Revised clinical trial rules during COVID-19 pandemic may benefit patients, survey shows

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David Gerber, M.D., conducts a telehealth visit with a cancer patient. Adjusted protocols for cancer clinical trial participation such as increased use of telemedicine have been largely viewed as positive by UTSW research professionals surveyed. Credit: UT Southwestern Medical Center

The COVID-19 pandemic has led to new rules and expectations for clinical trials. Following guidance from federal agencies, institutions such as UT Southwestern adjusted clinical trial operations. To protect patient safety, changes such as utilizing remote consents, conducting telehealth study visits, and shipping oral study treatment to patients' homes have streamlined the clinical trial participation process.

A survey of UTSW clinical research professionals found that most clinical trial coordinators, managers, and nurses report positive experiences with these COVID-related adjustments. In fact, a majority are in favor of keeping the new protocols even after the pandemic ends.

"With COVID-19, we've seen more changes to clinical trial practices than at any other time in my career," says David Gerber, M.D., a professor of internal medicine at UTSW, associate director of clinical research in the Harold C. Simmons Comprehensive Cancer Center, and first author of an article on the survey results published online this week in the *Journal of the National Comprehensive Cancer Network*. "My hope is that this whole ordeal leads to long-term simplification of the clinical research process."

On March 16, UT Southwestern announced restrictions on clinical trials in response to COVID-19, halting new enrollments and cutting back on in-person, nonessential research visits for ongoing trials. Two days later, the Food and Drug Administration issued its own guidance, allowing clinical researchers to make temporary changes to trial conduct, including implementing telehealth appointments and allowing electronic signatures. This guidance remains in effect until the official COVID-19 national emergency is ended by the federal government. The National Institutes of Health also issued revised trial guidance.

"Shutting everything down for new enrollment was a hard decision for us, but ultimately we had to consider what was best for patients," says Erin Williams, associate director of clinical research operations at the Simmons Cancer Center. "Our goal was to get everything reactivated as quickly as possible, but we needed time to figure out how to make clinical trials work in the wake of COVID-19."

Before ramping clinical trials back up, Williams' team had to cross many technical barriers. Those included putting systems into place for researchers and patients to remotely access documents and information, as well as new ways for researchers to communicate virtually with patients.

From April 27 to June 1, the Simmons Cancer Center gradually resumed clinical trial enrollments, but with new measures in place. For instance, patients no longer had to visit in person to consent to participate in a trial—a lengthy process that involves learning about the risks and benefits of participation. That process was shifted to video calls and electronic signatures. Moreover, some patients who previously had to visit the Simmons Cancer Center to receive drugs could now have them shipped to their homes. And some visits to check on patients' progress or symptoms were converted to telehealth calls.

"I think the longer someone works in clinical research, the more they tend to question the status quo," says Gerber, associate director of clinical research for the Harold C. Simmons Comprehensive Cancer Center. Credit: UT Southwestern Medical Center

"Things behind the scenes changed, too," says Williams. "Our workflow and that of any sponsoring pharmaceutical company are very different now."

Gerber, Williams, and their colleagues saw the changes as an opportunity for research. On May 22—roughly a month after the new procedures were launched—they invited 108 UTSW clinical research professionals to participate in a webinar and respond to an emailed survey about the changes.

Ninety-four responded to the survey, including administrative professionals who coordinate trial logistics and finances, research nurses, research managers and coordinators, and data specialists. Of those, 58 percent had more than five years of professional experience with clinical research and 56 percent had personal experience with a COVID-19-related change.

Overall, survey respondents said that the changes had a positive impact on patient safety, treatment efficacy, patient and staff experience, and communication with patients, investigators, and sponsors. More than 90 percent thought that it was pretty important, important, or very important to continue any positive COVID-19-related clinical research adjustments after the pandemic ends.

For some specific changes, those who had firsthand experience with the new protocols were more likely to recommend continuation. For instance, 61 percent of respondents who had used telehealth were in favor of keeping it going, compared with 36 percent of those who had not used this technology. Similarly, 63 percent of those who had been involved in shipping therapies were in favor of the practice continuing, while only 29 percent of those without experience shipping therapies suggested the practice continue.

"It goes to show that things that might look or sound complicated from the outside are actually less scary when you're the one who gets it worked out and does it," Williams says.

Research professionals with more than five years of experience in the field also were more open to keeping the changes in place. "I think the longer someone works in clinical research, the more they tend to question the status quo," Gerber says.

More information: David E. Gerber et al. Experience, Perceptions, and Recommendations Concerning COVID-19–Related Clinical Research Adjustments. *JNCCN* Online Publication Date: 07 Oct 2020 DOI: doi.org/10.6004/jnccn.2020.7643

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