UC San Diego News Center

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Cancer Isn't Taking a Timeout for COVID-19; Neither are Clinical Trials



Before the COVID-19 pandemic, physician-scientists Drs. Ezra Cohen, Catriona Jamieson, Dan Kaufman and Stephen Schoenberger discussed one of 195 cancer therapeutic clinical trials available at UC San Diego Health. These life-saving studies continue to be offered.

With additional safety measures in place, clinical trials offer patients potentially lifesaving therapies during the pandemic

As a last-ditch effort to halt the head and neck cancer that had spread to Bernard Thurman's lymph nodes and lungs, the 56-year-old Orange County resident was referred to a clinical trial offered at Moores Cancer Center at UC San Diego Health. It was just a week before California initiated a shelter-in-place ordinance.

"Initially, the trial I was going to undergo involved a surgical procedure and an ICU (intensive care unit) stay, but it was put on hold by all hospitals because they wanted to preserve ICU beds in case they were needed for patients with COVID-19," said Thurman. "That changed my care plan. It was disheartening."

Catherine Circo, 32, was a month into a clinical trial for the treatment of cervical cancer when the novel coronavirus forced hospitals to re-evaluate which clinics would continue to see patients in person, which would need to move to telehealth and which would need to pause treatment altogether. Circo watched with growing concern.

"It was scary for a couple of weeks," she said. "My cancer was growing rapidly. From one scan to another, it grew one centimeter (approximately one-third of an inch). The idea of pausing was scary, but they decided that my treatment plan was essential so we continued. It was a relief."

Continuing clinical trials through a pandemic

"Cancer does not stop. It will grow without treatment. It is not an elective disease or procedure," said Dr. Ezra Cohen, associate director for translational science at Moores Cancer Center. "It remains critical to continue to do research during this time. Especially for patients like Mr. Thurman who have exhausted treatment options. More than 1,600 people die of cancer each day in the United States. That's not going to abate because of COVID-19."

Thurman was initially referred to a cell therapy trial led by Cohen. When it was paused in March, Cohen conferred with colleagues and identified <u>Duet 2</u>, a phase I clinical trial for select advanced solid tumors that did not require a hospital stay and has the potential to have a positive result on Thurman's cancer.

The trial uses a bispecific monoclonal antibody—an artificial protein that binds to two different types of antigen—to engage multiple T-cell targets simultaneously with the intent of making combination immunotherapies more effective.

"UC San Diego Health stepped up and made sure I got the next best thing," said Thurman. "It's literally a matter of life or death for me. None of the treatments I have undergone so far have worked. This is one of my last remaining options."



Bernard Thurman was referred to Moores Cancer Center at UC San Diego Health for a clinical trial just as hospitals began to implement safety measures during the COVID-19 pandemic. The trial was paused, but he enrolled in alternative study that has been keeping his cancer at bay.

With 195 cancer therapeutic trials available at UC San Diego Health, ranging from experimental therapeutics to specific tumor types such as breast, blood and marrow transplant, lung and more, patients are guaranteed to receive the highest level of care available. Through these trials, patients may also benefit from the newest therapies offered only through clinical trials.

"To pause clinical trials during a pandemic would be a disservice to patients facing life-threatening diseases like cancer," said Dr. Sandip Patel, director of the Moores Cancer Center Clinical Trials Office.

"The risk of COVID-19 is not subsiding and no patient with cancer can wait for a year—or potentially longer—for a vaccine before continuing their cancer therapy. Why not offer cancer treatment on clinical trials if we know we can do it safely?"

"My family and I were already expecting to go into quarantine knowing my immune system was bad," said Circo. "When the pandemic hit, I wasn't worried about contracting COVID because I saw that Moores Cancer Center took quick action. Patients and employees were wearing face masks and visitors restrictions were put in place. I had peace of mind knowing they were taking such strong action."

At the start of her treatment, Circo was so weak from radiation therapy that her father wheeled her to appointments. When the pandemic hit, visitor restrictions were added as an extra safeguard to protect patients, visitors and team members. Circo's father could now only wheel her to the door. Her health care team would take it from there.

"It was a weird shift," she said. "You go into chemo thinking you'll have someone there with you, but then you're alone. The staff and nurses were always



Patients facing life-threatening disease, like cancer, cannot wait for the pandemic to end to receive care. UC San Diego Health has made changes to keep patients and team members safe during visits so that needed health care and clinical trials can continue.

supportive and had smiles on their faces—smiles you could even see through the masks. That made it easier."

Thurman also observed the many <u>changes made to keep him and others safe</u>. Among them are monthly COVID-19 testing of patients receiving infusion services, more frequent cleaning, health screening of patients, visitors and staff as they arrive each day and a requirement that everyone wear masks. When his appointments did not require a physical presence, Thurman also benefited from <u>telehealth visits</u>, doing follow-up visits via video chat.

"Telehealth was very convenient, but when I have to go in person, I know I am going to a cancer specific building with restrictions and safeguards making it safer than going to the grocery store," said Thurman.

Enrollment down, up

Unfortunately, enrollment in clinical trials slowed as California began to shelter-in-place and hospitals and clinics reduced in person visits because of the COVID-19 pandemic. In most cases, patients already enrolled, like Circo, continued their treatment but recruiting new participants began to fall in March.

"Clinical trials depend on referrals, but if a gastroenterologist is unable to perform a colonoscopy or a biopsy then we don't know if a patient has cancer," said Patel. "We won't know if someone with a cough has a severe cold or lung cancer until patients are seen in person. As in-person visits have increased, and patients feel safe seeing their doctors again, we are seeing enrollment in clinical trials pick up again."

In April, enrollment hit its lowest point with a 50 percent drop in patient accrual. May and June enrollment increased, showing a 30 percent decrease compared to previous years. July data is showing a further uptick in enrollment, demonstrating the need patients have for cancer therapies at UC San Diego Health.

Circo was visiting Moores Cancer Center five days a week for nearly two months while enrolled in the clinical trial NRG Oncology GY017, a phase I trial investigating the optimal sequence of immunotherapy and chemoradiation. The trial also looks at the underlying immune mechanisms of response to therapy with radiation.

Patients who are node-positive compromise 25 percent of the 500,000 cervical cancer cases globally. Unfortunately, these patients have the lowest survival rates for cervical cancer because of the disease's propensity to invade tissues outside of the cervix. Patients whose



Catherine Circo was already receiving cancer treatment through a clinical trial when stay-at-home orders began in California. Despite some restrictions, she was able to continue in the trial and is now in recovery.

disease has spread are not candidates for surgery.

"The trial allows us to stimulate a patient's own immune system while receiving chemotherapy and radiation," said Dr. Jyoti Mayadev, chief of Gynecology Oncology Radiation Services at UC San Diego Health and principal investigator for the NRG Oncology trial. "This course of chemo-radiation is crucial. It has the potential to offer longstanding curative therapy. If a patient recurs after standard radiation, the disease is often incurable. The clinical trial represents a national effort to personalize treatment for cervical cancer."

Circo has since completed her treatment and is feeling better every day. At her weakest, she needed to pause when she walked up a flight of stairs in her home. It would take her a few minutes. Now, although still

slower than normal, she can go up and down several times per day without stopping.

"Who knew walking up and down stairs would be such a great thing?" asked Circo. "You're going to have good moments and bad moments, whether or not there is a pandemic. Don't let COVID factor into your decision to get care or enroll in a clinical trial. Your health is more important, and the pandemic is temporary."

Search for available clinical trials for cancer, heart disease, mental health and more at <u>clinicaltrials.ucsd.edu</u>.