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TAKING EARLY PHASE TRIALS TO MINORITY PATIENTS

Thirteen percent of the U.S. population is Black, and 18 percent is Hispanic, yet these groups each account for less than four percent of the patients enrolled in clinical trials for cancer. That startling number is even lower for early phase cancer trials, most of which are conducted through major cancer centers such as the Yale Cancer Center.

“We’ve begun to recognize a huge need to give underrepresented minorities access to early phase clinical

trials,” said Patricia M. LoRusso, DO, FASCO, Professor of Medicine (Medical Oncology) and Chief of Experimental Therapeutics. She also leads the Cancer Center’s Early Phase Clinical Trials Program. “As a result of scientific breakthroughs, the drug development community is developing some outstanding drugs and seeing very encouraging responses in early phase trials,” she continued, “and the opportunity to participate shouldn’t be only for the privileged who can access major NCI Cancer Centers or afford to travel to the Phase I sites.”

Dr. LoRusso is directing a new initiative intended to improve minority enrollment in Yale's early phase cancer trials by bringing the trials to clinics in urban communities beyond Smilow Cancer Hospital in New Haven. The idea is to make participation easier and less intimidating for minority populations who might otherwise be left out.

In the project's first phase, Dr. LoRusso and her team went to the Smilow Cancer Hospital Care Center in Trumbull and interviewed patients, physicians, and nurses to identify barriers that impede minority participation in early phase trials. "We felt that to develop the clinical component successfully, we first had to identify the barriers and the necessary tools to overcome them," said Dr. LoRusso.

The team is now completing its analysis of the interviews. As expected, some of the identified barriers stem from social and structural determinants related to income, education, housing, and neighborhood safety. Other barriers were more surprising. A big one was location. Patients said that participating in trials at Smilow Cancer Hospital in New Haven would be difficult because of time, distance, and expense. They disliked the necessity to drive or find transportation to New Haven, to leave work and family, and to find a caregiver for their children. Patients also expressed some reluctance to leave their communities and the medical staff they know for the unfamiliarity of Smilow's main hospital.

This reinforced one of the primary rationales for the new project. "We feel that if we're going to increase recruitment among underrepresented minorities, we'll

have to bring the trials to the patients," said Dr. LoRusso. "They're familiar with their community physicians, their community oncologists, their community practices and the nurses there. It's close to home and it's easier for them, which breaks down some of the barriers preventing them from joining early phase clinical trials."

Another obstacle was the patients' understandable fears about early phase trials, which were largely unfamiliar to them and to some of the medical staff as well. Some patients worried about being "experimental objects." Dr. LoRusso's team explained how the trials work, why they're important, and the advantages of participating in them. "Thinking about joining a Phase I trial can be frightening," said Dr. LoRusso. "The consent forms themselves, which are necessary to read and sign by the patients, are 25 or 30 pages long and, depending on your literacy level and your language skills, can be overwhelming to read."

The program is funded through generous support from Genentech, Loxo@Lilly, Gilead Sciences, and Boehringer Ingelheim. Dr. LoRusso and her team are working to bring other pharmaceutical support on board.

"To make this project successful," said Dr. LoRusso, "we need a portfolio of clinical trials that our early phase clinical trials team can bring forward into the community sites, and these companies have joined forces with us to carry out that goal as they too recognize the importance of health equity for clinical trial participation."

The pharma companies have been receptive, she adds, because most of them have been working with her Phase I team of clinical physicians, research nurses, and research

coordinators for eight years, and she has assured the companies that the same team will be running the clinical trials at the satellite sites. "Aside from financial reasons and their portfolio of trials," said Dr. LoRusso, "we brought them on because they have operational brain power and are used to overcoming operational barriers. We hope to have them as engaged as possible in this hybrid decentralization project for early phase clinical trial participation."

Dr. LoRusso also sought buy-in from the communities where the trials will take place. The project's team includes Yale's Center for Community Engagement and Health Equity, led by director Marcella Nunez-Smith, MD, MHS, and deputy director Jessica Lewis, PhD, LMFT. They are training community health workers, navigators, and cultural ambassadors specifically for early phase clinical trials for cancer. "We're hoping that they will enhance recruitment," explained Dr. LoRusso.

Another factor crucial to the project's success are the community physicians. "Before enrolling in an early phase trial," said Dr. LoRusso, "we identified the importance that patients place on getting 'buy-in' from their physicians. If their physician wants them to do something else for their cancer, they oftentimes will listen to that physician because they have already built a trusting relationship with them." Her team plans to work collaboratively with these physicians to create a plan for each patient.

The project's first site is the Trumbull Care Center, a large practice with eight oncologists. Dr. LoRusso and her team have been seeing patients there once a week since November, to assess the patients and their eligibility

for early phase trials. In the first few weeks, three patients enrolled onto a trial that may not have even had the opportunity previously.

This new project dovetails with Dr. LoRusso's Early Phase Clinical Trial Program, in which about 10 percent of the participants are minorities. She hopes that this new decentralized model for early trials will democratize accessibility and increase minority enrollment by 100 percent. Once the Trumbull site is running smoothly, in about a year, she expects to expand to Saint Francis Hospital in Hartford, another facility that serves a large, underrepresented population. "We're focusing on two sites where we know the need exists to increase accessibility," she said, "not only to those sites specifically but to neighboring communities, so that all cancer patients can benefit from early phase trials."

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