Use of Broader Criteria for Clinical Trial Enrollment Would Double Number of Eligible Patients With Lung Cancer

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Contact
Julianne Lee
571-483-1381
julianne.lee@asco.org

ASCO Perspective

“Only about 3% of patients with cancer in the United States currently enroll in a clinical trial, and restrictive eligibility criteria established in an era before advances we have made in supportive care is one reason for this low number. This study makes the case for universal adoption of broader clinical trial eligibility criteria, such as that proposed by ASCO and Friends of Cancer Research, so that more lung cancer patients and others have the opportunity to safely participate in potentially lifesaving research,” said ASCO Expert David L. Graham, MD, FACP, FASCO.

CHICAGO – A study looking at 10,500 health records of advanced non-small cell lung cancer (aNSCLC) patients from ASCO’s CancerLinQ database found that the use of expanded clinical trial inclusion criteria, as proposed by ASCO and Friends of Cancer Research in 2017, would nearly double the percentage of patients eligible to enroll in clinical trials – from 52.3% to 98.5%. The expanded clinical trial eligibility criteria would allow aNSCLC patients with brain metastases, previous or concurrent cancers, and limited kidney function to enroll in clinical trials.

The study will be featured in a press briefing today and presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting.
“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,” said lead study author R. Donald Harvey, PharmD, BCOP, FCCP, FHOPA, Director of the Winship Cancer Institute of Emory University’s Phase I Clinical Trials Section, Atlanta, GA. “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.”

**About the Study**
Researchers looked at electronic health records in ASCO’s CancerLinQ database from 2011 to 2018 and focused on adults with aNSCLC who had two or more oncologist visits and at least one dose of a systemic treatment after diagnosis. CancerLinQ collects and analyzes real-world data from patients at practices nationwide, drawing from electronic health records, to improve the quality of cancer care. CancerLinQ Discovery provides access to high-quality, de-identified datasets derived from patient data to academic researchers, non-profit organizations, government agencies, and others in the oncology community.

Using this data, researchers evaluated the number of patients eligible for clinical trials using traditional criteria and using the proposed criteria from ASCO and Friends of Cancer Research, which would allow for brain metastases, previous or current cancer diagnoses, and creatinine clearance levels as low as 30 milliliters per minute. Low levels of creatinine clearance can indicate kidney damage or impaired function. Traditional criteria, on the other hand, do not allow for these conditions and exclude patients with creatine clearance levels less than 60 milliliters per minute.

In November 2018, the National Cancer Institute revised its clinical trial protocol template to broaden eligibility criteria for cancer clinical trials based on the recommendations of ASCO and Friends of Cancer Research. More time is needed, however, to assess if these broader criteria are being widely adopted.

**Key Findings**
Sixty percent of the people had an advanced, stage IV diagnosis, and 80% were former or current smokers. The median age of patients was 67.6 years; 56% were male and 44% female. When the researchers applied traditional clinical trial enrollment criteria, 5,005 (47.7% of patients) would not meet trial eligibility criteria. If, however, expanded criteria were adopted, only 154 (1.5% of patients) would not meet eligibility criteria. Use of the expanded criteria would allow 4,851 more people to meet these eligibility criteria, resulting in nearly twice as many people with a NSCLC who would.
Adoption of expanded criteria compared with traditional criteria would also enhance the characteristics of aNSCLC patients in the following ways:

- Older patients, raising the median age from 66.1 to 67.5 years.
- Females, raising from 40% to 44%.
- Stage IV diagnoses, raising from 55% to 60%.
- Non-squamous types of lung cancer, raising from 45% to 47%.
- Never smokers, raising the rate from 13% to 16%.

**Next Steps**

Researchers are currently performing other analyses to look at differences between people who have been treated for their disease and remained stable, and people with ongoing brain metastases.

The researchers are also doing sub-analyses to further refine which patients would be eligible for modern-day clinical trials. They note that none of these efforts would be possible without the use of ‘big data’ via CancerLinQ.

Dr. Harvey remarks that what is most needed is greater knowledge about drug-specific and population-specific outcomes in this disease in order to quickly and safely expand eligibility criteria. Expanded eligibility should also help to reduce disparities in enrollment, both socially and economically, he concluded.

This study received funding from ASCO.

**Study at a Glance**

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<tr>
<th>Study Focus: Expanding clinical trial enrollment eligibility</th>
<th>Guide to NSCLC</th>
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<tbody>
<tr>
<td>Study Type: Retrospective, observational analysis</td>
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<tr>
<td>People Studied: 10,500 advanced non-small cell lung cancer patients</td>
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<td>Modification Tested: Expanding access to clinical trial enrollment</td>
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<td>Primary Finding: 47.7% of people do not meet standard trial eligibility criteria for trials in advanced nonsmall cell lung cancer but if criteria were expanded only 1.5% of people would be excluded</td>
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**Secondary Finding(s):**

- Expanded criteria would permit more women, more older people, more people with stage IV diagnoses and more people who never smoked to enroll in clinical trials for nonsmall cell lung cancer

**ATTRIBUTION TO THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY ANNUAL MEETING IS REQUESTED IN ALL COVERAGE.**

**MEDIA CONTACT:**
Julianne Lee
571-483-1381
julianne.lee@asco.org

PATIENT AND CAREGIVER INQUIRIES:
Contact Cancer.Net

About ASCO:

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