

Dramatic drop in new cancer drug trials during the COVID-19 pandemic



Data showing a 60% decrease in new clinical trials for cancer drugs and biological therapies during the pandemic further highlights the impact that COVID-19 is having on oncology research, leading organisations have warned.

A comparison of trials launched between January and May, 2020, using information from the Medidata Enterprise Data Store found a dramatic decline compared with the previous 5 years.

During the 40-month observation period, 1440 phase 1–4 oncology trials were launched in 91 countries, the US researchers reported in their study in *JAMA Network Open*. Of these trials, 1249 were started in the years before the pandemic, but just 191 since COVID-19 hit.

Further calculations based on a month-by-month analysis showed an incidence rate ratio of 0.40 (95% CI 0.28–0.55) compared with the pre-pandemic period.

Study leader Elizabeth Lamont, senior medical director of Acorn AI at Medidata (Boston, MA, USA), said that 29% of the world's industry-sponsored interventional trials of oncology drugs or biological agents run on the platform they used for the analysis. Their figures, the team say, "raise concerns" about the development of new cancer therapies.

Fahreed Melham, senior vice president at Acorn AI Labs, pointed out that they have previously reported a dip in patient enrolment. "This is just another piece of data that adds to that story, so it wasn't just ongoing trials, but it was also new trial starts where we saw decline."

Logistical challenges in keeping existing trials running have been reported by several organisations. In July, 2020, a survey by the American Society of Clinical Oncology (ASCO) found that clinical trials had been halted or priorities shifted.

At the start of 2021, ASCO published a Road to Recovery report, setting out five goals for getting clinical research back on track, including designing more pragmatic and efficient trials, reducing regulatory burden, and improving accessibility.

"It is not surprising to see a decline in the launch of new trials, it is consistent with other work showing a 50% decline in enrolment during the early months of the pandemic", said Richard Schilsky, chief medical officer for ASCO.

Anecdotally at least, it seems that recruitment to trials has started to recover as sites adapt to new ways of working, even as cases have spiked once more in many countries, including the USA and across Europe, he added.

"This pandemic will come to an end and when it does, cancer will still be with us. We had to redirect our focus, it had to be done, but we have to get cancer research back on track as soon as possible."

Aoife Regan, head of clinical research at Cancer Research UK (London, UK) explained that at the start of the pandemic in early 2020, 95% of cancer trials were halted. There followed a concerted effort to get the existing portfolio back up and running, "but that does leave limited capacity for bringing in new studies", she says.

It is likely to be a while before new study launches are back at the rate they once were, despite a handful of sites having now started new trials, she said. There is also country-wide variation in what trial sites are managing to do, as well as the global problem of a backlog of recruitment for existing studies, she added.

A rapid drop in fundraising revenue also means that Cancer Research UK is planning for a decrease in research spending from £400 million to £250 million. "The first thing we did was a rapid review of the entire portfolio because we wanted to be

really confident that our trials were still viable and feasible", said Regan.

"Some will take longer to complete, some of them may need more money to complete, and some of them may never meet their endpoints. I wouldn't be surprised if we have to close more studies that are struggling."

However, it is not all doom and gloom, she pointed out. They are still funding, and there is work happening to better embed research in UK National Health Service networks, take a look at contracts, and generally remove the barriers that slow trials down. "It is going to be a challenge and we may need to think about how to make that room for those new studies coming through, but there is a real will to make it happen."

Lamont added that there are signs of recovery and that the industry is starting to learn how to work in this new world. "Clinical trial operations writ large have really adapted to this awful pandemic. In a way that, in the end, may leave us better off in our ability to carry out efficient trials that minimise the burden on patients."

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For the **Medidata Enterprise Data Store** see <https://www.medidata.com/en/clinical-trial-solutions/unified-platform/enterprise-data-store>

For the **study report** see *JAMA Netw Open* 2021; 4: e2036353

For more on the **American Society of Clinical Oncology survey** see *JCO Oncol Pract* 2020; 16: 417–21

For more on the **American Society of Clinical Oncology Road to Recovery report** see *J Clin Oncol* 2021; 39: 155–69

For more on **cuts in cancer research funding due to COVID-19** see *Lancet Oncol* 2021; 22: e6