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ASCO and Friends of Cancer Research say cancer clinical trials should be inclusive of broader range of patients

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The 2 organizations issued a joint research statement published in the Journal of Clinical Oncology. According to the statement, researchers have traditionally excluded certain groups from clinical trials out of concerns that they may be more likely to experience adverse events. However, testing cancer therapies on a narrower subset of patients can make it harder to apply the trial findings to the patient population in the real world.



Clinical trials researching cancer therapies should be more inclusive of a broader range of patients, according to the American Society of Clinical Oncology (ASCO) and Friends of Cancer Research.

According to an ASCO press release, it is the result of a joint initiative launched in 2016 that focused on bringing a more inclusive approach to cancer trials so they involve participants who are more representative of the general population with cancer.

Specifically, their recommendations center on 5 eligibility criteria that often keep patients out of trials:

- Minimum age requirements for enrollment
- HIV/AIDS status
- Brain metastases
- Organ dysfunction
- Prior or concurrent malignancies

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Furthermore, the working groups established by this joint initiative found little data to support the concerns that have contributed to the restrictive exclusion criteria in most cancer clinical trials. Many patients meeting these criteria could have benefited from investigational drugs, but had their treatment delayed because there was insufficient evidence to support the drug's safety and efficacy in those populations.

Therefore, the research statement recommends that “trial enrollment criteria should strive for inclusiveness.” Patients should only be excluded if there is a compelling and specific rationale for doing so, which “should be clearly articulated and reflect expected toxicities associated with the therapy under investigation.”

For instance, renal function criteria should include patients with a range of creatinine clearance levels, unless the therapy being studied specifically involves renal excretion. Children should be included in initial trials meant to determine dosages, and later phase trials should include patients older than 12 years if they have a cancer that spans adult and pediatric populations.

“This joint initiative provides a roadmap for how to safely employ broader eligibility criteria for cancer clinical trials and promote a culture of inclusion,” said ASCO President Bruce E. Johnson, MD, FASCO, in the statement. “Allowing more patients to participate in clinical trials will ultimately enhance our understanding of how a given treatment should be utilized to treat the diverse patients we see in everyday clinical practice.”