



ITCC clinical fellowship program, Copenhagen

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To: The ITCC consortium

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The Phase 1-2 Trials Unit

The Phase 1-2 Trials Unit is part of the Clinical Trials Unit (CTU) for Children & Adolescents with Cancer, in the Department of Paediatrics and Adolescent Medicine at Copenhagen University Hospital – Rigshospitalet in Denmark. Rigshospitalet is a tertiary/quaternary referral hospital, so the department of paediatrics has a limited local service area. The section for children and adolescents with cancer serves a background population of approximately 3 million inhabitants and annually diagnoses and treats approximately 100 new childhood cancer patients. Furthermore, the department hosts the national centre for allogeneic haematopoietic stem cell transplantation and cell-based therapies, thus covering all children and adolescents of Denmark (6 million inhabitants).

The Phase 1-2 Trials Unit is the Danish national centre for experimental cancer therapies. Nearly half of the patients enrolled and treated in phase 1-2 clinical trials in the unit are referred from abroad – mainly from Norway, Sweden, and Finland, but also to some extent from countries south of Denmark. The phase 1-2 CTU staff comprises 2½ consultant-level physicians, 8 study nurses including one charge nurse, a research coordinator, one research secretary and a half-time regulatory specialist. Since 2019, the phase 1-2 trials unit has coordinated the NOPHOMatch research project, aiming at having the 6 ITCC centres in the Nordic countries work closer together and referring relevant trial candidates to each other. As of January 2024, the unit has 31 actively recruiting phase 1-2 trials (or, for platform trials, distinct trial arms) for children and adolescents with relapsed or refractory cancer, and 22 patients on active phase 1-2 trial therapy. The phase 1-2 trials unit works closely with and supports The National CTU for Children and Adolescents with Cancer, which supports physicians and study nurses at all the four Danish childhood cancer centres in opening, maintaining, and conducting clinical trials on children and adolescents with newly diagnosed cancers. The national CTU employs 1½ regulatory specialists and 2 study nurses.

The department's research lab ([Paediatric Oncology Research Lab, Bonkolab](#)) employs more than 130 persons, including 2 professors, 2 assistant professors, several post-docs, PhD students, Master students and 8 lab technicians. The main research areas of Bonkolab are cancer aetiology (including WGS of germline DNA), tumour biology, pharmacology of anticancer agents, cohort studies of ALL and CNS tumours, host genome variants and treatment response (efficacy and toxicity), physical activity, rehabilitation and psychosocial research.

The fellowship training

The fellow will work full-time in the phase 1-2 CTU with all aspects of developing and conducting of phase 1-2 clinical trials for children with cancer. This will span the whole process, from the initial steps, with feasibility questionnaires and site selection visits to trial submission to the authorities. Further the fellow will participate in investigator meetings, site initiation visits, patient referral (including many referrals from abroad), screening, randomization / enrolment, treatment, coordination (including many patients living abroad), response evaluation, and end of treatment or end of trial visits. Other tasks include safety reporting, and safety meetings. The trials will be with academic as well as commercial sponsors. The fellow will be assigned a mentor, one of the senior consultants of the trial unit. Initially, the fellow will work directly together with a senior consultant from the trial unit. The fellow is expected within the first few months to become capable of working independently, supervised by the senior consultants. All patient-related activities are carried out in a close collaboration with the study nurses of the CTU.

During the one-year fellowship, the fellow may be involved in basic or preclinical research at Bonkolab (see above) or other major collaborating laboratories at The Danish Cancer Society or Biotech Research and Innovation Center, Copenhagen University). The fellow may also work part of the time with the Phase 1-2 CTU for adult oncology and/or haematology. The fellow is expected to participate in the EORTC-ESMO-AACR workshop on Methods in Clinical Cancer Research (MMCR). The fellow is also expected to participate in the ITCC Training Days, the ITCC annual meeting, the ITCC scientific days, and relevant national and international paediatric haematology & oncology meetings and conferences, depending on the fellow's personal specific academic field.

The fellow will be supervised and guided during weekly team meetings, weekly physician's meetings, and biweekly meetings with the mentor.