



A Faster, Broader Pipeline for Phase I Clinical Trials

Five years after the Phase I Clinical Trial Infusion Center opened its doors at Smilow Cancer Hospital, Director Patricia LoRusso, DO, still gets a thrill reporting to her clinic every day.

The state-of-the-art facility serves as the dynamic hub of Yale Cancer Center's cutting-edge Phase I Clinical Trial Program. The program advances promising cancer therapies through the FDA approval pipeline and provides hope for patients with advanced stage cancers in need of another option beyond the standard treatment.

Under the leadership of Dr. LoRusso, Associate Cancer Center Director, Experimental Therapeutics, the program, and its dedicated highly-trained staff, have not only significantly increased the number of immune-based therapies and other treatments entering phase I trials, but also dramatically shortened the timeline for introducing those therapies to patients for whom time is of the essence.

Joseph Paul Eder, MD,
and Patricia LoRusso, DO

A CUTTING-EDGE TRIAL PORTFOLIO

Yale Cancer Center is home to some of the world's leading investigators and scientists whose breakthroughs in cancer biology, pharmacology, and drug development show great promise in the treatment of a wide range of human cancers. In particular, its reputation as an innovator in immune-based therapies provided a distinct advantage to the Phase I Clinical Trial Program from its very start.

"What distinguishes our program is that it combines both immune therapies and targeted therapies," said Joseph Paul Eder, MD, Clinical Director of the Program. "Many other cancer centers divide these approaches, so patients don't get looked at by the same set of eyes for which might be the most appropriate clinical trial for them. The fact that our patients are served by one committed team of investigators gives them broader opportunities for trials that might benefit them."

The program currently has nearly 60 active phase I trials open, and that number is growing. It's one of the most active participants nationwide in government-sponsored cancer clinical trials through the National Cancer Institute's Cancer Therapy Evaluation Program (CTEP). "We've opened 27 new trials since July 2020, just to keep our portfolio fresh and stay on the cutting edge of what novel therapies are out there that could benefit our patients," said Nicole Sinclair, phase I clinical trials team manager.

Among the most exciting trials underway are five using "checkpoint inhibitor" immunotherapies that activate the immune system and shrink tumors. These trials target melanoma, kidney cancer, and lung cancer, among others.

"A lot of the drugs are now more selective for specific tumor types,"

explained Dr. LoRusso. "So we have to have a large portfolio to be able to service a large number of patients with different tumor types and different scenarios. If you have a drug in your early pipeline that targets a specific mutation, it offers patients another therapeutic option that potentially could be as good if not better than the typical standard of care."

CATERING TO PATIENTS' NEEDS

A phase I trial, by its very nature, has a lot of unknowns. Its primary goal is to establish the maximum tolerated dose of a drug that is safe to use in humans. It might be the first time a particular drug has been given to a patient. As a result, patients often spend long days at the infusion center, so that the nurses can conduct special labs and tests before, during, and after the infusion and closely monitor for any reactions to the novel medication.

The infusion center was designed with the comfort of the patients, and their families, in mind. "It's a warm, welcoming place," Dr. LoRusso described. "We have an amazing staff that really focus on our patients. We recognize how frightening it can be for patients to go on a novel treatment; to enter this new environment and new unknown. Our patients are our heroes. We try to make it as comfortable as possible for them."

Behind the scenes, clinical trial team managers, such as Ms. Sinclair, orchestrate the incredibly complex process of ushering a phase I trial through to completion. She coordinates with industry sponsors and pharmacists, nurses and data managers, regulatory and research teams to make sure that every step of a trial goes seamlessly. "We're the glue that holds all of the pieces together," she said.

With five years of industry-leading experience to draw on, the team

continually evaluates its processes to improve the patient experience and patient outcomes. For example, Ms. Sinclair spearheaded a phase I pilot that reduced the average launch time for trials from 250 days down to around 120 days, with an end target of 90 days. "Our goal is to have an even greater variety of trials open more quickly for our patients," she said.

Those extra months are precious for patients who are in advanced stages of cancer. "Doing early phase trials is intense, but it's also exciting," Dr. LoRusso said. "If a new therapy can get a patient through their daughter's graduation, son's wedding, the birth of their grandchild, or beyond, it's so rewarding."

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-Dr. Patricia LoRusso