Experimental Therapeutics Fellowship, Hematology and Oncology
University of Cincinnati

Goals and Objectives

Overview

The Experimental Therapeutics Fellowship is designed for physicians interested in clinical trials in oncology. This is a one-year, non-ACGME-accredited program. The ideal candidate is a person interested in being a clinical researcher with a focus on conducting clinical trials in any disease area of hematology and oncology. This one-year program can be pursued either before or after a traditional three-year ACGME-accredited Hematology/Oncology Fellowship.

Goals

The overall goal is to learn the conception, design, conduct, analysis, and reporting of clinical trials in hematology/oncology. The expectation is to become acquainted with new therapies, manage patients on clinical trials, report results of treatments, and present findings whenever possible in a published form. Additionally, trainees are expected to participate in writing research protocol(s) for experimental drugs, design clinical trial(s) and become more independent in their work. Presenting their work at national meetings and conferences will be encouraged strongly.

Objectives

- To learn and practice scientific literature search and review to select a good area of clinical investigation.
- To formulate a clinical trial idea and prepare an initial design.
- To learn about various study designs – phase I, Ib, II, III.
- To understand broad statistical implications – recommended phase II dose, pick-the-winner versus direct comparison designs, etc.
- To write a letter of intent (LoI) or initial submission to appropriate sponsor/grantor.
- To write a full study protocol, with emphasis on treatments chosen, schedules, safety and efficacy assessments, endpoints, and statistical plans.

- To learn the principles of Good Clinical Practice (informed consent, protection of vulnerable subjects, formal HIPAA/IRB training, FDA training modules).
- To become familiar with the roles of major entities involved in clinical trials: pharmaceutical companies, NCI, NCTN structure and cooperative groups, CTEP, CROs, FDA, etc.
- To submit protocol to PRMC and IRB and work with the review process.
- To become familiar with budgeting and contracting aspects of the study start-up.
- To attend SIVs.
- To manage patients on a clinical trial: presenting the trial and consenting; screening and reviewing eligibility to finalize enrollment; treating the patient, following for toxicities and managing them; assessing, grading and reporting adverse events and serious adverse events; checking study data being collected and reported.
- To work with the study team: nurses, APPs, pharmacists, clinical research coordinators, data monitors, auditors, medical monitors, and study PIs.
- To analyze clinical trial data in conjunction with biostatisticians.
- To write up abstracts and manuscripts; to submit, present, and publish results.

Clinical Components:

Management of patients on clinical trials, under supervision of program faculty. Management will be in the outpatient clinics. There are no inpatient or call responsibilities.

Participant's Supervisory and Patient Care Responsibilities:

Fellows attend approximately 3-4 half days of clinic weekly where they are expected to see approximately 5 patients in a day under the supervision of the teaching faculty. They learn about experimental agents, the complications of treatment and manage the patients' symptoms and other medical problems.

Teaching and Service:

Fellows will run the Molecular Tumor Board – a meeting focused on precision oncology. They will present cutting edge data on cancer therapies targeting molecular alterations in cancers. This

meeting will be attended by Faculty and trainees (Residents, other Fellows), as well as translational scientists.

Fellows will also attend the weekly Experimental Therapeutics meeting, presenting scientific highlights of various drugs in our clinical trials portfolio, as well as interesting results from ongoing studies in the field.

Research

Research opportunities are available for Experimental Therapeutics fellows in both basic science and clinical settings in the various divisions and departments of the University of Cincinnati. Fellows identify a major research project(s) upon beginning of fellowship, and are expected to produce a minimum of two abstracts and one publishable manuscript upon completion of one year of training. Fellows are expected to attend the research meetings and conferences taking place on campus, and participate in at least one national or international research conference per year to present their work.

Didactic Components

The Division of Hematology and Oncology has an integrated didactic program that incorporates all training programs and is designed to provide a comprehensive teaching curriculum that includes didactic lectures, weekly oncology grand rounds, numerous disease specific multidisciplinary tumor boards and M&M presentations. Fellows will have opportunities to choose and attend various programs, lectures, seminars – in person and online – around campus. Pharmacology, biostatistics, ethics, regulatory aspects, are some of the key areas pertaining to this program.

Supervision

Fellows are supervised by each teaching faculty whom they rotate with in clinic. Key faculty include:

- Davendra Sohal, MD, MPH
- Trisha Wise-Draper, MD, PhD
- Emily Curran, MD
- Muhammad Kashif Riaz, MD
- Shuchi Gulati, MD