Is Remote Clinical Trial Monitoring Here to Stay?

Tuesday, March 30, 2021

By the end of February 2021, just over one year since the novel coronavirus emerged and disrupted our lives, approximately 136 million people worldwide had received at least one dose of COVID-19 vaccine.1 Interestingly, the disruption itself fueled the innovation that allowed such rapid development and deployment of the vaccine. Government issued stay-at-home orders, combined with a desire to protect researchers and the public from infectious disease, made it highly challenging to conduct clinical trials as usual. Yet the need for carefully controlled trials was, arguably, greater than ever.

With the world in the grips of a deadly pandemic, many in the pharmaceutical industry, researchers, and clinicians leaned on remote clinical trial monitoring – primarily because they had no other choice.

Clinical Trial Monitoring 101

One of the most critical elements of conducting clinical trials of new drugs, vaccines or medical devices is ensuring the accuracy and reliability of data generated by the trial.

“Monitoring of clinical trials is required by federal regulations,” says Lauren Litzinger, Executive Director, Global Site and Study Operations and the Monitoring Business Process Owner for Pfizer. “It includes review of data and essential documents and focuses on protocol adherence by participating investigative sites. We conduct these activities to make sure that patient safety is maintained and that the data we ultimately submit for product approval is of the highest quality.”

Not only must clinical trials follow federal regulations, the trial's sponsors often develop detailed standards and practices of their own. Understanding and applying the federal and independent monitoring policies is a priority for facilities like Diablo Clinical Research, a stand-alone research site that's conducted more than 900 clinical trials in collaboration with a variety of sponsors, including Pfizer, Bayer, Merck and Roche.

Before COVID-19, clinical monitors physically visited testing sites every few weeks to talk with staff, tour the facility, check up on such things as product storage and cleanliness, and review a lot of paperwork.

“We keep paper charts here, so when a monitor would visit, we’d bring all the binders to the monitor room and they would review them," says Catherine Morimoto, Director of Clinical Operations at Diablo Clinical Research.” Monitors put little sticky notes on the charts where they noticed an issue or had a question, and then we’d address those issues.”

COVID Shutdowns Trigger Pivot to Remote Monitoring

When widespread shelter in place orders were issued in March 2020, regular on-site monitoring became impossible, but many projects couldn't afford to be put on hold. So, Pfizer and their clinical research partners quickly shifted gears to support patients and ongoing trials from afar, including adapting their approach to predominantly remote monitoring.

“We had to lean on technology, such as WebEx and Zoom and Florence, a digital platform for data sharing ,” Litzinger says, "not to replace what we had but to do the very best we could under the circumstances. “The industry had used some of these tools before, but they hadn’t been embraced, partly because it’s burdensome for research sites to upload

their data in a timely manner.”

Morimoto agrees. “We’d done it for a few studies, but we really wanted monitors to come here and look at our data,” she says.

With that option off the table and a pressing need for a COVID vaccine, Diablo Clinical Research partnered with Pfizer to apply remote clinical monitoring to conduct their vaccine trials. The switch to remote monitoring — along with a data entry person — allowed Diablo (and other clinical research sites around the world) to share data almost as soon as it was available – and gave monitors the opportunity to quickly review and address concerns .

“The turnaround time for this was like nothing we’d ever really experienced,” Morimoto says. Teams of remote monitors reviewed data nearly ‘round-the-clock.

“Earlier review means earlier submission which hopefully leads to earlier approval, so we can get products to waiting patients,” Litzinger says. “That’s what happened with the COVID-19 vaccine.”

The Future of Remote Monitoring

It's easy to get swept up in the excitement about how technology made so much possible during an extraordinary time in our history. And the expectation might be that these new methods will become permanent, replacing the way monitoring was done before. However, those in the thick of things say pandemic-inspired remote clinical trial monitoring revealed two truths:

Remote monitoring can be practical and efficient. There’s still great value to on-site monitoring.
“We’ve learned that remote monitoring is most effective when it supplements on-site work,” Litzinger says. “It allows on-site monitors to engage in strategic discussions and problem-solving during site visits. Instead of sitting in a room looking at papers, the monitor can observe processes and address protocol deviations.”

Still, remote clinical trial monitoring is far from becoming the norm. “The state of monitoring is still in flux,” says Helen Stacey, MD, MPH, Principal Investigator at Diablo Clinical Research. “Many sponsors have not and are not allowing remote monitoring. However, I certainly think this will hasten the uptake of virtual monitoring. I think a lot of the changes that were thrust upon us by COVID are here to stay, and they’re not all bad.”

References

Data on COVID-19 (coronavirus) cases, deaths, hospitalizations, tests: All countries. Our World in Data. https://ourworldindata.org/coronavirus

Originally published, Tuesday, March 30, 2021