

HOW COVID-19

IMPACTED

CLINICAL TRIAL

DESIGN

With the help of technology, research is becoming more flexible

The COVID-19 pandemic upended or drastically impacted most things, and clinical trials were no exception. Just like schools, hospitals, and other institutions, research centers had to assess the situation in real time and make decisions to prioritize safety. This meant research centers sometimes had to create their own policies, and emerging technologies got a boost from necessity.

University of Kansas Medical Center Neurology Professor Jeffrey Statland, MD, who is also co-principal investigator for ReSolve (Clinical Trial Readiness to Solve Barriers to Drug Development in FSHD), an ongoing observational study that aims to validate new clinical outcome assessments and evaluate physiological biomarkers to support the design and implementation of future clinical trials, says that in hindsight, what researchers accomplished over the course of the pandemic was really impressive.

“In the United States, we had about 60 active studies during the pandemic, and we have about the same number now. Research is really a team enterprise and being able to have that many studies is a testament to that,” Dr. Statland says.

Technology and tools

Researchers made several pivots to their original plans to make the best of the situation and maintain health and safety. "For example, in our ReSolve study, when people couldn't come to the research site, we changed the visiting structure to collect those outcomes we could collect locally with questionnaires and diaries. In some cases that required in-person visits, we expanded study windows to allow people to come in when they were able to collect primary outcomes," Dr. Statland says.

Researchers also devised new methods of data capture and turned the challenges of the pandemic into opportunities to pilot new technology. "We implemented one approach that mimicked what we do in a clinical trial from home," Dr. Statland says. "Using two-way video, we'd have an evaluator walk someone through motor functional measures at home and get a reasonable approximation of what you'd get in person. Another approach was to use digital technology motion analysis to monitor what people were doing outside of the clinic in home environments."

Another critical tool that wasn't necessarily new, but had not been widely utilized, was home health. "The use of home health to collect labs or in some cases perform infusions in clinical trials is going to be persistent," Dr. Statland says, after seeing its use spike to keep clinical trials moving. "In the same way that telehealth was an unanticipated benefit of the pandemic, the same is true of home health. There are a lot of pluses to it, but it has its limitations."

Being prepared

As COVID restrictions are lifted, researchers and their sponsors are looking at future trials with a greater appreciation for the risk of another pandemic or other event that could cause similar disruption. It is becoming common practice to build backup plans into studies.

"In a way, the pandemic was a wakeup call showing that something like this can happen," Dr. Statland says. "We learned a lot about how to make trials more flexible and how to adapt them."

To view current clinical trials, visit:

- [MDA Clinical Trial Updates](#)
- [Antidote - Clinical Trial Finder Tool](#)