Cancer clinical trials bounce back after significant COVID-19 disruption: Data from two large US cancer centers

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Data from two large cancer centers in the United States have shown that the COVID-19 pandemic caused substantial disruption to clinical trials

for cancer treatment and care.

The research, published in the leading cancer journal *Annals of Oncology* today, shows that, compared to the immediate pre-pandemic period, there was a 46% decrease in new patient accruals, and a 24% decrease in newly activated trials between March and May 2020.

In particular, a pronounced decrease in the numbers of new patients recruited to trials at Dana-Farber Cancer Institute (Boston, Massachusetts) and the Tisch Cancer Institute at Mount Sinai Medical School (New York) occurred in academically sponsored trials as opposed to industry sponsored trials.

The research also shows that non-White patients were one and a half times more likely than White patients to be taken off trials during the pandemic.

Co-author, Dr. Chris Labaki, a postdoctoral research fellow, at Dana-Farber, said: "Oncology clinical trials experienced a significant disruption during the early phase of the COVID-19 pandemic, with fewer new patients enrolled to trials and fewer trials started. This major decline probably reflects the strain imposed on the healthcare system during the pandemic as resources were diverted towards immediate hospital and patient needs.

"However, the good news is that both patient accruals and trial activations gradually recovered during the subsequent periods of the pandemic and have now returned to higher-than-normal levels, despite the ongoing nature of the pandemic. This shows that cancer centers are able to adapt to the COVID-19-related disruptions in clinical trial activities, which is crucial if we are to achieve better and novel therapeutic options for patients with cancer."

Compared to the immediate pre-pandemic period (December 2019 to March 2020), by March to May 2021 the numbers of patients recruited to trials had increased by nearly 3%, and the numbers of newly activated trials had increased by 30%.

The researchers say their findings show that lessons learned during the pandemic may help to improve the running of clinical trials, improve patient access to them and ensure their stable and consistent conduct in the event of possible disruptions in the future, not just in the two cancer centers but also further afield.

Dr. Labaki said: "The substantial development and implementation of telehealth appointments during the COVID-19 pandemic represents a potentially important step in facilitating meetings between clinicians and patients, monitoring and follow-up. Postal delivery of oral experimental medications may also decrease geographic barriers to clinical trial enrollment. However, it is still too early to say if this will have a significant impact on clinical trials in the normal, non-pandemic setting. We will be following this up from this summer."

The research, led by Dr. Deborah Doroshow, Assistant Professor of medicine at the Tisch Cancer Institute, and Dr. Toni Choueiri, the Jerome and Nancy Kohlberg Professor of Medicine at Dana-Farber, aimed to assess the enrollment on, accrual to, and activation of clinical trials for new cancer therapies. They looked at a total of 4,756 new patients enrolled to clinical trials between December 2019 and June 2021, and 467 clinical trials newly activated between June 2019 and June 2021.

Co-author, Dr. Ziad Bakouny, an internal medicine resident at Brigham and Women's Hospital, Boston, said: "There are a number of causes for the decrease in newly enrolled patients, one of them being a lower number of newly activated trials overall. Other explanations include a

slower recruitment to already existing and activated trials."

Dr. Doroshow said: "At Mount Sinai, we actually had a hold on accrual for several months at the height of the pandemic, with some exceptions, with the goal of limiting patient exposure to healthcare settings. This likely explains our drop in accruals in the early part of the pandemic."

The researchers believe that industry sponsored trials may have adapted better to the pandemic than academically sponsored trials. However, Dr. Bakouny said: "An important consideration is the fact that academically sponsored trials might have been more prone to disruptions during the pandemic because they can be more resource-intensive and often require research biopsies and frequent visits by patients to the clinic."

The finding that more non-White patients were taken off trials during the pandemic warrants further investigation, say the researchers.

"Patients can be taken off trial due to disease progression, toxicity or patient refusal to remain on a trial. While keeping in mind that most patients were taken off trial due to disease progression, the fact that non-White patients appear to be taken off trial more commonly as compared to White patients parallels some of our previous findings, as part of the COVID-19 and Cancer Outcomes Study, where we identified that non-White patients were more prone to experience disruptions in cancer care, such as in-patient and telehealth oncology visits, during the pandemic," said Dr. Labaki.

Limitations of the study include the inability to include another group of patients from another academic institution to further validate the findings.

More information: Oncology clinical trial disruption during the COVID-19 pandemic: a COVID-19 and cancer outcomes study, *Annals*

of Oncology (2022). DOI: 10.1016/j.annonc.2022.04.071

Andrew L. Schmidt et al, Cancer Care Disparities during the COVID-19 Pandemic: COVID-19 and Cancer Outcomes Study, *Cancer Cell* (2020). DOI: 10.1016/j.ccell.2020.10.023