ITCC FELLOWSHIP IN EARLY PHASE CLINICAL TRIALS IN PEDIATRIC ONCOLOGY

HOSPITAL U I P LA FE, VALENCIA

INTRODUCTION

Hospital La Fe's Pediatric Oncology Department offers a comprehensive training program designed to provide clinical practical experience in clinical management of pediatric patients undergoing phase 1/2 clinical trials for solid tumors, CNS tumors, and hematological malignancies. The program focuses on developing expertise in study design, development, and comprehension of the study drug response and patient safety. The department manages an extensive portfolio of clinical studies, approximately 50 trials, with 50% of them being sponsored by commercial entities and the other 50% sponsored by non-commercial sponsors.

The training program is designed to provide the fellow with practical experience in various aspects of the clinical studies. The fellow will learn how to participate in patient selection, including reviewing inclusion/exclusion criteria, the consenting process, organizing patient visits, interpreting pediatric preclinical and clinical data, and providing direct patient care under the supervision of the principal investigator or senior sub-investigator. The fellow will also be trained in accurate record-keeping and reporting of adverse events, serious AEs, classification of toxicity and CTCAE grading, definition of DLTs, managing clinical grading, and dosing adjustments.

Additionally, the fellow will learn how to collaborate with other departments such as the radiologic department to evaluate the response assessments in accordance with criteria such as RANO and RECIST or the nurse department to coordinate samples with study nurses and perform pharmacokinetic evaluations. The department emphasizes the importance of multidisciplinary teamwork, with the fellow working alongside study coordinators, data managers, and monitors. They will attend site initiation visits, investigator meetings, participate in trial monitoring, and closeout visits. These experiences will provide the fellow with an understanding of the efficient management of clinical trials and develop necessary communication and cooperation skills with the different investigators involved in the studies.

The fellowship program also includes comprehensive training in preclinical aspects of clinical research, protocol development, regulatory issues, ethics, and pharmaceutical industry practices. The fellow will develop an understanding of interpreting pediatric preclinical data, phase 1/2 study designs, dose escalation rules, definition of toxicities, and defining DLTs.

The program will also provide training in the integration of biology, biomarkers, PK, statistics of study designs, defining response criteria, working with drug combination studies, and understanding randomized phase 2 designs. The trainee will also learn about regulatory requirements, the role of the EMA Paediatric Committee, the role of the sponsor and principal investigator, making applications to regulatory authorities, ICH-GCP concepts, and AE/SAE/SUSAR reporting.

The ethics component of the program covers the Declaration of Helsinki/ICH, the legal framework of Europe, informed consent in children and their caregivers, and confidentiality and data protection.

In conclusion, Hospital La Fe's Pediatric Oncology Department's fellow program provides a comprehensive training experience for pediatricians specialized in peditric oncology seeking to develop their skills in clinical management of pediatric patients undergoing phase 1/2 clinical trials.

JUSTIFICATION OF THE TRAINING ACTIVITY

The field of research and early clinical trials in paediatric oncology has experienced exponential growth in the last 10 years. The training of paediatricians dedicated to this field of paediatric oncohaematology particularly in early clinical trials is often non-existent given the complexity and the fact that it is only carried out in tertiary referral hospitals. This training contract aims to train a paediatrician dedicated to research and early clinical trials in a centre designated as a training reference centre within the structure of the ITCC (Innovative therapies for children with cancer). These needs have been identified through professional feedback because of the quick development of this area in the last 5-10 years.

OBJECTIVES

***GLOBAL OBJECTIVE**

Comprehensive training in research and early clinical trials in paediatric oncohematology.

***SPECIFIC OBJECTIVES**

- Clinical management of patients in clinical trials in advanced stages of oncological disease.

- To become familiar with the concepts of early phase research, Phase 1 pharmacokinetic studies and Phase 2 efficacy studies.

- To be familiar with the fundamentals of ethics, good clinical practice and sample processing.

- Training in the processes of opening trials, monitoring visits and closing clinical trials.

- Understanding and learning the legal and ethical process for the opening and contracting of clinical trials.

- Participate in national patient registries, national paediatric tumour registry, compassionate use drug registry.

- Active membership and participation in ITCC (Innovative therapies for children with cancer) activities.

- Possibility of concomitant development of a doctoral thesis on an aspect related to research in paediatric oncology.

TIMETABLE

The program will be developed from Monday to Friday from 8 am to 15 pm alongside hospital ordinary medical activities. The entire program is presential. If necessary punctual modifications can be made if an activity requires afternoon implication (ej: PK sample processing, urgent medical needs, patients in palliative setting, etc).

Daily activity begins with a general admission session with all the pediatric oncology team with a summary of the relevant information of the situation of the patints since the previous day. Afterwards the trainee will attend the tumor boards in which the unit participates when they take place. The central part of the day will be spent managing patients in the early phase clinical trial setting weither in the outpatient clinics or the pediatric oncology tumor board. This activity will be supervised directly by one of the tutors.

The final part of the day will be either dedicated to administrative tasks related to clinical trials or scientific update or manuscript preparation ir order to publish the most relevant findings. On Thursdays the trainee will also participate in the CORE tumor board where other centres in the Valencian Comunnity also participate virtually by teleconference. See below the proposed timetable for the fellow.

	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
8:15-8:30	Admission session	Admission session	Long revision Admission session	Admission session	Admission session
8:30-9:30	Personalized medicine tumor board	Pediatric tumor board	Long revision Admission session	Scientific revision session	Hematology pediatric tumor board
9:30-13:00	Clinical trial activities (outpatient clinics)	Clinical trial activities (outpatient clinics)	Clinical trial activities (outpatient clinics)	Clinical trial cactivities (pediatric oncology ward)	Clinical trial activities (pediatric oncology board)
13:00-15:00	Administrative clinical trial activities	Administrative clinical trial activities	Scientific revision / Manuscript preparation	Pediatric interhospital tumor board (CORE)	Scientific revision / Manuscript preparation

ETHICAL ASPECTS

At our hospital, we have a comprehensive plan to deliver the necessary learning in ethical aspects and palliative care to students participating in clinical trials. We ensure that our training adheres to the legal framework in Europe, as well as the ICH guidelines, besides, there are regular courses that reviews the GCP and ensures that everyone involved in clinical research is aware of the regulatory requirements.

As part of the training, we cover topics such as informed consent and the particular considerations necessary when obtaining consent from children and the legal tutor. We also prioritize the importance of confidentiality and data protection to protect the privacy and safety of our patients.

Our training ensures that students have a thorough understanding of ethical considerations and palliative care in the context of clinical trials. We are committed to provide the fellow with the necessary knowledge and skills to conduct research with integrity and compassion.