

ASCO Urges Expansion of Cancer Research to Include More Older Adults

Points to overly restrictive clinical trial eligibility that impedes evidence base for treating older adults with cancer

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ALEXANDRIA, Va. – The American Society of Clinical Oncology (ASCO) today issued landmark recommendations calling for federal agencies and the cancer research community to broaden clinical trials to include older adults. ASCO also called for redefining eligibility for clinical trials. Both calls to action were published in the *Journal of Clinical Oncology*.

More than 60 percent of cancers in the United States occur in people age 65 and older, a population that will grow exponentially over the coming years. Yet, the evidence base for treating older adults is sparse because they are underrepresented in clinical trials and trials designed specifically for them are rare.

“Older people living with cancer often have different experiences and outcomes in their treatment than younger cancer patients,” said ASCO President Julie M. Vose, MD, MBA, FASCO. “As we age, for example, the risk of adverse reactions from treatment significantly increases. Older adults must be involved in clinical trials so we can learn the best way to treat older cancer patients resulting in improved outcomes and manageable toxicity.”

Developed by ASCO’s Cancer Research Committee, the ASCO position statement, “*Improving the Evidence Base for Treating Older Adults with Cancer*,” makes the five following over-arching recommendations:

- Use clinical trials to improve the evidence base for treating older adults.
- Leverage research designs and infrastructure to improve the evidence base for treating older adults.
- Increase Food and Drug Administration (FDA) authority to incentivize and require research on older adults with cancer.
- Increase clinicians’ recruitment of older adults with cancer into clinical trials.
- Utilize journal policies to incentivize researchers to consistently report on the age distribution

and health risk profiles of research participants.

ASCO also details 16 specific action steps to implement its recommendations, including asking regulatory agencies, research funders, and researchers to carefully consider whether evidence exists to support eligibility criteria based on age, performance status, or comorbid conditions—three primary reasons older adults are excluded from clinical trials.

Furthermore, ASCO encourages researchers to adopt innovative trial designs that would fill knowledge gaps in the treatment of older adults with cancer.

“We need to see clinical trials that mirror the age distribution and health risk profile of patients with cancer,” said Arti Hurria, MD, Director of City of Hope’s Cancer and Aging Research Program and co-author of the ASCO position statement. “ASCO has laid out a multi-pronged approach to expand the participation of older adults in clinical trials, ensuring that all patients will receive high-quality, evidence-based cancer care.”

Redefining Eligibility Criteria for Clinical Trials

In a related effort, ASCO’s Cancer Research Committee released a paper, *Modernizing Eligibility Criteria for Molecularly Driven Trials*, which examines the need to redefine eligibility criteria around the specific population being researched especially as molecular medicine advances.

“Understanding the risks and benefits of a treatment in the intended patient population is the fundamental goal of clinical trials,” said Edward Kim, MD, Chair of Solid Tumor Oncology and Investigational Therapeutics at Carolinas HealthCare System’s Levine Cancer Institute and Immediate Past Chair of the ASCO Cancer Research Committee. “Enrollment into clinical trials has not been optimal and needs urgent reassessment. The era of molecularly-targeted therapy is an exciting one and requires us to reevaluate how we meet this primary objective in order to expedite approval of promising drugs into the clinic.”

Next Steps

To advance the issues raised in its position statement and paper, ASCO plans to organize a public meeting with input from regulatory bodies and key stakeholders with the ultimate goal of developing an algorithmic approach to determining eligibility criteria for individual study protocols which may help guide future investigators in the era of molecularly-driven therapy. The meeting will be held in the Fall of 2016.

To read both statements, please click on the titles below:

- [Improving the Evidence Base for Treating Older Adults with Cancer: ASCO Statement](#)
- [Modernizing Eligibility Criteria for Molecularly Driven Trials](#)

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About ASCO:

Founded in 1964, the American Society of Clinical Oncology (ASCO) is the world's leading professional organization representing physicians who care for people with cancer. With nearly 40,000 members, ASCO is committed to improving cancer care through scientific meetings, educational programs and peer-reviewed journals. ASCO is supported by its affiliate organization, the Conquer Cancer Foundation, which funds groundbreaking research and programs that make a tangible difference in the lives of people with cancer. For ASCO information and resources, visit asco.org. Patient-oriented cancer information is available at Cancer.Net.
