

Trial Nation

CENTER FOR HEMATOLOGY
A network of Danish hematology clinics

Your clinical hematology research partner

Trial Nation Center for Hematology

Trial Nation offers one point of contact to all hematology clinics in Denmark. And a fast, guided, national, 5 working day feasibility process and collaboration on initiation of clinical trials.

The main purpose of the center is to facilitate clinical trials regarding pharmacological interventions in hematological diseases.

Trial Nation Center for Hematology is a Danish network of eight hematology clinics involved in clinical research with medicinal products and medical devices. Medical Lead for the center is professor, Chief Consultant and Clinical Research Unit Leader Niels Abildgaard from Odense University Hospital.

Characteristics

The hematology clinics are characterized by:

- Comprehensive experience with commercial and non-commercial phase I, II, III & IV clinical trials, including First In Human trials and pediatric hematology trials
- Extensive experience with gene profiling and sequencing that has been translated into clinical use at hospital and regional tumor board meetings
- Immunotherapy implemented at all clinics
- Referral of patients for clinical trials on regional, national, and international level
- Access to the Danish Cancer Biobank, a national cooperation between hospital pathology departments and laboratories handling fresh frozen tissue, blood, and bone marrow samples from patients with hematological cancer.

Special advantages:

- Short start-up time
 - Competent authority: [≤35 days](#) from check-in to first response (≥95%) and ≤14 days for First In Human trials
 - Ethics committees: [≤60 days](#) from check-in to approval (4 of 5 regions deliver on ≥85% of the submissions)
 - Clinical trial agreements: 45-90 days from submission to approval. National clinical trial agreement templates are available. Negotiation of a company

specific national clinical trial agreement template is also possible

- Parallel submission and approval of applications and agreements
- Unique possibilities for characterization of patients and follow-up of patients via the unique national personal identification number (CPR no.)
- Fully publicly funded health care with a high level of standard of care
- Close collaboration between patient associations, companies, clinics, and multidisciplinary cancer groups within hematology
- New EMA approved treatments are adopted at an early stage in the Danish Health Care system.



The uptake area covers the whole of Denmark and for pediatrics and adolescents the Nordic countries:

REGION	CENTER DEPARTMENTS	ANNUALLY UPDATE
Capital Region of Denmark 1.8 million inhabitants	Herlev & Gentofte Hospital - Dept. of Hematology	35,000 consultations 1,000 new cases
	Rigshospitalet (University of Copenhagen) - Dept. of Hematology	11,500 out-patient visits 1,800 new cases
	Rigshospitalet (University of Copenhagen) - Dept. of Pediatrics and Adolescent Medicine	The Nordic countries (>25 million)
Region Zealand 837,000 inhabitants	Zealand University Hospital - Dept. of Hematology	40,000 consultations 2,000 new cases
The Central Denmark Region 1.3 inhabitants	Holstebro Hospital (Hospital Unit West) - Dept. of Hematology	14,000 consultations 900 new cases
	Aarhus University Hospital - Dept. of Hematology	22,000 consultations 400-500 new
The North Denmark Region 589,000 inhabitants	Aalborg University Hospital - Dept. of Hematology	20,000 consultations 400-500 new cases
The Region of Southern Denmark 1.2 million inhabitants	Odense University Hospital - Dept. of Hematology	15,000 out-patient visits 1,000 new patients
	Vejle Hospital - Dept. of Hematology	13,000 consultations 600 new patients

Patients

Trial Nation Center for Hematology recruits patients for clinical trials with all hematological diagnoses.

In Denmark, the prevalence is approximately 30,000 individuals. Annually about 3,000 patients are diagnosed with a hematologic cancer.

Patient involvement is powered by shared decision-making in several of the clinics.

Location of specialty functions can be found in the [National Plan for Medical Specialties](#), which also provides an estimate of the num-

ber of patients per diagnose group. Please contact Trial Nation for updated number of patients per diagnose per hospital upon request.

National treatment guidelines follow European guidelines closely. Links to the latest treatment guidelines are available at the Danish Hematology Association website (www.hematology.dk) in Danish.

Experience

Clinic	Phases	Open & prospective clinical trials/year		NGS, partial/whole	Local tumor board	Immunotherapy
		Commercial	Non-commercial			
Herlev & Gentofte Hospital	II, III, IV	~17 II: 2	>30 I: 1 II: 5	+/+	+	+
Holstebro Hospital	II, III, IV	>10 II: 3 III: 5	~5 II: 3 III: 2	+/-	+	+
Odense University Hospital	Ib, II, III, IV	>30 Ib: 5 II: ~5	>30 Ib: 0 II: ~5	+/+	+	+
Rigshospitalet, Hematology	I* incl. FIH, II, III, IV	>35 FIH: ~5 I: ~13 II: ~25	>X II: ~8	+/+	+	+
Rigshospitalet, Pediatrics and Adolescent	Ib*^, II*^, III*^, IV*^	>10 Ib: 5	>10 Ib: 2	+/+	+	+
Vejle Hospital	I incl. FIH, II, III, IV	~26 FIH: ~2 I: ~4 II: ~6	~1-2	+/+	÷	+
Zealand University Hospital	II, III, IV	>31 II: 4	>40 II: 6	+/-	÷	+
Aalborg University Hospital	II, III, IV	~15 II: ~3	~10 II: 5	+/+	÷	+
Aarhus University Hospital	Ib, II, III, IV	>20 Ib: ~4 II: ~6	>20 II: ~5	+/+	+	+

Notes: *National referral clinic, ^ = Nordic referral clinic, NGS = Next

Herlev Hospital

The conduct of clinical trials is supported by a clinical trials unit with 4 associate professors, 7-10 PhD students, 6 study nurses, a research secretary, and a specialized Hematology Laboratory. The primary contacts for clinical trials are Chief Consultant & Clinical Research Unit Leader, Lars Moller Pedersen (lars.moeller.pedersen.01@regionh.dk).

The clinic is associated with in-house labora-

tories which perform advanced procedures of molecular biology such as next generation sequencing (NGS) and whole exome sequencing were required by protocol and for specific subgroups as part of the standard of care.

The clinic works closely with the internationally leading Center for Cancer Immunotherapy and is a national referral center.

Center for Cancer Immunotherapy performs 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.

Holstebro Hospital

The conduct of clinical trials is supported by a clinical trials unit with 1 associate professor, 8 consultants, 2 PhD students, 3 study nurses, and a research secretary. The primary contact for clinical trials is Chief Consultant Stanislaw Pulczynsk (stanislaw.p@vest.rm.dk).

Odense University Hospital

The conduct of clinical trials is supported by a clinical trial unit with 3 professors, 2 adjunct professors, 5 associate professors, ≈6 PhD students, and 10 study nurses. The clinic has established early phase (Ib-II) study capabilities. Professor, Chief Consultant & Clinical Research Unit Leader Niels Abildgaard (Niels.Abildgaard@rsyd.dk) is the Medical Lead of Trial Nation Center for Hematology.

The department is a national referral center for amyloidosis, mastocytosis, hyper-eosinophilia syndrome, and the regional referral center for all acute leukemias, aggressive lymphomas including Hodgkin's lymphoma, rare diseases, and autologous transplantation. Moreover, the department has a clinic for follow-up of allogeneic transplanted patients. Advanced next generation sequencing (NGS) and minimal residual

Rigshospitalet, Department of Hematology

The conduct of clinical trials is supported by a clinical trials unit with 2 professors, 6 associate professors, ≈ 18 PhD students and ≈ 19 study nurses, and a research secretary. The primary contact for phase I clinical trials is Chief Consultant & Phase I Responsible Martin Hutchings (Martin.Hutchings@regionh.dk). For phase II-IV clinical trials the primary contact is Chief Consultant & Clinical Research Unit Leader Peter Brown (Peter.Brown@regionh.dk).

The clinic is experienced in immunotherapy, bi-specific antibodies, and hemopoietic stem cell transplant and recently CAR-T therapy. Imaging facilities include whole body MRI, PET/CT and PET/MRI.

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

The clinic performs diagnostics and treatment of most hematological diseases and was awarded a First Prize for the treatment quality of lymphoma and myelomatosis in 2019 by the medical journal, Dagens Medicin.

disease (MRD) analyses are used for diagnostics and treatment evaluation. The department is experienced in immunotherapy including radio-immunotherapy and protocols for PD1/PD-L1 inhibitors, bi-specific antibodies/BITES, other T-cell engaging constructs, and partners a newly established Elite Research Center for Cellular Immunotherapy in Hematological Cancer (CITCO) that strives for establishment of academic CAR-T cell therapy.

The hospital is patient oriented; there are several patients in the hospital research council, and there is a patients and relatives council at the department of hematology, that has also established a Center for Quality of Life Research and Patient reported Outcome (QoL Research OUH).

The Phase I Unit is the national referral center for Denmark for phase I hematology patients with its 5,7 million inhabitants and regularly includes patients from the other Nordic countries. The Phase I Unit includes 40-50 hematology patients per year. The Phase I Unit also includes ≈100 solid tumor patients in phase I clinical trials per year and has performed whole exome sequencing, RNAseq, and SNP array of all referred patients since 2013. The Phase I Unit has extensive experience in early clinical trials. The majority of studies are first-in-human studies, including complex immunotherapy trials including T-cell bispecific and combinations.

Rigshospitalet, Department of Pediatrics and Adolescent Medicine

The phase I-II trial unit for children and adolescents with cancer is a national, Nordic and northern European referral center with a catchment area of >25 million inhabitants. The contact for clinical trials is Chief Consultant & CRU Leader Karsten Nysom (Karsten.Nysom@regionh.dk).

The department is also the national center for allogeneic hematopoietic stem cell transplantation and CAR-T cell therapies in children and adolescents.

The conduct of clinical trials is supported by a clinical trials unit with 2 senior consultants, 6 study nurses, 1 study coordinator, and

The conduct of clinical trials is supported by a clinical trial unit with \approx 1 professor, \approx 2 consultants, \approx 6 study nurses, 2 research lab technicians, and 1 part-time secretary. The primary contact for clinical trials is Prof., Chief Consultant & CRU Leader Torben Plesner (Torben.Plesner@rsyd.dk).

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

The conduct of clinical trials is supported by a clinical trial unit with 1 professor, 2 associate professors, \approx 10 PhD students, 9 study nurses, 1 research assistant, and 1 research secretary. The clinical trials unit covers phase II-IV clinical trials, phase I clinical trials (drugs with new indication) and has experience in national coordination of Nordic and European clinical trials. The primary contact for clinical

The conduct of clinical trials is supported by a clinical trial unit with 3 professors, 3 associate professors, 9 PhD students, 7 study nurses, and 2 research secretaries. The clinical trial unit has experience with phase II-IV trials and all aspects of running a clinical trial and has been the national and Nordic trial office for multicenter clinical trials. The primary contact for clinical trials is Chief Consultant & CRU Leader Henrik Gregersen (henrik.gregersen@rn.dk).

The clinic forms part of the Clinical Cancer

part-time lab staff.

Annually, the unit enrolls 15-20 children or adolescents in phase I-II trials, half of which are referred from abroad (typically the Northern Europe). Several trials are conducted in a close collaboration with the Phase I Unit at Rigshospitalet, the Clinical Trial Unit at the Department of Hematology at Rigshospitalet, and the Center for Cancer Immunotherapy at Herlev & Gentofte Hospital.

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

The hospital is patient oriented and involves patients in the hospital's research council and has an in-house Center for Shared Decision Making.

The clinic was the first in the world to administer Daratumumab to a myeloma patient and regularly performs first in human phase I trials. The clinic covers the whole spectrum from phase I-IV clinical trials.

trials is Chief Consultant & CRU Leader Christian Bjorn Poulsen (cbpo@regionsjaelland.dk).

The clinic performs immune profiling incl. gene expression analyses (NanoString) when required by protocol and for specific subgroups as part of the standard of care. It further assists the Medical Clinical Trial Unit with COVID-19 trials.

Research Center at Aalborg University. The clinic performs whole exome sequencing and whole genome sequencing of patients with recurrence or progression of hematologic malignancies as well as drug sensitivity profiling experiments. The clinic holds a biobank dating back to 2007 containing more than 35,000 diagnostic samples of various hematological diseases from more than 4,000 patients.

The clinic is further dedicated to patient involvement through its patients and relative's council.

The conduct of clinical trials is supported by a clinical trial unit with 3 professors, 4 associate professors, 5 PhD students and 1 functional manager, 1 senior study nurse, 10 study nurses and 1 project manager. The primary contacts for clinical trials are Prof., Chief Consultant & Research Responsible Francesco Annibale D'Amore (fran-damo@rm.dk) and Chief Consultant & CRU Leader Hans Beier Ommen (hanomm@rm.dk).

The clinic also holds a lymphoma biobank of plasma samples for ctDNA assessment and hosts the Clinical Trial Office (A-CTO) of the Nordic Lymphoma Group (NLG). A-CTO is responsible for the set-up and running of clinical trials initiated by NLG investigators, often in collaboration with external corporate partners.

The clinic also performs clinical trials in Hemophilia.

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