

ITCC Fellowship Training Centre Application

The Regina Margherita Children's Hospital is part of the Città della Salute e della Scienza of Turin hospital network, affiliated with the University of Turin. We provide highly specialized paediatric diagnostic and treatment services. Our primary goal is to enhance our commitment to deliver top-quality care, elevate the standard of excellence in the treatment of all diseases and improve satisfaction among patients, their families, and staff.

The Paediatric Oncohematology Department enjoys a distinguished national reputation as a leading centre for paediatric haemato-oncology and stem cell transplantation. It is a member of the Italian Association of Haematology and Paediatric Oncology (AIEOP) and serves as the coordinator of the Piedmont and Valle d'Aosta Paediatric Oncohematology Network. This membership ensures the delivery of optimal patient care and facilitates the efficient transfer of patients across Italian regions to access the best available treatments.

The department specializes in managing oncohematological diseases in children and adolescents (ages 1–18), but also treats patients over 18 years who qualify for paediatric trials or require continuity of care within our unit. Annually, we diagnose approximately 150 new cases and provide comprehensive cancer care throughout the disease pathway, from diagnosis to follow-up.

Key conditions treated at our centre are haematological malignancies, solid tumours (including central nervous system tumours), and other rare cancers.

Our multidisciplinary team comprises a director, 19 doctors, 8 psychologists, 46 paediatric nurses, 27 auxiliary staff, as well as volunteers, teachers and cultural mediators. The team operates across five main units:

- Inpatient Ward
- HSCT and Cell Therapy Unit
- Day Care Unit
- Outpatient Clinic
- Isola di Margherita Hospice

Diagnosis and treatment adhere to national and international protocols and are conducted in collaboration with the Clinical Trials and Research Unit (URSC). The URSC coordinates approximately 80 observational and experimental clinical trials (Phases I–III) in different areas, including paediatric oncohematological diseases, haematopoietic stem cell transplantation, cell therapy, rare metabolic diseases, and supportive care. This unit also ensures high ethical and quality standards through quality control measures and a dedicated training management system.

Clinical trials promoted by the hospital are supported by the University of Turin and the Città della Salute e della Scienza di Torino network. The URSC employs four clinical research coordinators, two research pharmacists, and one research nurse. It oversees various aspects of clinical trials, including site selection, document submission to ethics committees, budget management, data handling, and patient care. The unit also manages compassionate use and off-label drug programs. In addition, the unit provides support to all the medical and the

nursing staff and constantly monitors the application of the existing regulations. In 2017, the Paediatric Oncohematology Unit was certified by the Italian Medicines Agency (AIFA) to conduct Phase I clinical trials.

Our centre offers trainees hands-on involvement in the clinical management of children participating in Phase I/II clinical trials for conditions such as solid tumours, CNS tumours, haematological malignancies, transplantation, and rare tumours. Trainees will attend MTD/multidisciplinary tumour board meetings together with the team, including:

- Leukaemia and Lymphoma MDT (biweekly)
- Solid Tumour MDT (biweekly)
- Neuro-Oncology MDT (weekly)
- Secondary Tumours and Late Toxicity MDT (monthly)

They will also participate in study initiation visits (SIVs), investigator meetings, monitoring visits, close-out visits, and audits/regulatory inspections.

Trainees will collaborate closely with the research team and engage in patient-related activities such as protocol screening, obtaining consent, organizing and attending patient visits, CRF completion, adverse event reporting, dosing adjustment, response assessment (RECIST, RANO, INRC etc). They will gain the skills to manage screening procedures, assess eligibility, complete CRF and coordinate patient care during clinical trials.

Theoretical and practical training includes cellular and molecular techniques, flow cytometry, cell manipulation, and GMP practices. Trainees will learn to interpret preclinical data, review Phase I/II study designs, understand dose escalation, define toxicities/define DLTs/MTD/RP2D and generally understand the methodological, perform statistical analyses, technical and organisational support behind the design, conduct and analysis of academic clinical trials.

The centre offers comprehensive training on regulatory matters (including EU requirements), the role of the Sponsor, the role of the Principal Investigator, ICH-GCP guidelines, ethical considerations, informed consent (especially for vulnerable populations), and data protection. The collaboration with pharmacologists can ensure the fellow support in acquiring knowledge of pharmacokinetics, absorption, distribution, metabolism and excretion, half-life, clearance, volume of distribution, PK modelling, population PK, bioavailability and bioequivalence of different drugs.

Additionally, our collaboration with the Italian Institute for Genomic Medicine enables trainees to deepen their expertise in precision medicine, molecular targeting, and immunology through daily clinical practice.

Ethical aspects and palliative care are integral to our approach. The Isola di Margherita Hospice is specialized in paediatric palliative care. The Isola di Margherita staff organizes interdisciplinary discussions and regular team meetings to align decisions with principles of self-determination, beneficence, non-maleficence, and justice. Internal training sessions are also planned in order to develop a common way of thinking and sensitivity, in line with international scientific thinking. Fellows will be involved in all these aspects and in the care of patients according to the ethical criteria listed above.