Virtualizing Your Clinical Trials

With modern innovation and advances in medical technology, clinical studies and the way they're conducted are changing. The traditional method of having to travel to a lab, hospital, or test site is inconvenient. Although facility-based studies have consumed the research market for the last century, it should no longer be a mandatory requirement for much of today's clinical trials.

With innovative advances, site-less clinical research is on the rise. Virtual trials, as they're often called, allow communication between trial participants and facilitators — and data collection — without the need for face-to-face visits and site visits.

Virtual Trials 101: What You Need to Know

Virtual trials are simply clinical trials that aren't 100% site-based and use mobile and digital technology to help relay information. These trials can be referred to by different names, including:

- Virtual trials
- Decentralized trials
- Remote trials
- Digital trials
- Site-less trials
- Direct-to-patient trials
- D2P trials
- Hybrid trials

With the assistance of cutting-edge technologies, clinical research and trials can now range from 100% on-site research to 100% off-line with no face-to-face contact, and many fall somewhere in between. This "Trial Dial" allows for clinical trials to reach the needs of its participants, researchers, and sponsors while remaining consistent and efficient with data collection and management.

Is There Really a Need for Virtualization?

It's estimated that fewer than 10%[1] of Americans have participated in a clinical study. Researchers and trial sites often struggle to get patients to participate and fully engage with the study throughout its duration. Less than 7% ever follow through and complete a clinical trial.

But virtualization of clinical trials changes these statistics. Medidata is running one of the largest virtual trials, the ADAPTABLE Study where we have seen significant improvement, with 48.4% of interested patients end up consenting to the trial and an estimated 95% following through until the trial's completion.

What Are the Benefits of Virtual Trials?

It's no surprise we've seen the participation statistics improve with virtual trials. With traditional, on-site trials, 23%[2] of participants were unhappy with site location, and 11%[2] felt it was too time-consuming to travel back and forth to the research facility or clinic, causing 30%[3] to drop out of studies. What's more, nearly 35%[4] of patients were lost to the study due to some sort of misunderstanding, whether it was their obligations, what they were to do, or what was going to happen.

Virtualization eliminates these pain points for participants and keeps patients engaged for the duration of the trial. But remote clinical trials do more than just increase participation and commitment. By utilizing technological advances like connected sensors and direct data capturing tools, we see an increase in patient convenience, and we also have an improvement in data quality. Researchers can increase both the size and diversity of their participant pool, making it more representative of their targeted population. With the automatic digital transmitting of data and the elimination of human error, data is more consistent and reliable.

Virtualization also significantly decreases the cost of clinical trials. There's less overhead with fewer site management costs, if any, and with so many more participants engaging in the trial, there is less money lost due to patient drop out.

What Kinds of Technology Are Used in Virtual Trials?

As virtual clinical trials become more popular, researchers become more adept at solving the challenges presented. Platforms like Medidata's make the process even easier. Depending on the needs of each particular trial, participants may e-sign consent forms or use an app to complete diaries providing information about how they're feeling or what they're doing. Patients may wear a sensor that relays information from blood glucose level to how many hours they sleep at night. And to make analyses even easier, data can be kept on a unified platform, where it's easily available to researchers, doctors, and sponsors, each with their own level of privileges. PV

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Editor's Notes:

[1] 2017 Research America, An Alliance for Discoveries in Health – Public Perception of Clinical Trials

[2] 2017 CISCRP Perceptions & Insights Study

[3] 2006 Impact Report - Tufts CSDD

[4] 2013 CISCRP Report on Ineligible Participants and Those Who Terminate Participation Early

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