Is Pharma Ready To Embrace Virtual Trials?

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WHITE PAPER

Using a virtual, or decentralized, approach to clinical trials has the potential to improve patient experience and data quality while also accelerating the time it takes to get new drugs on the market. Although these benefits have been apparent for years, the COVID-19 pandemic created an urgent need to implement virtual approaches. As cities, states, and countries enacted stay-at-home orders or put restrictions on face-to-face interactions, patient assessments, monitoring visits, and regulatory inspections were all moved to phone and video-based interactions to keep patients and research teams safe and clinical trials on track.

This quick transition demonstrated that these patient-centric models can work even on large scales. It also helped those involved in clinical trials feel more comfortable and confident in virtual approaches that will likely be the new normal moving forward.

Pharmaceutical companies are realizing that now is the time to take a serious look at the best approaches for designing and implementing virtual clinical trials. Forging ahead with this new way of doing things will require a new mindset, new protocols, and new ways of collecting and handling data.

Why Go Virtual?

Whether incorporating virtual components or making an entire clinical trial virtual, some of the most important benefits are experienced by patients. Today, only about 30% of people say that they would consider participating in a clinical trial,[1] and for cancer patients, the number is less than 5%. For those who do participate, almost a quarter of them say they dislike the distance to the clinic and the length of those visits.

Allowing study participants to visit with clinical staff virtually is safer during the COVID-19 pandemic and also much more convenient and accessible. This means that incorporating more virtual components into a trial design could greatly increase the number and diversity of people willing to participate while also upping retention.

Incorporating virtual components into a trial can also help automate manual processes such as site selection and data collection that enhance study results while significantly reducing both the time and cost of a trial.

A barrage of new sensors and devices are now available to measure various biological or behavioral events, with minimal effort on the part of the patient. This opens the potential to collect data outside of those small moments in time when patients are in the clinic, providing more real-world data for clinical trials. This data provides investigators with valuable patient insights and allows sponsors to answer their scientific questions even faster.

What Are The Barriers, Beyond Technology?

Learning and implementing new technology is often viewed as the biggest challenge to executing virtual approaches. However, decentralized approaches cannot be applied successfully without considering barriers in the areas of people, process, and mindset.

When it comes to people, getting buy-in at all levels is critical but not always easy. It is equally important for the sponsor's senior management to be on board as it is for the different functional areas and project teams that will be implementing new protocols. While senior management will want to understand the benefits and the risks of a new approach, those doing the day-to-day work will need education and training that gives them a real idea of what to expect when putting virtual approaches into practice.

In terms of process, the fact that clinical research is very regulated can make sponsors wary of undertaking changes. There are many unknowns because no standards exist for defining how new technology can and should be applied in clinical trials. Also, the best ways to work with regulatory agencies to apply these technologies in late-stage trials is still an open question.

Mindset comes into play because it is difficult to change the way things have always been done. Clinical trial protocols are often designed from templates that have been used for years. These templates are not based on virtual approaches and new ways of working and can, in fact, hinder the ability of an organization to embrace considerations for a particular population or trial.

How Can We Work With Sites to Adapt to Virtual Trials?

Although COVID-19 forced some clinical trials to pivot to virtual visits mid-study, designing virtual components into protocols from the very beginning makes for smoother implementation at clinical sites. Trying to convert completed protocols to fit a new paradigm is like trying to rewire a house after it has been built. It can be done, but with great difficulty and serious effects on the structure.

Many of today's protocols are so complex that it becomes almost impossible to recruit participants. Even when a patient meets clinical trial requirements and might be willing to participate, their healthcare provider may not be aware of the trial or know enough about it to adequately inform patients.

Starting from scratch can ensure that protocols are manageable and incorporate technologies that automate manual processes. For example, protocols might include new strategies for informing healthcare providers about trials and recruiting patients or be designed to help clinical sites improve compliance, adherence, and engagement.

How Can Protocols Be Designed To Optimize Data Flow?

As clinical trials incorporate more virtual components, it is easy to think that clinical sites will experience the biggest shifts. However, these changes also mean that clinical trial data is no longer limited to traditional forms. It is not enough to choose a patient-facing technology; the entire data flow needs to be optimized. This requires considering the effects on data quality, healthcare professional workflow, the patient's ability to comply, and the feasibility of conducting a trial in many different locations.

This is, in fact, a critical opportunity for improvement. Traditional data collection approaches tend to decrease productivity. Methods used to identify study participants and collect data are difficult to incorporate into the research site workflow and are usually not integrated with other systems used to run the trial.

When deciding if virtual data collection approaches are right for a clinical trial, it is important to examine whether the study and disease state lend themselves to remote data collection. For some cases, it might not be possible to remotely collect data effectively and safely in real time. In other cases, it might be possible but might introduce an entirely new end point that needs to be evaluated. Changing the way in which data is collected can sometimes change the data itself. Regulators tend to be supportive of approved devices being used to collect data but will need more information if the end points change.

The focus should be on finding strategies that provide the best data to answer the scientific question within the patient population of the trial. It is equally critical to identify the best technologies for capturing, analyzing, storing, and improving data flow. This will ensure that the data is ready at the right time to make the decisions.

As clinical trials incorporate more virtual components, study teams and sites need more patient information, clinical insight, and control with less system complexity and burden. Oracle Health Sciences developed the Clinical One advanced eClinical platform to support all types of trials in the simplest, most user-friendly way, providing a way to collect and manage all the clinical data in one place.

The cloud-based platform is ideal for incorporating virtual components because it allows trials to be set up in just days with point-and-click design. This makes it easy to incorporate study design changes or to develop completely new patient-centric protocols. It also helps meet changing data flow needs by making it easy to share data across people, processes, and systems throughout a trial.

We have arrived at a crucial time for advancing decentralized clinical trials. To reap all the benefits of these new approaches and technology, it is key that pharmaceutical companies find ways to fully address barriers that might slow down the implementation of decentralized clinical trials.

References

1. *https://forteresearch.com/news/infographic/patient-recruitment-enrollment-clinical-trials-infographic/*

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As a leader in life sciences cloud technology, Oracle Health Sciences' Clinical One and Safety One are trusted globally by professionals in both large and emerging companies engaged in clinical research and pharmacovigilance. With over 20 years' experience, Oracle Health Sciences is committed to supporting clinical development, delivering innovation to accelerate advancements, and empowering the life sciences industry to improve patient outcomes.

Build a study once,
enter data once,
do everything in
one place.