Clinical Research Slows as COVID-19 Surges

As the COVID-19 pandemic worsens, the cancer clinical research community is grappling with how to continue providing access to experimental but potentially lifesaving therapies while keeping immunocompromised patients safe. To that end, cancer centers are making changes to their clinical trial programs, while pharmaceutical companies are deciding how—or whether—trials should continue.

“We believe for the 10% to 20% of patients on clinical trials that [these trials] offer the best chance of the most effective therapy,” explains Bruce Johnson, MD, chief clinical research officer at Dana-Farber Cancer Institute in Boston, MA, which is continuing trials for now. However, he adds, “we’ve also taken a number of steps to minimize exposure to the staff and to our patients.” For example, three quarters of the clinical trials workforce is working remotely, and patients are evaluated by phone or video conference whenever possible.

Similar steps are being taken at the University of Arizona Cancer Center in Tucson. “Right now we are trying to move forward with any sort of interventional treatment trial that could potentially be life prolonging,” says Rachna Shroff, MD, the center’s director of clinical trials, while ensuring sufficient staff to care for patients and minimizing risk of COVID-19 transmission. At the center, three teams are rotating every 7 days, with two working in the clinic and one working remotely. Staff is conducting COVID-19 phone screenings before patient visits, as well as scheduling phone and online appointments in lieu of in-person follow-ups.

Other cancer centers are stratifying trials based on their likelihood of success. The Perlmutter Cancer Center, NYU Langone Health in New York, NY, “has instituted a rule whereby the only trial patients that will be treated are those for whom there is significant evidence of clinical activity,” says Deputy Director Jeffrey Weber, MD, PhD. This includes phase II and III trials with standard-of-care and experimental arms, plus single-arm phase I and II trials testing targeted agents. The center is no longer enrolling patients on inpatient trials and is halting early-phase trials that lack clear evidence of benefit.

The Yale Cancer Center in New Haven, CT, is continuing ongoing trials but limiting the activation of new ones. Additionally, the center is enrolling patients principally on “trials that would be considered an important medical necessity as part of the care of the patient,” says Charles Fuchs, MD, MPH, the center’s director. “We are reducing our clinical trial efforts at the moment, but we look forward to resuming full operations as soon as circumstances allow.”

Pharmaceutical companies are also deciding whether trials should continue. Lilly announced it will delay the start of most new trials and pause enrollment in most ongoing trials; Pfizer released a similar plan. Bristol-Myers Squibb will continue enrollment in existing trials but will postpone activation of new trial sites and new trials.

A recent FDA guidance recommends that sponsors be flexible about protocols for continuing trials. At NYU Langone, sponsors have allowed patients to transition from inpatient to outpatient treatment, or to delay or skip doses or to skip routine blood draws and biopsies; sponsors are making similar accommodations at other centers (see www.fda.gov/media/136238/download).

Still, Weber thinks the situation “is definitely going to disrupt clinical trials—it will put a crimp in trial accrual. It will just take longer to get trials done.”

Yet ultimately, COVID-19 may pose an even greater threat than limited trial enrollment. “My concern is that unless we … flatten the curve,” Shroff says, “in the next few weeks, we are going to be severely short on resources to continue cancer research, and frankly, cancer care.” –Catherine Caruso

Thermo to Buy Qiagen for $11.5 Billion

Thermo Fisher Scientific announced plans this month to acquire Qiagen in an $11.5 billion deal that could bring more diagnostic offerings and sample-preparation technologies to one of the world’s leading manufacturers of scientific instruments, research services, and laboratory consumables.

Qiagen garnered headlines in February for rapidly adapting its test kits to detect the novel coronavirus, creating a molecular diagnostic for use in China—and Thermo has since done the same in the United States. Among cancer researchers, however, Qiagen is...
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