

Streamlined Lung Cancer Trial Begins Enrolling Patients

The Pragmatica-Lung Study, with fewer and simpler eligibility criteria, will test whether Cyramza plus Keytruda improves survival.

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Pragmatica-Lung Study, a streamlined model for future cancer clinical trials, begins enrolling patients

The National Cancer Institute, part of the National Institutes of Health (NIH), has helped launch a phase 3 randomized clinical trial ([NCT05633602](#)) of a two-drug combination to treat patients with advanced non-small cell lung cancer (NSCLC). Called the [Pragmatica-Lung Study \(or S2302\)](#), this is one of the first NCI-supported clinical trials to use a trial design that removes many of the barriers that prevent people from joining clinical trials. This “pragmatic” approach aims to increase accessibility to clinical trials.

The study is part of a broader effort by NIH and the U.S. Food and Drug Administration (FDA) to modernize clinical trials. Pragmatic clinical trials have fewer and simpler eligibility criteria than conventional trials, while still ensuring the safety of patients. The hope is that this type of simplified trial can be less burdensome to patients and investigators, accrue study participants faster, be more representative of the real-world patient population, and serve as a model for future cancer clinical trials.

“This study is designed to eliminate potential barriers to enrollment and provides a model for increasing diversity and enrollment in clinical trials,” said Monica M. Bertagnolli, MD, director of NCI. “Pragmatica-Lung, with its critical public and private partnerships, reflects the innovative approaches NCI is taking to achieve the Cancer MoonshotSM goals, including reducing the cancer death rate by 50% within the next 25 years.”

The trial will evaluate whether a combination of two FDA-approved medications, ramucirumab (Cyramza, manufactured by Eli Lilly and Company) and pembrolizumab (Keytruda, manufactured by Merck), improves overall survival (how long people live) over standard treatment in people with advanced NSCLC whose disease has progressed after previous treatment with immunotherapy and chemotherapy.

“These trials will make it easier for physicians who do not work in big academic medical centers to enroll their patients, resulting in participation by more diverse populations,” said James H. Doroshow, MD, director of NCI’s Division of Cancer Treatment and Diagnosis. “Making trials more accessible, while upholding rigorous scientific and safety standards, means that more health care practitioners and patients will have an opportunity to participate.”

The trial will enroll up to 700 participants from around the United States. Adults ages 18 and older with stage 4 or recurrent NSCLC who were previously treated with immune checkpoint inhibitors (a type of immunotherapy) and chemotherapy will be randomly assigned to receive either ramucirumab plus pembrolizumab or standard treatment. The study will look primarily at how long patients in the two groups live and is expected to complete enrollment by the end of 2025.

Pragmatica-Lung seeks to confirm the encouraging results of a [randomized phase 2 clinical trial \(S1800A\)](#) conducted as part of the [Lung Cancer Master Protocol \(Lung-MAP\)](#), the first lung cancer precision medicine trial supported by NCI. That trial involved 136 patients with advanced NSCLC who had been previously treated with chemotherapy and immunotherapy, and it found evidence that the combination of ramucirumab plus pembrolizumab extended survival compared with standard treatment. Ramucirumab is a targeted drug that works by preventing new blood vessels from growing, and pembrolizumab is an immunotherapy that helps the body’s immune system attack the cancer.

The pragmatic approach is most appropriate for trials in which the drugs being studied have already been approved and their side effects are well understood, Dr. Doroshow said.

NCI collaborators for the Pragmatica-Lung Study include the SWOG Cancer Research Network, which designed and is leading the trial in collaboration with the Alliance for Clinical Trials in Oncology.

The study will be conducted with the participation of SWOG, Alliance, and two other U.S. [NCI National Clinical Trials Network \(NCTN\)](#) groups that focus on cancer in adults, ECOG-ACRIN Cancer Research Group and NRG Oncology. Together, these four NCTN groups represent more than 1,600 cancer treatment institutions in the United States, and doctors from any of these sites can enroll patients on the trial.

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