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Virtual Clinical Trials: Regulatory Concerns

Clinical Trial vs Virtual Clinical Trial

Digital elements of clinical trials like electronic medical records, wearable devices, and digital sensors and apps have all previously been employed as supplements to traditional data collection. Before COVID-19, the demand for the kind of technology needed to support virtual clinical trials was much lower. Digital alternatives to in-person appointments, testing, and check-ins experienced a sudden demand increase due to the pandemic and have caused digital clinical trials to accelerate at an unprecedented speed. Now, these technology platforms are being used to collect clinical trial data that would otherwise be disrupted or unobtainable caused during COVID. Using these tools can help mitigate spreading of the virus in doctor's offices and hospitals, but policies and regulations to address participant safety, privacy, data integrity, and the responsibilities of investigators in a decentralized trial environment need to be in place.

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The terms "clinical trial" and "virtual clinical trial" are not explicitly defined in Health Insurance Portability and Accountability Act6 (HIPAA) regulations, but HIPAA defines research as "a systematic investigation that has as its primary purpose the development of, or contribution to, generalizable knowledge." When applied broadly, this means that identifiable data collected from devices, platforms, or apps as part of a clinical trial remain covered under HIPAA. However, existing user data residing on the patient's mobile phone, such as data from apps like Fitbit and Apple Watch are a bit more of a grey area, said Deven McGraw, General Counsel and Chief Regulatory Officer for Citizen Corporation during a virtual clinical trials workshop panel in 2019. He says that differentiation may lie in the origin of the device. If the mobile device is given to the participant for use in the trial, the data in the device should be covered by HIPAA. However, additional data and liability of data breach may be the responsibility of mobile device and communications companies under the Federal Trade Commission. Some companies like Apple and 23&Me have sought to remedy this data privacy disparity by asking new users to agree to vague consents that allow for "future research", but McGraw says in the context of a specific trial for medical product development, consent likely needs to meet both FDA regulations and Common Rule requirements.

Data and Privacy Laws

Recent developments in privacy laws, like California's Consumer Privacy Act (CCPA) and the European Union's General Data Protection Regulation (GDPR), seek to regulate data in general more stringently. These laws enforce more explicit consents and have raised the standard for deidentified data. While these laws intentionally do not address the already intensely regulated data collection in clinical trials, they set a precedent for protecting data regardless of the source. These laws are also important for subsequent uses of data collected in clinical trials, like replication of results or additional studies, which may be exempt from these laws.

The FDA says that in the midst of COVID, safety of trial participants continues to take precedent. It recognizes that protocol modifications may have to be made to preserve patient safety and trial integrity and encourages sponsors to evaluate alternative data collection methods in order to overcome delays in trial progress. Participant safety in a decentralized or virtual trial would require access to qualified professionals to address adverse events, safety monitoring of data in interventions. Luckily, remote technologies are creating opportunities for greater oversight of safety by replacing episodic monitoring with continuous monitoring of variables such as blood glucose levels or heart rate and rhythm. Conversely, it is important to ensure that potential technology failure would not jeopardize participant safety or data integrity.

As technology and data legislation catch up, the demand for decentralized virtual trials has continued to rise. Now, regulations on data privacy and patient safety are more important than ever. Leonard Sacks, Associate Director for Clinical Methodology for the FDA says he envisions these trials operating like a hub-and-spoke model. Investigators at the center, participants at the periphery, all connected by local providers and technology platforms. Implementation of these new technologies in decentralized trials could shorten trials and increase participant retention and compliance overall, ultimately improving clinical trials in the long term, rather than simply providing mitigating tools for data collection during the pandemic.

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Considering a virtual clinical trial?

Salus IRB has experience in assisting its clients with virtual clinical trials – from consulting in trial design, remote and risk-based monitoring plans, to e-consent platforms. To learn how we can help your company with your virtual clinical trial, contact us at **clientservices@salusirb.com**.

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