ASCOR Urges Raising the Bar for Cancer Clinical Trials, Encourages Researchers, Industry to Achieve More Meaningful Results for Patients

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ALEXANDRIA, Va. - The American Society of Clinical Oncology today called on cancer researchers, clinical trial sponsors, and drug developers to employ clinical trial designs that aim to significantly extend the lives of people with cancer.

In a Special Article published today in the Journal of Clinical Oncology, ASCO outlines overall survival goals for cancer clinical trials in several diseases that researchers should aim for -- and patients should expect. The recommendations, developed by the ASCO Cancer Research Committee working with other experts and cancer patient advocates, provide examples of "clinically meaningful outcomes" in four types of cancer: advanced pancreatic, lung, breast, and colon cancers.

"We're urging our colleagues to implement clinical trials that if successful, would provide a significant and clinically meaningful improvement in survival," said Lee M. Ellis, MD, FASCO, immediate past chair of the ASCO Cancer Research Committee and lead author of the article. "People with cancer are living longer due to new therapies that target specific molecular drivers of cancer. As our understanding of the molecular drivers of cancer expands, we should be able to design clinical trials that achieve better results."

The authors note that additional benefits associated with "raising the bar" include the ability to design smaller and smarter clinical trials that can be conducted faster than larger trials that aim for smaller benefits for patients.

"These aspirational trial goals must be based on sound, reliable preclinical studies that provide the foundation for significantly improving outcomes for our patients," Dr. Ellis said. "In our
recommendations, we also address the importance of quality of life and toxicity issues. If a patient experiences more toxicity than with current therapies, the therapy should provide a greater benefit."

ASCO also recommends that clinical trial sponsors establish comprehensive biospecimen banks for each trial, with informed consent from patients, so researchers can connect biospecimens with treatment outcomes to better understand which patients are most likely to benefit from treatment. Access to information about patients’ outcomes will enable investigators to ask scientific questions before and after trials are completed -- a step that would better enable the discovery and validation of biomarkers, molecular markers in the body that are signs of normal or abnormal conditions, that can help guide treatment planning.

Development of ASCO’s recommendations involved a public comment process and review by the ASCO Board of Directors. The ASCO Cancer Research Committee established working groups to study the unmet needs in four cancers -- pancreatic, lung, breast, and colon. The working groups, composed of experts and patient advocates for each cancer type, identified the most optimal, yet feasible, goals for future clinical trials that would offer meaningful benefit to patients and significantly improve the duration and quality of life.

In addition to being a priority topic area for the committee and working group leadership, the recommendations are also connected to ASCO’s research report "Accelerating Progress Against Cancer: ASCO’s Blueprint for Transforming Clinical and Translational Cancer Research."

The draft recommendations were released in April 2013 for public comment and discussed at ASCO’s 2013 Annual Meeting. The groups were led by Emile Voest, MD, PhD (pancreas), Roy Herbst, MD, PhD (lung), Lowell Schnipper, MD (breast), and Alan Venook, MD (colon).

To view the ASCO Special Article and the accompanying editorial, please click here.

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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 more than 35,000 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.