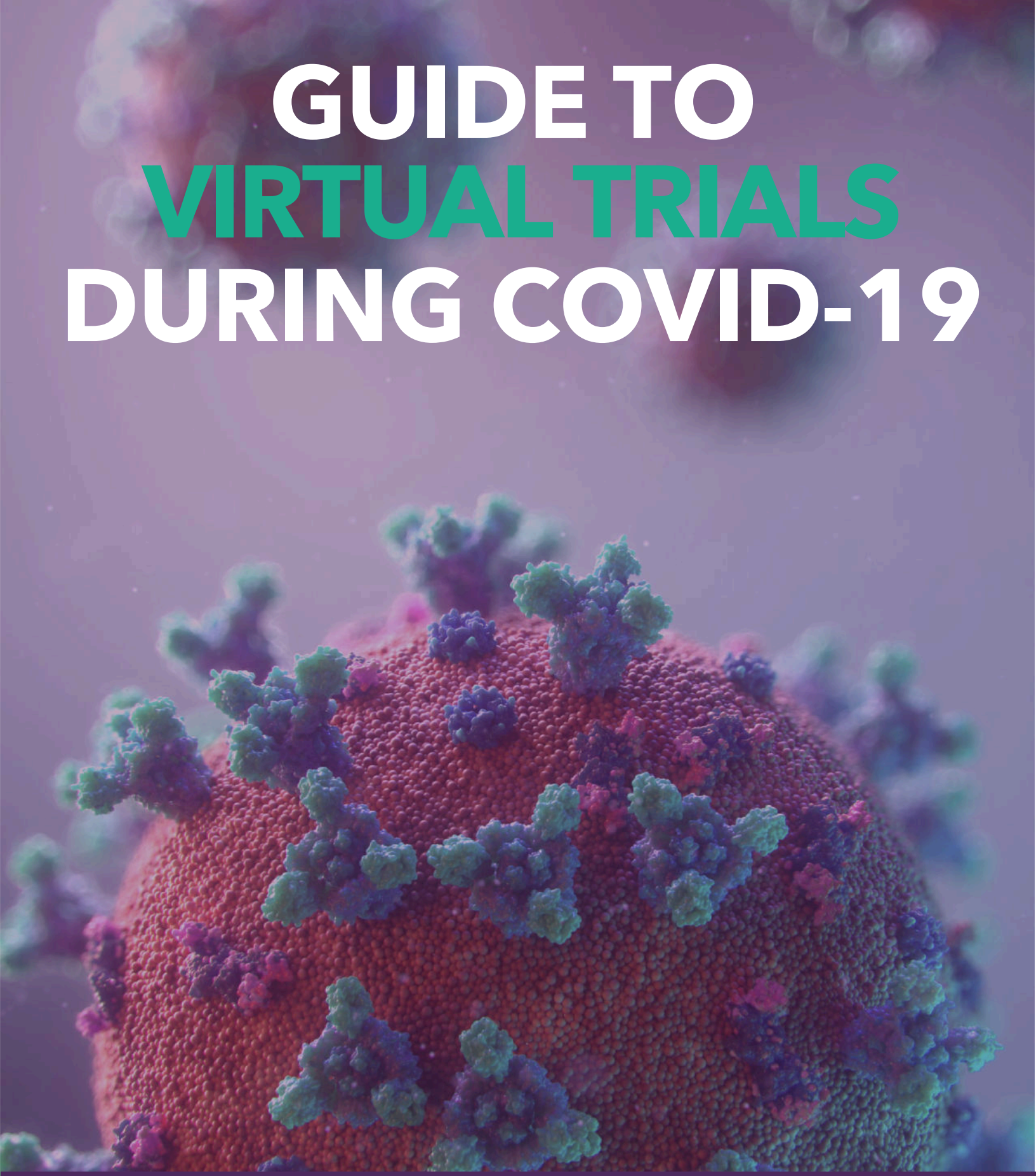
GUIDE TO VIRTUAL TRIALS DURING COVID-19



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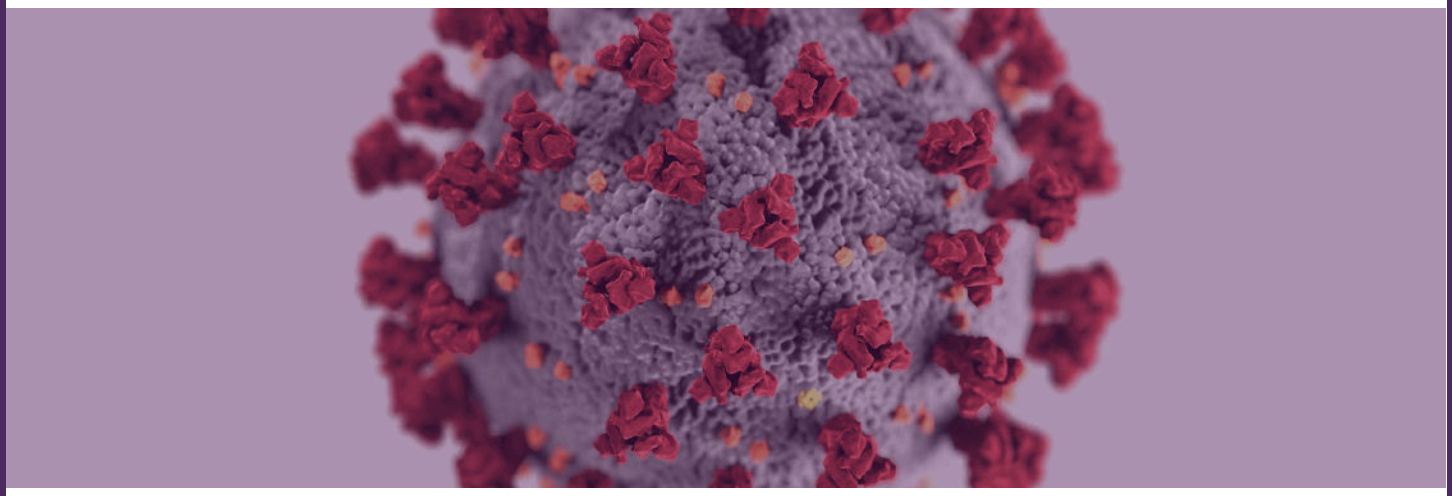
CORONAVIRUS OUTBREAK

New Approaches to Clinical Research: Decentralized and Virtual Trials



COVID-19

June 21, 2020

As COVID-19 continues to pose a serious threat to individuals all over the globe, clinical researchers are looking for ways to safely continue their trials to progress medicine and medical treatments. One of the main concerns surrounding the traditional clinical trial model is what to do if patients aren't able to attend in-person visits. *How will the data be collected in a compliant manner?* The answer may be to take a more "patient-centric" approach to research. Decentralized trials have been a topic of discussion in the clinical research industry for several years. However, the Coronavirus pandemic has shifted this topic to the forefront. The industry, which has been slow to adopt a decentralized or virtual approach, is now much more compelled to consider the idea. There are several areas to consider when planning a virtual trial. In this guide, we will discuss some of these considerations and how they relate to Electronic Data Capture (EDC).

Considerations:

What constitutes a virtual trial?

What is the FDA guidance for conducting virtual trials?

Which eClinical products are necessary for conducting virtual trials?

What functionality should be available within these products?

What compliance factors should be assessed?

Which security features are important?

Overview of Virtual Trials

On March 18, the FDA issued a guidance for sponsors conducting clinical trials during COVID-19 restrictions which stated, "Considerations include, among others, sponsors evaluating alternative methods for assessments, like phone contacts or virtual visits and offering additional monitoring for those trial participants who may no longer have access to investigational product or the investigational site." To run a successful virtual or decentralized trial, sponsors should consider how the source data is collected, how the data is transferred and stored in a compliant manner, and how the data is reviewed and assessed for accuracy.

Telemedicine products such as eSource, eConsent, and eCOA/e-PRO were designed to lower the barrier for patients to participate in clinical trials, thereby improving patient recruitment and retention. These products have also made it easier for remote study conduct, which increases efficiency and ensures timelines are being met. Sponsors who utilize these products for a patient-centric approach have seen an overall improvement in clinical outcomes.

When selecting the appropriate solution for a virtual trial, assessing these functionalities is essential. An ideal vendor will have one unified platform designed for accommodating virtual visits and data collection. All products should be fully integrated to ensure data is being transferred in real-time for utmost accuracy. The products should also be geared toward decreasing operational costs, improving patient experience, and improving timelines.

Electronic Source (eSource)

eSource is a vital tool for remote data collection. eSource is a Direct Data Capture (DDC) feature of EDC, meaning data can be captured electronically on a validated system. The following will explain why eSource is a necessary component of virtual trials.

In traditional trial models, the clinical data would be collected on paper and reviewed via onsite monitors for source data verification (SDV). However, when utilizing eSource, the source data is entered directly into the electronic system. The data can be entered onto the eCRF by a remote investigator or by ePRO/eCOA by the patient. This data is transferred in real-time into the EDC and is captured on the audit log as the source document. When data is captured electronically, there is only one dataset and no need for transcription. The data is immediately available for remote monitoring which eliminates the need for onsite monitoring and SDV and reduces the costs for sponsors. Entering the data directly into the electronic fields also allows for automatic edit checking and querying which ensures cleaner data. Remote data collection can save up to weeks of time and allow sponsors to have a broader geographical reach than traditional models.

When assessing eSource products, compliance should be a prominent consideration. The FDA lists the following requirements: identification and specification of authorized source data originators; creation of data element identifiers to facilitate examination of the audit trail by sponsors, FDA, and other authorized parties; ways to capture source data into the eCRF using either manual or electronic methods; clinical investigator(s) responsibilities with respect to reviewing and retaining electronic data; and use and description of computerized systems in clinical investigations.

Electronic Consent (eConsent)

eConsent, simply put, is the electronic version of a paper Informed Consent Form (ICF). eConsent, however, serves a larger purpose than digitizing a form. The following will explain why a regulatory compliant eConsent solution is useful in improving patient understanding and retention.

Obtaining patient consent is a necessary step in the clinical trial process. eConsent allows sponsors to obtain patient consent and signatures in a more efficient and standardized way. However, obtaining consent is just one step of the patient recruitment process. eConsent helps sponsors avoid the common barriers which prevent patients from participating and staying enrolled in clinical trials. eConsent allows sponsors to customize their approach to patient engagement and to help improve patient comprehension. eConsent helps sponsors engage with broader populations, including socially and financially disadvantaged groups. Forms may include embedded instructional videos and graphics to better explain complex protocols to patients to increase the likelihood of enrollment. Forms should be able to be localized to different languages to help enroll more diverse groups of patients.

eConsent should decrease the administrative burden for sponsors' study teams. eConsent decreases the risk of lost pages and human error. Patients are automatically enrolled into the EDC system for real-time insights and tracking management. This will also ensure the correct, most up to date version of the consent form is signed which will reduce the risk of audit findings.

Electronic Clinical Outcomes Assessment (eCOA/ePRO)

Clinical Outcomes Assessment (eCOA) measures patient safety and outcomes through direct electronic collection of Patient Reported Outcomes (ePRO), as well as clinician reported outcomes, and observer reported outcomes. The following will explain eCOA as it relates to virtual trials.

Similar to eConsent, eCOA was built to increase patient comprehension, retention, and engagement. eCOA solutions should be extremely customizable in order to optimize these areas. eCOA solutions should support several different scheduling options depending on the study protocol. Whether the patients are filling out eDiaries or surveys, eCOA should support scheduled triggers, on-demand triggers, and adapt to changes in visit schedules for maximum flexibility. eCOA solutions should include a flexible design tool so the questionnaires can be completed by the patients in as few clicks as possible for higher patient engagement rates. The questionnaires sent should be accessible on all browsers and devices so no special hardware is required. Emails sent should be customizable to improve comprehension and convey the appropriate tone to the patients. eCOA solutions should also support custom fields within the questionnaires. These fields may include embedded video instructions, clickable images, sliding scales, and more, in order to collect the most accurate data for the specific protocol.

eCOA security options should be configurable to meet specific needs for each sponsor. Questionnaires may require a special timed security token or password in order for the patient access and all links should be encrypted. Data should be transferred into the EDC in real-time for accurate progress tracking and remote monitoring.

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