

Trial Nation

Clinical Trials Denmark

CENTER FOR HEMATOLOGY
A network of Danish hematology clinics

Your clinical hematology research partner

Trial Nation Hematology

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

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

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

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

Trial Nation Hematology Clinics

The hematology clinics constituting Trial Nation Center for Hematology are characterized by:

- Extended experience with commercial and non-commercial phase I, II, III & IV clinical trials including First In Human trials and pediatric hematology trials
- Extended use of gene profiling and sequencing that has translated into clinical use at hospital and national tumor board meetings
- Danish Cancer Biobank, a national cooperation between hospital pathology departments and laboratories handling fresh frozen tissue, and blood samples and bone marrow including vitally frozen cells from patients with hematological cancer
- Short start-up time
 - Competent authority: ≤45 calendar

days from check-in to first response (≥95%) , ≤14 days for first in human trials



DANISH UNIVERSITY CLINICS IN TRIAL NATION HEMATOLOGY	REGION
Dept. of Hematology, Herlev & Gentofte Hospital	Capital Region of Denmark
Dept. of Hematology, Rigshospitalet, University of Copenhagen	
Dept. of Pediatric and Adolescents, Rigshospitalet, University of Copenhagen	
Dept. of Hematology, Zealand University Hospital	Region Zealand
Dept. of Hematology, Odense University Hospital	The Region of Southern Denmark
Dept. of Hematology, Little Belt Hospital – Vejle Hospital	
Dept. of Hematology, Aarhus University Hospital	The Central Denmark Region
Dept. of Hematology, Aalborg University Hospital	The North Denmark Region

- Ethical committees: ≤60 calendar days from check-in to approval (4 of 5 regions has a response rate of 80% or more)
- Clinical trial agreements: 45-90 calendar days from submission to approval
- Parallel submission and approval of applications and 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 of patients via the unique personal identification number (CPR no.)
- A high level of standard of care - fully publicly funded health care
- Close collaboration between patient associations, companies, clinics and multidisciplinary cancer groups within hematology and Center for Hematology

The main purpose of Trial Nation Hematology is to facilitate clinical trials regarding pharmacological interventions in hematology diseases.

Patients

Trial Nation Center for Hematology recruit patients for clinical trials with all types of hematology diseases.

Hematologic cancers are frequent in Denmark with an incidence 3,000 cases per year and a prevalence of approximately 30,000 individuals.

Location of specialty functions and requirements for their fulfillment can be found in the National Plan for Medical Specialties, which also provide a rough estimate of the number of patients available within the disease. Trial Nation may help in the further specification of number of patients with specific diseases or at specific hospitals.

The clinics at Rigshospitalet, Little Belt Hospital, and Odense University Hospital work

dedicated with shared decision making.

All the clinics and Trial Nation have a close collaboration with the patient associations on clinical research.

National treatment guidelines are available for the treatment of almost all hematological diseases and usually follow European guidelines closely. The latest treatment guidelines are available on the Danish Multidisciplinary Cancer Groups homepage.

Denmark is, in general, an early adopter of new EMA approved treatments based to a centrally evaluation process in the National Medical Council.

Experience

The experience with clinical trials at different phases, clinical use of gene sequencing and profiling, and immunotherapies varies across the clinics as indicated in the below

table. All hematology clinics participate in biobanking under the Danish Cancer Biobank, which secretariat is located at Herlev & Gentofte Hospital.

Clinic	Clinical trial phases	Clinical trials**/year		NGS, partial/whole	Local tumor board	Immunotherapy	Contact(s) for trials
		Commercial	Non-commercial				
Dept. of Hematology, Odense University Hospital	Ib, II, III, IV	>30 Ib: 5 II: ~5	>30 Ib: 0 II: ~5	+/+	+	+	Prof., CRU Leader & Trial Nation Medical Lead Niels Abildgaard Niels.Abildgaard@rsyd.dk
Dept. of Hematology, Rigshospitalet, University of Copenhagen in collaboration with The Phase I Unit at Rigshospitalet	I*, II, III, IV Incl. FIH	>35 FIH: ~5 I: ~10 II: ~25	II: ~6	+/+	+	+	Chief Consultant & CRU Leader (phase II-IV) Peter Brown Peter.Brown@regionh.dk Chief Consultant & Phase I responsible Martin Hutchings Martin.Hutchings@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
Dept. of Hematology, Herlev & Gentofte Hospital	II, III, IV FIH	~15 II: 2	>30 I: 3 II: 2	+/-	+	+	Chief Consultant & CRU Leader Lars Møller Pedersen lars.moeller.pedersen.01@regionh.dk
Dept. of Hematology, Little Belt Hospital – Vejle Hospital	I, II, III, IV	~26 FIH: ~1 I: ~4 II: ~6	~1-2	-/-	-	+	Prof. & CRU Leader Torben Plesner Torben.Plesner@rsyd.dk
Dept. of Hematology, Zealand University Hospital	II, III, IV	>39 II: 2	>8 II: 6	+/-	-	+	Chief Consultant & CRU Leader Christian Bjørn Poulsen cbpo@regionsjaelland.dk
Dept. of Hematology, Aalborg University Hospital	II, III, IV	~15 II: ~3	~10 II: 7	+/+	-	+	Chief Consultant & CRU Leader Henrik Gregersen henrik.gregersen@rn.dk
Dept. of Hematology, Aarhus University Hospital	Ib, II, III, IV	>20 Ib: 3 II: ~5	>20 II: ~5	+/+	+	+	Prof. Francesco Annibale D'Amore fran-damo@rn.dk Chief Consultant & CRU Leader Hans Beier Ommen hanomm@rn.dk

Notes: *National referral clinic, ^o = Nordic referral clinic, NGS = Next Generation Sequencing, Clinical trials: open, prospective, clinical trials with medicinal products or medical devices. I.e. clinical trials open for recruitment & open clinical trials closed for recruitment where patients are subject to treatment or follow up. CRU = Clinical Research Unit

Additional clinic details

Odense University Hospital

The Department of Hematology is research active and have authored >500 publications since 2000 in international, peer-reviewed journals. Professor & Clinical Research Unit Leader Niels Abildgaard is further the Trial Nation Medical Lead of the Center for Hematology.

The clinic has a catchment area of 1.2 million people, perform 15,000 consultations per year and see approximately 1,000 new referrals every year. Clinical trial conduct is

supported by a clinical trials unit with 3 professors, 2 adjudged professors, 5 associated professors, ~6 PhDs, 10 study coordinators, and 2 research secretaries.

The department is the national referral center for amyloidosis, mastocytosis, hyper-eosinophilia syndrome, and regional referral center for all acute leukemias, aggressive lymphomas incl Hodgkin lymphoma, rare diseases, and autologous transplantation. The clinic is experienced in immunotherapy

including radio-immunotherapy and protocols for PD1/PD-L1 inhibitors, bi-specific antibodies/bites, and tumor vaccination. The hospital as a whole is patient oriented; there are several patients in the hospital research council, and patients and relatives are including in a user council at the department of hematology. Moreover, the department is devoted to shared decision making. The department has established a research center for health-related quality of life, QoL

Rigshospitalet (Copenhagen University Hospital)

The Department of Hematology in collaboration with the Phase I Unit is highly research active and have annually authored >100 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 South Sweden (Skåne). The clinic performs 4,500 consultations and see approximately 650 new cases every year. Performance of clinical trials is supported by a clinical trials unit with 2 professors, 6 associated professors, \approx 13 PhDs and \approx 19 project nurses, and a research secretary.

The Phase I Unit is the national referral center for phase I hematology patients and see >600 (40 hematologic) patients referred yearly. The clinic further has patients referred from the South Sweden (Skåne). The Phase I Unit included \approx 100 patients in phase I clin-

Rigshospitalet (Copenhagen University Hospital)

The Department of Pediatrics and Adolescents 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

Research OUH, and partners the leadership of a Geriatric Cancer Research Center (Age-Care). The Hospital has highly developed imaging facilities including whole body MRI, PET/CT and PET/MRI.

The clinic has established particular early phase (Ib-II) study capabilities with mini-laboratorium, monitoring facilities and dedicated clinical staff.

ical trials per year and has performed whole exome sequencing, RNAseq, and SNP array of all referred patients since 2013. The clinic accordingly holds a database of a more than 1400 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 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.

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

phase I & II clinical trials per year, often in a close collaboration with the Phase I Unit at Rigshospitalet and the Clinical Trial Unit at Department of Hematology at Righospitalet, and the Center for Cancer Immunotherapy at Herlev & 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 Can-

Herlev and Gentofte Hospital

The Department of Hematology is highly research active and have authored >65 publications in international, peer-reviewed journals.

The clinic has a catchment area of 1.8 million people. The clinic performs ≈35,000 consultations and see approximately 1,000 new cases every year. Performance of clinical trials is supported by a clinical trials unit with 3 associated professors, 7-10 PhDs, 6 project nurses, a research secretary, and a specialized Hematology Laboratory.

The clinic performs next generation sequencing (NGS) and whole exome sequencing where required by protocol and for spe-

Little Belt Hospital – Vejle Hospital

The Department of Hematology is research active and have authored >141 publications in international, peer-reviewed journals.

The clinic has a catchment area of approximately 600,000 people, perform 13,000 consultations and see approximately 600 new cases every year. Performance of clinical trials is supported by a clinical trials unit with ≈ 1 professor, ≈1-2 PhDs, ≈ 4 project nurses, 1 research lab technician, and 1 part time secretary.

Zealand University Hospital in Roskilde

The Department of Hematology is research active and have authored >45 publications in international, peer-reviewed journals.

The clinic has a catchment area of 832,000 people, perform 40,000 consultations per year and see approximately 2,000 new cases every year. Clinical trial conduct is supported by a clinical trials unit with 1 professor, 2 associated professors, ≈10 PhDs, 8 project nurses, and a research secretary.

cer (ITCC) and a top tier recruiter on ITCC trials.

cific subgroups as part of the standard of care.

The internationally leading Center for Cancer Immunotherapy forms part of the department and is a and national referral center for patients. Center for Cancer Immunotherapy perform basic, translational and clinical research in cancer immunology and immunotherapy including adoptive T-cell therapy (ACT), dendritic cell (DC) therapy, cancer vaccines and genetic engineering.

The clinic further works closely together with the Danish Cancer Biobank which is also situated at Herlev & Gentofte Hospital.

The clinic has a Clinical Cancer Center accreditation from the Organization of European Cancer Institutes (OECI).

The hospital as a whole is patient oriented and involve patients in the hospitals research council and house Center for Shared Decision Making.

The clinic dosed the first patient world-wide with Daratumumab and regularly perform first in human trials. The clinic covers the whole spectrum from phase 1-4 clinical trials.

The clinic won The Patients Price 2018 at Zealand University Hospital in recognition of the professional and human qualities of the staff with a focus on the needs of the patients.

The clinic performs immune profiling incl. gene expression analyses (NanoString) where required by protocol and for specific subgroups as part of the standard of care.

Aalborg University Hospital

The Department of Hematology is research active and have authored 50 publications per year in international, peer-reviewed journals.

The clinic has a catchment area of 587,000 people, perform 20,000 consultations per year and see approximately 400-500 new cases every year. Clinical trial conduct is supported by a clinical trials unit with 3 professors, 3 associated professors, 2 PhDs, 5 project nurses, and a research secretary.

The clinic forms part of the Clinical Cancer Research Center at Aalborg University Hos-

Aarhus University Hospital

The Department of Hematology is research active and have authored >40 publications annually in international, peer-reviewed journals.

The clinic has a catchment area of 1,3 million people, perform about 15,000 consultations per year and see approximately 1,000 new referrals every year. Clinical trial conduct is supported by a clinical trials unit with 3 professors, 5 associated professors, ≈4 PhDs and 8 project nurses and a research secretary. Besides the CRU, the department also hosts an academic CRO with Professor

pital together with the Department of Oncology and actively work to implement precision medicine clinically. The clinic further dedicated to involved patients through the clinics Users Council

The clinical perform whole exome sequencing full genome sequencing profiling of patients with recurrence/progression of hematologic malignancies and drug sensitivity profiling experiments. The clinical further hold a Clinical trial office for national, Nordic and European protocols and is an experienced National Coordinating Investigator site.

Francesco d'Amore as the lead. This CRO supports most of the investigator initiated trials performed by the Nordic Lymphoma Group.

The department has a well-equipped laboratory for cancer cytogenetics, immunophenotyping of malignancies, and molecular techniques.

The department holds a large lymphoma and acute leukemia biobank of plasma and bone marrow samples, including separated cells.

For coordinated request to all clinics, please contact

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References

- Lægemiddelstyrelsen, Årsberetning 2018
- De Videnskabsetiske Komiteers fælles Årsberetning 2018
- Danish Multidisciplinary Cancer Group's home page, dmcg.dk
- The National Plan for Medical Specialties
- The National Medical Council's homepage, medicinraadet.dk

Trial Nation

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