Broadening Cancer Clinical Trial Eligibility Could Greatly Widen Participant Pool

ASCO and Friends of Cancer Research proposed new eligibility guidelines in 2017.

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By adopting broadened cancer clinical trial eligibility guidelines as proposed in 2017 by the American Society of Clinical Oncology (ASCO) and Friends of Cancer Research, study investigators could greatly increase the pool of potential participants in such research.

R. Donald Harvey, PharmD, director of the Winship Cancer Institute of Emory University's Phase I Clinical Trials Section in Atlanta, presented findings at the 2019 ASCO Annual Meeting in Chicago from a study that analyzed how such broadened eligibility criteria would affect the size of the potential participant population for a study of a lung cancer treatment.

Harvey and his colleagues analyzed electronic health records in ASCO's CancerLinQ database covering 2011 to 2018. They looked for individuals who had advanced non-small-cell lung cancer (NSCLC), had made at least two visits to an oncologist and had received at least one dose of a systemic treatment following their diagnosis. A total of 10,500 people fit these criteria.

The proposed new clinical trial eligibility criteria would allow for those with brain metastases, previous or concurrent cancer diagnoses, and creatinine clearance levels down to a minimum of 30 milliliters per minute. Low creatinine clearance can be an indicator of reduced kidney function or damage to the organ. Traditionally, cancer clinical trials have excluded those with creatinine clearance below 60 mm per minute.

In November 2018, the National Cancer Institute (NCI) took the recommendations of ASCO and Friends of Cancer Research and revised its clinical trial protocol template to widen eligibility criteria for participation in cancer trials. However, it is not yet clear how broadly such new guidelines are being implemented.

"Ongoing use of historic, narrow eligibility criteria based on antiquated safety concerns place potentially unnecessary restrictions on trial participants, thus making it increasingly difficult to conduct the clinical trials necessary to demonstrate safety and efficacy of new therapies," Harvey said in an ASCO press release. "Changes to eligibility criteria are particularly important as we step

further into the era of targeted therapies, including immunotherapies, that have different safety profiles than highly toxic systemic chemotherapies.”

Of the 10,500 people in the new data set, 60% had a diagnosis of Stage IV, or metastatic, NSCLC, and 80% had a history of smoking. The cohort had a median age of 67.6 years old; 56% of the individuals were male and 44% were female.

Under traditional clinical trial eligibility criteria, 5,005 (47.7%) of the cohort members were not eligible for a clinical trial. Using the expanded criteria reduced this figure to just 154 people (1.5%). Expanding the criteria would make 4,851 more people eligible for a clinical trial, about doubling the pool of potential participants.

Broadening the eligibility criteria would increase the median age of the group of potential participants from 66.1 to 67.5 years old, increase the proportion of women from 40% to 44%, increase the proportion of those with a Stage IV diagnosis from 55% to 60%, increase the proportion of those with non-squamous types of lung cancer from 45% to 47%, and increase the proportion of people who have never smoked from 13% to 16%.

To read the conference abstract, click here.

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