

Trial Nation

Clinical Trials Denmark

CENTER FOR ONCOLOGY
A network of Danish oncology clinics

Your clinical oncology research partner

Trial Nation Oncology

Trial Nation Oncology is a Danish Center of oncology clinics involved in clinical research with medicinal products and medical devices.

the center was divided in Center for Oncology and Center for Hematology to allow the inclusion of additional clinics.

The center was established in 2014 as Center for Oncology and Hematology. In 2018,

Trial Nation offers one point of contact to the oncology clinics.

Trial Nation Oncology Clinics

The clinics constituting Trial Nation Center for Oncology are characterized by:

- Extended experience with commercial and non-commercial phase I, II, III & IV clinical trials including First In Human trials and pediatric oncology trials
- Extended use of genomic profiling of tumor and host – regional and national tumor board meetings
- Danish Cancer Biobank, a national collaboration between hospital departments handling tissue and blood samples from cancer patients
- Short start-up time for initiation of clinical trials in 2018
 - Competent authority: ≤ 45 calendar days from check-in to first response ($\geq 95\%$) , ≤ 14 days for first in human trials

- Ethical committees: ≤ 60 calendar days from check-in to approval in 2018 (4 of 5 regions has a response rate of 80% or more)



DANISH UNIVERSITY CLINICS IN TRIAL NATION ONCOLOGY	REGION
The Experimental Cancer Therapy Unit, Dept. of Oncology, Herlev & Gentofte Hospital	Capital Region of Denmark
The Phase I Unit, Dept. of Oncology, Rigshospitalet, University of Copenhagen	
Dept. of Pediatrics and Adolescent Medicine, Rigshospitalet, University of Copenhagen	
Dept. of Oncology, Odense University Hospital	Region of Southern Denmark
Dept. of Oncology, Vejle Hospital, University Hospital of Southern Denmark	
Dept. of Oncology, Aarhus University Hospital	Central Denmark Region
Dept. of Oncology, Regional Hospital West Jutland	
Dept. of Oncology, Aalborg University Hospital	North Denmark Region
Department of Clinical Oncology, Zealand University Hospital Roskilde and Naestved	Region Zealand

- Clinical trial agreements: 45-90 calendar days from submission to approval
- Parallel submission and approval of applications and clinical trial agreement
- Authorities supportive of trials in children
- Regional, national and international referral of patients for clinical trials between clinics
- Immunotherapy implemented at all clinics
- Unique possibilities for characterization of patients and follow-up via the national personal identification number (CPR no.)
- A high level of health care - fully publicly funded health care
- National quality register data covering demographic-, diagnostic- and health care data
- Close collaboration between patient associations, sponsors and Center for Oncology.
- The main purpose of Trial Nation Oncology is to facilitate collaboration between hospitals and industry on clinical trials in oncology.

Patients

Trial Nation Center for Oncology recruits patients for clinical trials with any type of solid malignant disease.

Unfortunately, cancer is all too frequent in Denmark with an incidence of 37,745 cases and a prevalence of 294,000 people in 2016.

Most aspects of cancer treatment is centralized in Denmark. The National Plan for Medical Specialities provides information about location of highly specialized functions, and also provides a rough estimate of patient numbers within specific indications. Trial Nation may help in the further specification of number of patients with specific diseases or at specific hospitals.

The Center for Shared Decision Making at Vejle Hospital and the clinics Vejle Hospital, Odense University Hospital and Aarhus University Hospital work dedicated with shared decision making, where patients and consultants jointly decide on the treatment of choice for the patient based on evidence and patient preferences. The center further have a close collaboration with patient associations on clinical research.

Denmark is an early adopter of new treatments. National treatment guidelines are available for the treatment of nearly all indications in oncology. The latest treatment guidelines can be found on the Danish Multidisciplinary Cancer Groups home page.

Experience

The Center's experience with clinical trials phases, clinical use of gene profiling, and immunotherapy is indicated in the table below.

Clinic	Clinical trial phases	Clinical trials**/year		NGS, partial/whole	Tumor board L/N	Immunotherapy	Contact(s) for trials
		Commercial	Non-commercial				
The Phase I Unit, Dept. of Oncology, Rigshospitalet, University of Copenhagen	I*, II, III, IV Incl. FIH	>100 FIH: ≈10 I: >35	>50 I: 0	+/ Incl. RNA-seq and Archer	+/ +	+	Chief Consultant Kristoffer Rohrberg kristoffer.staal.rohrberg@regionh.dk Consultant Iben Spanggaard iben.spanggaard.01@regionh.dk
Dept. of Pediatric and Adolescents, Rigshospitalet, University of Copenhagen	Ib* ^o , II* ^o , III* ^o , IV* ^o	>10 Ib: 5	>10 Ib: 2	+/ +	+/ -	+	Senior Consultant Karsten Nysom karsten.nysom@regionh.dk
The Experimental Cancer Therapy Unit, Dept. of Oncology, Herlev & Gentofte Hospital	I, II, III, IV Incl. FIH	>75 FIH: I: >10	>75 I: 5	+/ -	+/ +	+	Professor Dorte Nielsen dorte.nielsen.01@regionh.dk Consultant Rikke L. Efsen rikke.helene.loevendahl.eefsen@regionh.dk
Dept. of Oncology, Vejle Hospital	II, III, IV	>20 II:12	>50 I: 1 II: 35	+/ -	+/ -	+	Staff Specialist Torben Frøstrup Hansen torben.hansen@rsyd.dk
Dept. of Oncology, Odense University Hospital	Ib, II, III, IV	>25 Ib: 1 II: 17	>25 Ib: 0 II: 19	+/ -	+/ +	+	Professor Per Pfeiffer per.pfeiffer@rsyd.dk Chief Consultant Karin Holmskov Hansen karin.holmskov@rn.dk
Dept. of Oncology, Aalborg University Hospital	Ib, II, III, IV	>20 II: 4	>15 I+II: 13	+/ -	+/ +	+	Professor Ursula Falkmer u.falkmer@rn.dk
Dept. of Oncology, Aarhus University Hospital	Ib, II, III, IV	20 Ib: 1 II: 6	20 II: 6	+/ +	+/ +	+	Professor Signe Borgquist signe.borgquist@auh.rm.dk
Dept. of Oncology, Zealand University Hospital	Ib, II, III, IV	>30	>15	+/ +	+/ +	+	Professor Jøn Herrstedt jherr@regionsjaelland.dk
Dept. of Oncology, Regional Hospital West Jutland	II, III, IV	8 II: 1	5 II: 5	+/ -	+/ -	+	Associate professor, seniorconsultant Halla Skuladottir hallskul@rn.dk

Notes: *National referral clinic, ^o = Nordic referral clinic, NGS = Next Generation Sequencing, L/N = Local / National, ** Number of open, prospective, clinical trials of medicinal products or medical devices. I.e. clinical trials for which are open for recruitment, ongoing clinical trials closed for recruitment, where patients are still being treated or subject to follow-up

Additional clinic details

Rigshospitalet (Copenhagen University Hospital)

The Department of Oncology is highly research active and have more than 200 annual publications in international, peer-reviewed journals.

The clinic has a catchment area of 1.8 million people and 7.5 million people for phase I clinical trials including the Skaane Region (South Sweden). The clinic performs 55,000 outpatient visits every year and receives approximately 4,000 new patients every year. The clinic has a strong trials unit with 8 professors, 30 PhD students, 35 research nurses, 1 data manager, 3 administrative coordinators, and 3 bio-technicians. All research nurses are examined monitors. The clinical research unit manages more than 150 clinical trials/year.

The Phase I Unit is the national referral center for phase I oncology patients and see >400 patients referred yearly. The clinic further has patients referred from South Sweden (Skåne). The Phase I Unit include \approx 100 patients in phase I clinical trials per year and has performed whole exome sequencing

(WES), RNAseq, and SNP array of all referred patients since 2013. The clinic accordingly holds a database of a more than 1,400 patients with WES, RNAseq and SNP array. Within 2019 the sequencing will move to whole genome sequencing. The phase 1 unit has extensive experience in early clinical trials and have ongoing more than 35 early clinical trials, 30-50% are first in human, more than 50% are complex immunotherapy trials including T-cell bispecific and combinations. The clinic further drug screen on patient organoids and PDX and plan for patient immune organoids for immunotherapy drug screen and evaluation of resistance mechanisms.

The phase 1 unit performs phase I clinical trials in all solid tumors and hematologic malignancies.

Phase I pediatric oncology trials are performed in collaboration with the Department of Pediatrics and Adolescents at Rigshospitalet. See Rigshospitalet, Department of Pediatrics and Adolescents below.

Rigshospitalet (Copenhagen University Hospital)

The Department of Pediatrics and Adolescent Medicine is highly research active and have published 58 papers in international, peer-reviewed journals in 2018.

The phase I-II trial unit for children with cancer is a national, Nordic and European referral center and consequently, for some trials, has a catchment area of >25 million people. The trial unit include \approx 20 patients with hematology or oncology disease in phase I & II clinical trials per year, often in a close collaboration with the Phase I Unit at Rigshospitalet (see Rigshospitalet, Department of On-

cology, above), the Clinical Trial Unit at the Department of Hematology at Rigshospitalet, and the Center for Cancer Immunotherapy at Herlev and Gentofte Hospital.

Performance of clinical trials is supported by a clinical trials unit with 1 senior consultant, 4 study nurses, 1 study coordinator and part-time lab staff.

The clinic is early phase accredited by the Innovative Therapies for Children with Cancer (ITCC) and a top tier recruiter on ITCC trials.

Herlev and Gentofte Hospital

The Department of Oncology is highly research active and have authored > 90 publications in international, peer-reviewed journals in 2018.

The clinic has a catchment area of 1.8 million people. The clinic is Denmark's largest oncology department and performs 130,000 consultations and see approximately 4,500 new cases every year. Performance of clinical trials is supported by a clinical trials unit with 3 professors, 3 associated professors, ≈ 18 PhDs and ≈ 25 project nurses and a research secretary.

The Experimental Cancer Therapy Unit has dedicated phase I facilities and perform gene profiling of all patients. The department work closely together with the nation-

al Center for Cancer Immunotherapy and the Danish Cancer Biobank which are both situated at Herlev & Gentofte Hospital too. The Center for Cancer Immunotherapy is an internationally leading site for basic, translational and clinical research in cancer immunology and immunotherapy. The Danish Cancer Biobank is a national collaboration between all oncology departments in Denmark on blood and tissue samples from cancer patients aiming to improve diagnostics and treatment of carcinomas and to boost Danish translational cancer research to the highest international level.

The Experimental Cancer Therapy Unit further chair the Nordic Network for Early Phase Clinical Trials (Nordic NECT).

Vejle Hospital, University Hospital of Southern Denmark

The Department of Oncology is research active and have authored >25 publications in international, peer-reviewed journals last year.

The clinic has a catchment area of 1.2 million people, perform 57,000 outpatient consultations, including 23,000 chemotherapy treatments and 9,300 radiotherapy treatments. Performance of clinical trials is supported by a clinical trials unit with 2 professors, 2 associated professors, ≈10 PhDs and ≈8 project nurses and a research secretary.

The clinic has a Clinical Cancer Center accreditation from the Organization of Europe-

an Cancer Institutes (OEI) and >50% of the clinic's patients participate in research protocols (clinical trials as well as biomarker trials – translation research).

The clinic is characterized by a short response time from agreement on a new project to acceptance and inclusion of first patient. The hospital as a whole and the department of oncology in particular is patient oriented: involve patients in the hospital's research council and house Center for Shared Decision Making.

The clinic further has a Designated Centre of Integrated Oncology and Palliative Care.

Odense University Hospital

The Department of Oncology is highly research active and author more than 100 publications annually in international, peer-reviewed journals.

The clinic has a catchment area of 1.2 million people and see approximately 5,800 new cases per year. Clinical trial conduct is supported by a clinical trials unit with 4 professors, 9 associated professors, ≈10 PhDs and 25 project nurses and a research secretary.

The clinic perform genome sequencing of up to 700 patients per year across all solid tumor types, for precision directed medicine.

Aalborg University Hospital

The Department of Oncology is integrated in the Clinical Cancer Research Center. The scientific work is based on the strategic plans 2011- 2022, with national and international cooperation and a publication rate of approximately 100 studies per year in international in peer-reviewed journals.

Department of Oncology covers the area of North Jutland with about 600,000 inhabitants. In 2018 the department performed 25,000 consultations and saw approximately 9,000 unique cancer patients of which 4,000 were new cases.

Aarhus University Hospital

The Department of Oncology is highly active in initiating and conducting cancer research and authored 177 publications during the year 2018 in international, peer-reviewed journals.

The clinic has a catchment area of 1,3 million people, perform 110,000 consultations per year and see approximately 8,000 new cases every year. Clinical trial conduct is supported by a large clinical trial unit with 16 project nurses and a research secretary.

Large experimental research laboratory for translational cancer research incl. biomarker discovery immunotherapy and drug resistance mechanism.

The clinic is experienced in immunotherapy and has dedicated phase I facilities and further host a Geriatric Cancer Research Center (AgeCare).

The hospital as a whole is patient oriented: 50% of the members of the hospitals research council are patients and the department is further devoted to shared decision making.

The clinical trial conduct is supported by the clinical trial unit with 2 professors, 2 associated professors, ≈7 PhDs and 9 research nurses and two research secretaries.

In 2019, the Dept. of Clinical Medicine, Aalborg University has established a professorship especially designed for precision medicine as part in the multidisciplinary research group for personalized medicine.

At the Department of Oncology there are 10 professors, 9 associated professors, and several PhD-students and post-docs.

The department is devoted to performing evidence-generating research, translational research and deliver active research communication.

The clinic collaborates with all Danish Multidisciplinary Cancer Groups at the national level and internationally through extensive scientific networks abroad.

Regional Hospital West Jutland, Western Jutland

The Department of Oncology has a catchment area of ca. 750.000 for medical treatment of the largest cancer diseases; breast-, lung-, colorectal-, pancreatic-, ovarian cancer and malignant melanoma. Annually we get referred approximately 1000 patients and we have 27.000 ambulatory visits, including chemo- and/or immunotherapy treatments. The clinic has a clinical trials unit, with three research nurses, a research secretary, one associate professor and five senior consultants. The clinic does not have multiple competing trials, most of the patients are seen by senior consultants, leading to high inclusion rate and delivery of high quality data.

Zealand University Hospital

The Region of Zealand launched a strategic plan for cancer research in 2017. This has so far resulted in recruitment of 3 full-time professors, one associate professor and one adjunct (visiting) professor. In 2017 the department published 4 peer-reviewed publications in international journals, in 2018 the number increased to 21 and in 2019 to 48. The clinic has a catchment area of 800.000, perform 122.000 outpatient consultations annually, including 75.500 chemotherapy treatments and 30.000 radiotherapy treat-

The Department of Oncology is devoted to deliver excellent patient care both during their outpatient and inpatient treatment. The department has integrated Patient Reported Outcomes (PRO) system for all patients, during their whole disease trajectory, and lead a national project in lung cancer patients to test whether signs of early progression can be detected by utilizing PRO.

The Department of Oncology collaborates with all relevant Danish Multidisciplinary Cancer Groups.

ments. Performance of clinical trials is supported by a clinical research unit with 3 professors, 2 associated professors, 4 PhDs, 2 post.docs, 8 project nurses and a research secretary. The Department is hosting one national research project (COMPAS) with a budget of 20+ mill DKK, one regional project (budget 10+ mill DKK) and one EU project (main investigator in the Intereg research project "Changing Cancer Care", budget 30+ mill DKK).

For coordinated request to all clinics, please contact

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References

Lægemiddelstyrelsen, Årsberetning 2018
De Videnskabetiske Komitéers Fælles Årsberetning 2018
Danish Multidisciplinary Cancer Group's home page, dmccg.dk

Trial Nation

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