Phase I & II Oncology & Hematology Capabilities in Denmark

- Short start-up timelines
  - Median competent authority approval time: 58 calendar days from submission to approval
  - Median ethical committee approval time: 65 calendar days from submission to approval
  - Median clinical trial approval time: 48 calendar days from submission to approval
- Highly experienced phase I & II clinical sites
- Clinical Research Unit
- Unique possibilities for characterization of patients and follow-up of patients via the unique personal identification number (CPR no.)
- Danish Cancer Biobank, a national cooperation between hospital departments handling tissue and blood samples from patients diagnosed with cancer
- High patient willingness to participate in clinical trials
- A high standard of care level
- Fully publicly funded health care
- Patients on clinical trials fully covered by the health care system's public self-insurance

Phase I & II Oncology Capacity in Denmark, Solid Tumors

Department	Phase I & II capability	Trial experience Last year / last 5 years		Key points
		# Commercial	# Non-commercial	
The Experiment Cancer Therapy Unit, Herlev Hospital Att. Professor Dorte Nielsen Dorte.Nielsen.01@regionh.dk +45 3868 2344	I & II	FIH:1/4 I (total): 10/19 II:10/31	FIH: 2/7 I (total): 2/18 II: 5/19	• Dedicated phase I facilities • Gene profiling of all patients • Denmark's largest oncology department (4.500 new cases/year) • Tumor board every week • National Center for Cancer Immunotherapy, including checkpoint inhibitors, adaptive cell therapy (TILs, dendritic vaccines, etc) • Danish Cancer Biobank • Member of the Nordic Network for Early Phase Clinical Trials (Nordic NECT)
Department of Oncology, Odense University Hospital Att. Professor Per Pfeiffer Per.pfeiffer@rsyd.dk +45 6541 1590	Ib-II	Ib: 5 II: 10	Ib: 1 II:11	• Gene profiling of selected patient groups • AgeCare (Geriatric Cancer Research Center) • 50% of the members of the hospital research board are patients
The Phase I Unit & Department of Oncology, Rigshospitalet Att. Chief Consultant Morten Mau-Sorensen paul.morten.mau-soerensen@regionh.dk +45 35 45 08 79	I-II	FIH: ≈9/ 35-40 I (total): ≈40/≈100 II-III: ≈100/ Paediatric: 3/5	FIH: TBC I (total):TBC II: TBC	• Approx. 120 patients included in phase I protocols / year • Approx. 600 patients referred / year • Full genome sequencing of all patients o Global top 5 sequencing site • Experienced in immunotherapy • Tumor board every 2nd week • Paediatric oncology trial experience • National referral center • Member of the Nordic Network for Early Phase Clinical Trials (Nordic NECT)

Phase I & II Oncology Capacity in Denmark, Solid Tumors

Department	Phase I & II capability	Trial experience Last year / last 5 years		Key points
		# Commercial	# Non-commercial	
Department of Oncology, Vejle Sygehus Att. Professor Anders M Jakobsen Anders.Jakobsen@rsyd.dk +45 7940 5000	II	II: 12/18	II: 11/20	• Patient Involvement (research council) • >50% of the patients participate in research protocols • Clinical Cancer Center accreditation (OECI) • Patient oriented – shared decision making • Neoadjuvant treatments (breast, ovarian, colon, rectum) • Biomarker trials – translational research • 23 and 19 ongoing non-commercial and commercial phase II-IV trials
Department of Oncology, Aalborg University Hospital Att. Professor Ursula Falkmer u.falkmer@rn.dk +45 9766 1411	II	II: TBC / 3	II: TBC / 21	• Experienced Clinical Research Unit (established 1991) • Experienced National Coordinating Investigator site • GCP audits – with no major findings • Fast and effective contract negotiations – down to 2 weeks • Reliable recruitment
Department of Oncology, Aarhus University Hospital Att. Chief Consultant Morten Ladekarl morlad@rm.dk +45 6139 9326	II	II: 3 /10	II: 2 /10	• Full genome profiling of patients with no further standard treatments and tumours of unknown origin • Tumor board every 2nd week • Collaboration with the Unit of Experimental Cancer Research and the Danish National Particle Center

Phase I & II Oncology Capacity in Denmark, Hematology Tumors

o

Department	Phase I & II capability	Trial experience Last year / last 5 years		Key points
		# Commercial	# Non-commercial	
Department of Hematology, Herlev Hospital Att. Chief Consultant Lars M Pedersen lars.moeller.pedersen.01@regionh.dk	I & II	FIH: 0/0 I (total): 0/0 II: 2/4 Ex. Center for Cancer Immunotherapy data	FIH: 3/4 I (total): 3/6 II: 2/6	• Dedicated phase I facilities • Gene profiling of selected patients • Danish Cancer Biobank • World leading Center for Cancer Immunotherapy o Basic, translational and clinical research in cancer immunology and immunotherapy o Adoptive T-cell therapy (ACT) o Dendritic cell (DC) trials o Cancer vaccines o Immune monitoring, immune biomarkers o Immune regulatory mechanisms (IO Biotech spin out) o Immune profiling incl. gene expression analyses o Genetic engineering
Department of Hematology, Odense University Hospital Att. Professor Niels Abildgaard Niels.Abildgaard@rsyd.dk +45 6541 1155	Ib-II	Ib: 2/TBC II: 5/TBC	Ib-II: 5/TBC	• Building phase Ib capabilities in collaboration with The Phase I Unit and the Department of Hematology at Rigshospitalet • Gene profiling of selected patients • AgeCare (Geriatric Cancer Research Center) • 50% of the members of the hospital research board are patients

Phase I & II Oncology Capacity in Denmark, Hematology Tumors

The Phase I Unit & Department of Hematology, Rigshospitalet Att. Chief Consultant Martin Hutchings Martin.hutchings@regionh.dk +45 3545 9696	I-II	FIH: 3/5 I (total): 9/12 II: 26/39	FIH: 0/0 I (total): 0/0 II: 6/14	• Full genome sequencing of all patients presenting • Top 5 site in terms of sequenced patients • Experience with immunotherapy • National referral center • Member of the Nordic Network for Early Phase Clinical Trials (Nordic NECT) • Worldwide first site in three lymphoma immunotherapy phase 1 studies (one active and two planned)
Department of Hematology, Vejle Sygehus Att. Professor Torben Plesner Torben.Plesner@rsyd.dk +45 7940 6313	II	I: 0/1 I/II: 5/5	I: 0/0 II: 1/1	• Phase 1 and phase 2 trials of novel compounds for treatment of patients with multiple myeloma • FISH analysis of all myomalytosis patients
Department of Hematology, Zealand University Hospital Att. Chief Consultant Christian B Poulsen cbpo@regionsjaelland.dk +45 4732 4809	II	II: 2/4	II: 2/4	• Experienced phase II center • Facility for full genome sequencing (NGS) • Immune profiling incl. gene expression analyses (NanoString)
Department of Hematology, Aalborg University Hospital Att. Chief Consultant Tarec El-Galaly tceg@rn.dk	II	I:0 II: 2/4	I:1/2 II: 2/4	• Clinical trial office for national, Nordic and European protocols • National Coordinating Investigator • GCP audit 2017 – with no major finding • Full genomic profiling of patients with recurrence/progression of hematologic malignancies • Drug sensitivity profiling experiments

Department of Hematology, Aarhus University Hospital Att. Professor Francesco D'Amore FRANCESCO.DAMORE@KI.AU.DK +45 7846 7567	II	Ib: 1/TBC II: 14/TBC	Ib: 1/TBC II: 7/TBC	• 22 phase I & II trials over the last 5 years • 3 phase I&II trials in pipeline • Lymphoma biobank of plasma samples for ctDNA • Clinical Trial Office for the Nordic Lymphoma Group • Member of the Nordic Network for Early Phase Clinical Trials (Nordic NECT)