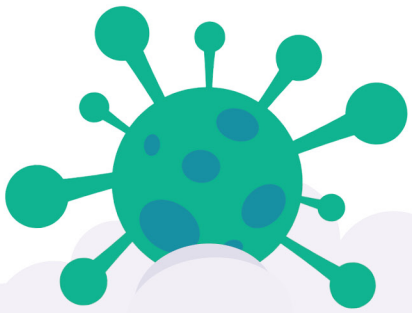
Guide to Remote Trials

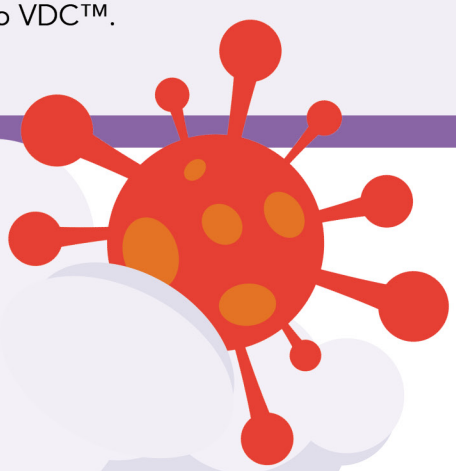
2021 Edition

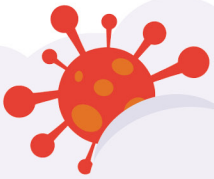
clinCapture

Coronavirus Update



As of Jan. 20, 2021, the World Health Organization (WHO) reported more than 48 million confirmed cases of COVID-19 and more than 1.1 million deaths. In December 2020, the United States Food and Drug Administration (FDA) issued an emergency use authorization for two COVID-19 vaccines. The vaccines were developed in record time due to the pandemic. As the pandemic progressed throughout 2020, clinical researchers looked for ways to safely continue trials to progress medicine and medical treatments for COVID-19 and a number of other diseases. The FDA provided guidance on how to conduct research during the pandemic and companies such as ClinCapture, provided efficient tools to continue clinical trials. There are several considerations to take while planning a remote clinical trial including the right tools to accelerate and effectively capture clinical trial data. In January 2021, ClinCapture announced Virtual Data Capture™ (VDC™), a system designed for remote trials. In this guide, we will share the topics you should consider and how it relates to VDC™.





Considerations:

1. What constitutes a remote trial?
2. What is the FDA guidance for conducting remote trials?
3. Which eClinical products are necessary for conducting remote trials?
4. What functionality should be available within these products?
5. What compliance factors should be assessed?
6. Which security features are important?
7. What is Virtual Data Capture™ ?

Overview of Remote Trials

On March 18, 2020, the FDA issued guidance for sponsors conducting clinical trials during COVID-19 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."

With our new feature, VDC™, conducting a remote trial is easier than ever. To run a successful remote 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.

VDC™ offers electronic Source (eSource), electronic Consent (eConsent), and electronic Clinical Outcomes Assessment (eCOA) and electronic Patient Reported Outcomes (ePRO) which were designed specifically to lower the barrier for patients to participate and improve recruitment. VDC™ makes your clinical trial efficient and ensures that your timeline is being met.

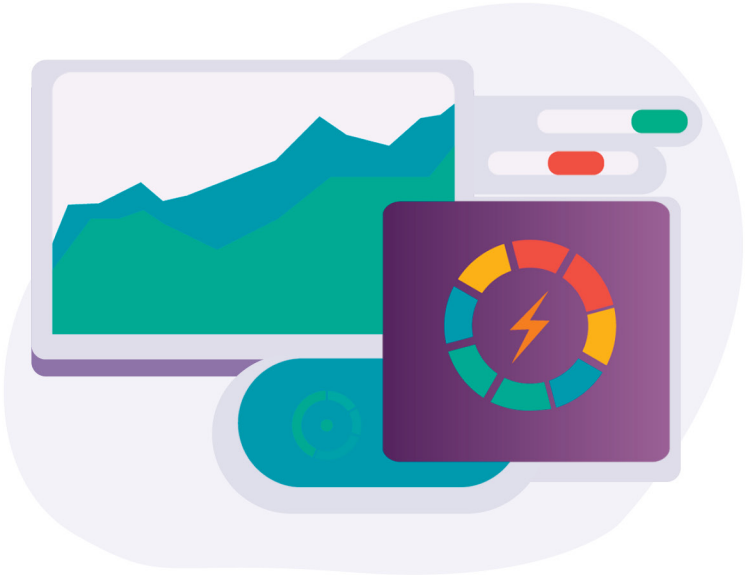
For those not using VDC™, selecting the appropriate solution for a remote trial, assessing these functionalities is essential. An ideal vendor will have one unified platform designed for accommodating virtual visits and data collection. All products should be fully integrated to ensure data is being transferred in real-time for utmost accuracy. The products should also be geared toward decreasing operational costs, improving patient experience, and improving timeliness.

electronic Source (eSource)

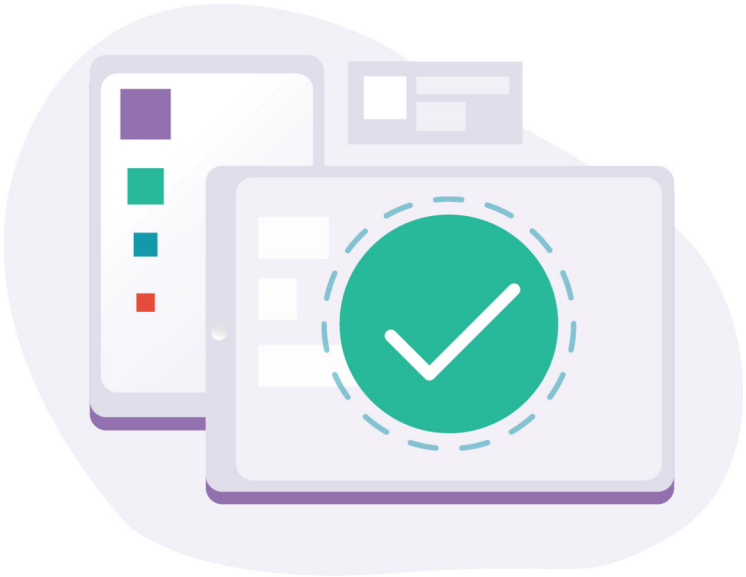
eSource is a vital tool for remote data collection. eSource is a Direct Data Capture (DDC) feature of Electronic Data Capture (EDC) and VDC™, meaning data can be captured electronically on a validated system. The following will explain why eSource is a necessary component of virtual trials.

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 system 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 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 for 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.

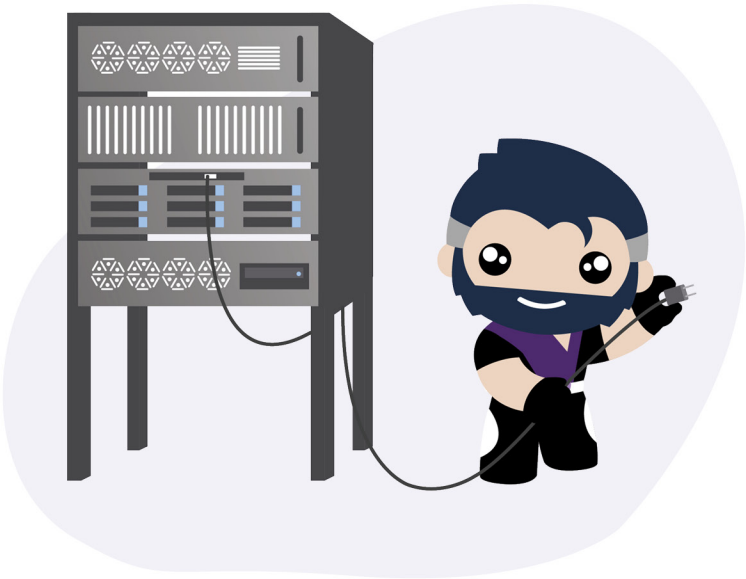
Obtaining patient consent is a necessary step in the clinical trial process. eConsent allows sponsors to obtain patient consent and signatures in a more efficient and standardized way. However, obtaining consent is just one step of the patient recruitment process. eConsent helps sponsors avoid the common 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)

Electronic 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.

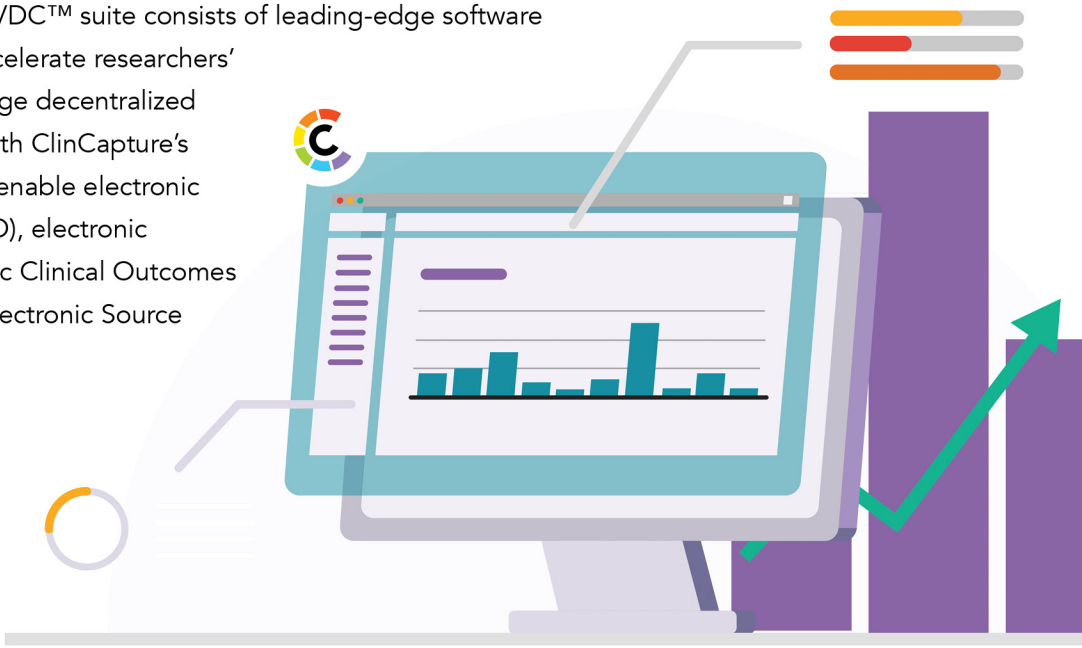
Similar to eConsent, eCOA was built to increase patient comprehension, retention, and engagement. eCOA solutions should be extremely customizable to optimize these areas. eCOA solutions should support several different scheduling options depending on the study protocol. Whether the patients are filling out electronic diaries 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, to collect the most accurate data for the specific protocol.



eCOA security options should be configurable to meet the specific needs of each sponsor. Questionnaires may require a special timed security token or password for 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.

VDC™ is a cutting-edge suite of proprietary products designed to expedite clinical trials. A decentralized or remote clinical trial is a study that is executed with the assistance of technology to reduce in-person contact or visits to the clinic. The VDC™ suite consists of leading-edge software modules that work together to accelerate researchers' ability to plan, execute, and manage decentralized and remote trials. VDC™ works with ClinCapture's powerful Captivate™ platform to enable electronic Patient Reported Outcomes (ePRO), electronic Consent (eConsent), and electronic Clinical Outcomes Assessment (eCOA), all utilizing electronic Source records (eSource) technology.

ClinCapture Virtual Data Capture™ (VDC™) also offers electronic Clinician Reported Outcomes (eCRO) and electronic Observer Reported Outcomes (eORO).



A message from our CEO

I see firsthand the struggles clinical researchers and data managers must endure in collecting, managing, and analyzing their data. From outdated paper forms to products that simply lack the capabilities necessary for remote trials, **ClinCapture is addressing the challenges researchers must overcome as trials continue to decentralize."**

- Scott Weidley

CEO of ClinCapture

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