



Individuals with Cancer Must Be Included in COVID-19 Vaccine Trials

New ASCO-Friends Joint Position Statement Encourages Enrollment of Patients with Cancer in Vaccine Studies

Alexandria, Va. and Washington, DC. – June 22, 2021 – Individuals with cancer or a history of cancer should be eligible for clinical trials—including COVID-19 vaccine trials—unless there is safety justification for exclusion, the American Society of Clinical Oncology (ASCO) and Friends of Cancer Research (*Friends*) assert in a [joint position statement](#) released today.

To date, clinical trials for COVID-19 vaccines have almost universally excluded patients with cancer, and many have excluded those who have a history of cancer. Because these studies enrolled narrower, more homogenous patient populations, many of our most vulnerable patients, who have comorbidities and, in some cases, specific immune-compromise, do not know if the vaccines are safe or effective for them. This raises risks for individuals and for society as a whole. Especially now that multiple vaccines have been authorized for emergency use by the U.S. Food and Drug Administration (FDA) and other national entities, ASCO and *Friends* say eligibility should be immediately expanded to include patients with cancer as the default.

“We’ve learned that patients with cancer are especially vulnerable to severe illness, hospitalization, or death due to COVID-19,” said ASCO President Everett E. Vokes, MD, FASCO. **“However, since clinical trials for COVID-19 vaccines have largely excluded patients with cancer, we still have a long way to go to better understand how safe and effective COVID-19 vaccines are for patients in active treatment. It is critically important to study adequate numbers of patients who have cancer or a history of cancer so that we can better understand the degree to which patients with cancer, various kinds of immunocompromise, or both respond to vaccines.”**

ASCO and other professional organizations [recommend](#) patients across the cancer continuum receive vaccinations (including vaccinations for COVID-19) unless specifically contraindicated, such as evidence of potential risk to patient safety. This recommendation is currently based, however, on consensus expert opinion in the absence of clinical evidence. There is a lack of understanding of the degree of immunity and clinical protection that COVID-19 vaccines provide in individuals with compromised immune systems. Until studies provide more specific insights about populations with cancer, patients with cancer who are vaccinated are encouraged to continue to follow all guidance on masking and physical distancing to reduce any potential exposure to SARS-CoV-2.

“We continue to emphasize that broadening eligibility criteria to clinical trials will help inform the optimal use of new medicines for more people, and the same principles apply to COVID-19 vaccines,” said Jeff Allen, PhD, President and CEO of Friends of Cancer Research. **“Because people with cancer**

are at greater risk for severe outcomes from COVID-19, we urge manufacturers and trial sponsors to enroll patients with cancer and develop studies specifically geared towards patients with cancer to fully characterize the level of protection these important vaccines provide.”

In the new joint position statement, ASCO and *Friends* recommend:

1. Vaccine trial sponsors should design studies to be as broadly inclusive as possible. Existing and future COVID-19 vaccine trials should only exclude people with cancer (current or history of) and/or people who are immunocompromised if there is specific and credible risk of harm to them from trial participation.
2. Vaccine manufacturers and trial sponsors should prioritize recruitment of patients with cancer through partnerships with oncology practices, cancer centers, and academic medical centers. COVID-19 vaccine trials should be prospectively designed and purposefully recruit sufficient numbers of individuals with cancer from diverse populations and age groups to enable valid subset analysis.
3. Government agencies with oversight of vaccine development and review should encourage and incentivize vaccine manufacturers to include patients with cancer in existing and future COVID-19 vaccine trials.
4. Public health agencies and other research organizations should design, collect, and analyze real world data on vaccine effectiveness in patients with cancer, in addition to clinical research data. For populations underrepresented in prior vaccine trials, this data collection would enable the most comprehensive understanding of practical clinical considerations.

This joint research statement builds on ongoing efforts between ASCO and *Friends* to broaden and modernize cancer research eligibility criteria, with the goal of making clinical trials more accessible to patients. In April 2021, the two organizations [issued recommendations](#) to address five specific common eligibility criteria: treatment washout periods, concomitant medications, prior therapies, laboratory reference ranges and test intervals, and patient performance status, and in 2017, the organizations [issued recommendations](#) related to brain metastases, minimum age for enrollment, HIV status, organ dysfunction, and prior or concurrent malignancies.

Read the [ASCO-Friends joint research statement on Inclusion of Individuals with Cancer on COVID-19 Vaccine Trials](#).

Learn more about ongoing efforts to broaden and modernize eligibility criteria from ASCO and *Friends*.

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About the American Society of Clinical Oncology

Founded in 1964, the American Society of Clinical Oncology, Inc. (the Society) is committed to the principle that knowledge conquers cancer. Together with the Association for Clinical Oncology, ASCO® represents nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of high quality, equitable patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. Conquer Cancer, the ASCO Foundation, supports the Society by funding groundbreaking research and education across cancer’s full continuum. Learn more at www.ASCO.org, explore patient education resources at www.Cancer.Net, and follow us on [Facebook](#), [Twitter](#), [LinkedIn](#), [Instagram](#), and [YouTube](#).

About Friends of Cancer Research

Friends of Cancer Research (*Friends*) is working to accelerate policy change, support groundbreaking science, and deliver new therapies to patients quickly and safely. We unite scientists, pharmaceutical companies, and policy makers with shared trust and guide them toward meaningful cooperation. This collaboration among partners from every healthcare sector ultimately drives advances in science, policy, and regulation that speed life-saving treatments to patients. For more information, please visit <https://friendsofcancerresearch.org/>.