ultrasound Doppler with colour contrast enhancement and a variety of other interventional diagnostic radiology and clinical physiological assessments.

Point of excellence

- Biobank for different types of cancer
- Clinical studies with translational research as an important part
- Immunotoxins
- Superantigens
- Dendritic cell vaccination
- Telomerase vaccination

- Cytotoxic peptide injection
- Micrometastases
- Immunotherapies
 - GMP Certified laboratory for preparation of therapeutic cellular products and evaluations/monitoring of immune responses
 - Production of both T-cells and DCs (including mRNA transfection) for clinical use

Approval process

- External review board:
Last ten protocols NOMA 53 days, EC 53 days
- Internal
All protocols will be presented at the Department of Oncology Internal Review Board
- All contracts with industry are handled by Inven2 (Tech Transfer Office)

Publication list

Clinical Cancer Research Unit: <http://www.ous-research.no/home/cru/Publications/7988>

Patient population; number of new patients

The Norwegian population: 5.1 million
Number of new cancer cases 2013: 30.401

Incidence Registry and Cancer statistics from *The Cancer Registry of Norway*
<http://www.kreftregisteret.no/en/The-Registries/Cancer-Statistics/>

Contact information

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Track record: Phase I and I/II trials conducted 2011- :

www.nordicnect.org - Advanced search, Keyword: Oslo