Nordic NECT – Early Phase Clinical Trial Course

April, 3rd-5th 2019, at Hotel Lilla Roberts, Helsinki, Finland

This is the first Nordic NECT Course for Early Phase Clinical Trials in Oncology. Helsinki University Hospital will be hosting this course, the first of a possible annual event. For your reference a Nordic Course in Clinical Trials Methodology in Oncology has previously been arranged 6 times, lastly in 2014.

Early clinical trials play a crucial role in drug development. They are in an essential interface between experimental laboratory knowledge and clinical application in patients and include administration of an investigational product to humans first time ("first in human" trials). Early clinical trials require tight adherence to protocol requirements and careful monitoring of patient safety. The field is highly competitive and the requirements for the staff not only include patient care but also maintenance of strict timelines, fast site initiation and patient recruitment, top quality data entry, keeping patient safety always as the priority. Overall, they require resources, dedicated staff and coordination skills.

These and many other issues will be discussed during the course. The aim of the course is to increase participant's knowledge in early clinical trial methodology and also strengthen important collaborations in research and network-building between the Nordic countries. The language in the course will be English.

The faculty

Sirpa Leppä, Katriina Peltola, and Marita Repo, Helsinki University Hospital, Joan Pietraszek, Rigshospitalet, Denmark, Kristin Øwre, Oslo University Hospital, and Kirsten Thorin Hagene, Nordic NECT

Cost

All costs including travelling (train or bus, flights and organized airport transportation) and accommodation will be covered.

Target group

Personnel involved in early clinical cancer trials. Basic knowledge in GCP (Good Clinical Practice) and experience in clinical trials is required.

Number of attendees

Number of attendees will be restricted to 30 (7-8 participants from each country). Selection is based on CV and a motivation letter.

Application

Follow this link to apply for the course. Please have your CV and motivation letter ready to be uploaded. *Due to short timelines this application is binding.*
For more information contact, Sirpa Leppä at Sirpa.Leppa@hus.fi, or Kirsten Thorin Hagene at kihage@ous-hf.no
Last day of application is March 5th, 2019.
All applications will be confirmed within March 10th, and travel arrangements will be centralized.

The course is supported by unrestricted grants from Finnish Cancer Foundation, Abbvie, Roche, Novartis, BMS, MSD and Nordic Trial Alliance.

Early Phase Clinical Trial Course

Program, 3-5 April 2019

Wednesday 3rd	**Chair: Sirpa Leppä**	**Presenter**
11:30-12:30	Registration & Lunch	
12:30-13:10	Welcome, practical aspects, presentation of the delegates	Sirpa Leppä
13:10-13:20	Aim of the course, Introduction of early clinical trials in the Nordic region	Sirpa Leppä
13:20-13:50	Trial design- from dose escalation to basket	Rikke Løvendahl Eefsen
13:50-14:20	Break	
14:20-14:50	From bench to bedside-Introduction to preclinical drug development	Mika Mustonen
14:50-15:20	Pharmacokinetics & Pharmacodynamics	Mikko Niemi
15:20-15:40	Protocol template presentation	Kirsten Thorin Hagene
15:40-16:10	Patient Reported Outcome - Noona	Mari Metso-Lintula
16:10-16:30	Break	
16:30-17:00	Biobanking	Olli Carpen
17:00-17:30	Molecular screening - Why and how?	TBC
19:00	Dinner	

Thursday 4th	**Chair: Katriina Peltola**	
08:45-09:00	Introduction to day 2	Katriina Peltola
09:00-10:00	Translational substudies in early trials	Anna Kreutzman
10.00-10.30	Challenges and pitfalls in translational research (to make it happen), experiences	Mika Kontro
10:30-10:45	Break	
10:45-11:45	Statistical methods in clinical research	Eva Skovlund
12:05-12:50	Lunch	
12:50-13.20	Radiological response criteria	Hanna Lauren
13:20-13:50	Clinical Trials in the Nordics - Quality system, Oslo University Hospital	Signe Øien Fretland
13:50-14:05	Essential documents and related procedures	Kirsten Thorin Hagene
14:05-15:00	Time for walk, incl. coffee/tea	
15:00-17:45	Discussion and group work: Challenges in clinical trials. All delegates bring their own question	Faculty, Katriina Peltola
19:00	Dinner	

Friday 5th	**Chair: Rikke Løvendahl Eefsen**	
08:30-08:40	Introduction to day 3	
08:40-09:10	Pharma - academic collaborations; challenges	Steinar Aamdal & Pharma TBC
09:10-09:40	GDPR and DPIA - challenges in practice	TBC
09:40-09:50	Break	
09:50-10:20	Safety and emergency	Pharma
10:20-10:50	Audit, inspections	Sarianne Päivike
10:50-11:20	Ethical principles and other challenges in phase I trials	Steinar Aamdal
11:20-11:40	Discussion	Faculty
11:40-12:00	Closing remarks	Sirpa Leppä
12:00-13.00	Lunch	