

ITCC Fellowship Training Program at Niño Jesús Hospital

The Niño Jesús University Children's Hospital is a monographic health center dedicated exclusively, and since its foundation, to pediatric pathology. Due to its patient volume and the high degree of specialization in the pathology it addresses, it is one of the main pediatric oncology centers in Spain.

The trainee's year-long program will be divided into distinct sections that can be pursued simultaneously:

Clinical Activity

The trainee will carry out the activity both in the outpatient clinic and in the inpatient wards of patients participating in phase I and II clinical trials since the beginning of the fellowship. He/she will be included as sub-investigator in the ongoing early phase pediatric cancer trials at our site (more than 25 trials) covering a wide range of experimental therapies, from conventional chemotherapeutics, to small molecules, antibodies and cell therapy. He/she will be involved in all tasks of the participation of patients in clinical trials: pre-screening, consent form, screening, SAE report, safety and efficacy evaluations (including bone marrow aspirates/trephines, lumbar puncture, etc), IMP administration and accountability, etc.

The trainee will also participate in the local weekly tumor boards (solid, hematological and molecular tumor boards). Additionally, he/she will also participate in the committees we have with the adult oncology service of another institution for the transition of young adult patients, and in national multi-institutional molecular committees in Spain.

He/she will participate in the regular safety TCs from active trials organized by the sponsors, SIVs, MVs, audits and close out visits.

The trainee will maintain communication with study coordinators, data entry personnel, and research nurses for the organization of pharmacokinetics/pharmacodynamics (PK/PD) samples and their shipment. They may also liaise with the trial pharmacy section for drug order processing, reception, management, countability, and investigational product destruction.

Preclinical Activity

Opportunities to spend time in our GMP facility with an Advanced Therapy Medicines Production Unit (ATMPU) will be provided for gaining knowledge in preclinical, translational research, and immune-oncology. The trainee will actively participate in ongoing preclinical projects, including testing target therapies in animal models, developing oncolytic viruses, and projects involving the isolation and characterization of tumor-infiltrating lymphocytes for pediatric tumors. The duration and structure of the laboratory stay will depend on ongoing project activities and the trainee's interests. Regular participation in lab meetings and seminars is expected.

In addition, he/she will be involved in the studies developed by the Oncogenomic Unit of our institution (ie liquid biopsy, tumour methylation...etc) and will actively participate in discussions concerning the application of these procedures to our patients.

Protocol development

The trainee will be supported in the development of a clinical trial protocol with the assistance of the Trial Unit and in conjunction with our pre-clinical lab and the established relationships with a technology company.

We would encourage the fellow to attend research ethics committee meetings.

Education

At the beginning of the fellowship, we will prepare an academic curricula that the trainee has to complete before the end of the training that comprises:

- Development of protocol
- Ethics
- Pharmaceutical Industry
- Pre-Clinical
- Regulatory

This academic training is based on the study of landmark manuscripts and text-books he will be studying along this year.

The trainee will also be encouraged to undertake two post-graduate courses: "Basics in Pediatric Oncology" (directed by Dr. Luis Madero, head of the Pediatric Oncology and Hematology Department) and "Good Clinical Practice and Clinical Trial Methodology" (directed by Dr. Alba Rubio). Additionally, the trainee will have the option to pursue a master's degree in "Advances in Pediatric Oncology and Hematology" (directed by Dr. Luis Madero) and initiate preparatory research for a higher degree (MD or PhD).

1 Year Fellowship Training Program – Hospital Niño Jesús

