



CEO's Guide to EDC

2021 Edition



About ClinCapture

ClinCapture provides a powerful eClinical platform that enables sponsors and CROs to rapidly build and deploy studies, lower clinical trial costs, and streamline data capture processes. Offering a host of private cloud solutions, ClinCapture's technologies help advance the evaluation and development of drugs, biologics, and devices that demonstrate promise for the diagnosis and/or treatment of a wide range of diseases or medical conditions.



Fight for Your Right to Features

Free Build

Dashboard

WYSIWYG

**Risk Based
Monitoring**

Form Library

Versioning



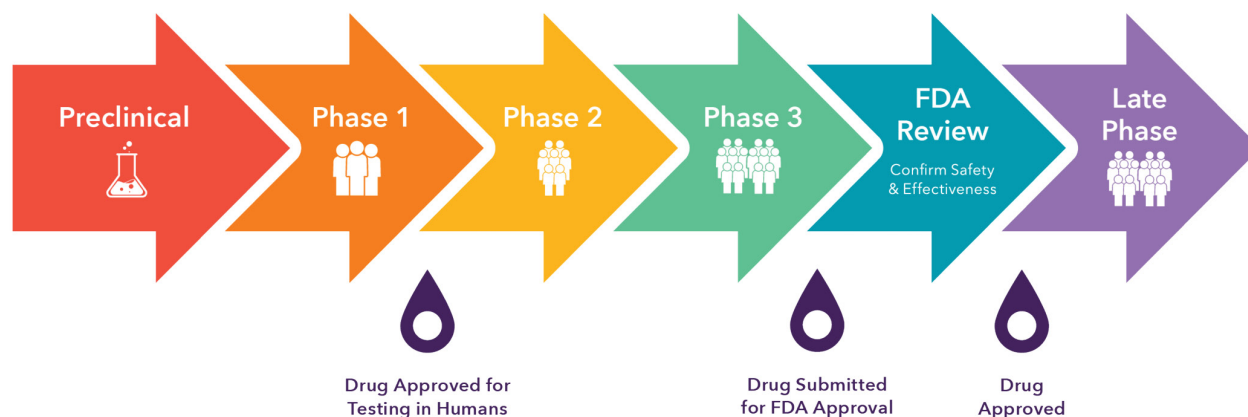
Overview

Your company is looking for a new Electronic Data Capture (EDC) system for an upcoming study. By now, you've spoken to several vendors and they all seem to promise the same things: low cost, fast and easy-to-use software. As a Chief Executive Officer (CEO), or another member of the executive team, how do you know if an EDC system is right for your study?



An EDC system is an investment, sometimes for the long term for your company. As the CEO, you have to look past the same basic features every vendor claims to provide and look at the big picture: how will the EDC system help your company be successful? What features should it have? By being equipped with the right information, you can meet the goals of the data management team and overall business goals. In the 2021 edition of the CEO's Guide to EDC, we will share helpful tips on how to choose the right system.

No matter where you are in the process, choose the right EDC for your study.

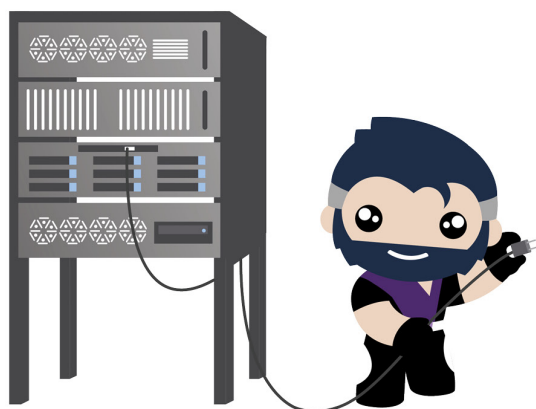


01

Proven Track Record



When you're evaluating an EDC provider, consider their track record of helping companies achieve regulatory approval. You will want to ask potential vendors about recent companies that used their EDC product and achieved regulatory approval. At ClinCapture, we are proud to have been a part of potentially life-saving products successfully receiving approval and entering the market.



02.

eClinical Suite

Many EDC systems only offer basic functionality and are difficult to scale, forcing customers to switch to another system when their study calls for more advanced study designs and workflows. Whether you are running your first pilot study or managing dozens of studies with complex criteria, ClinCapture has the infrastructure to support all of your needs.

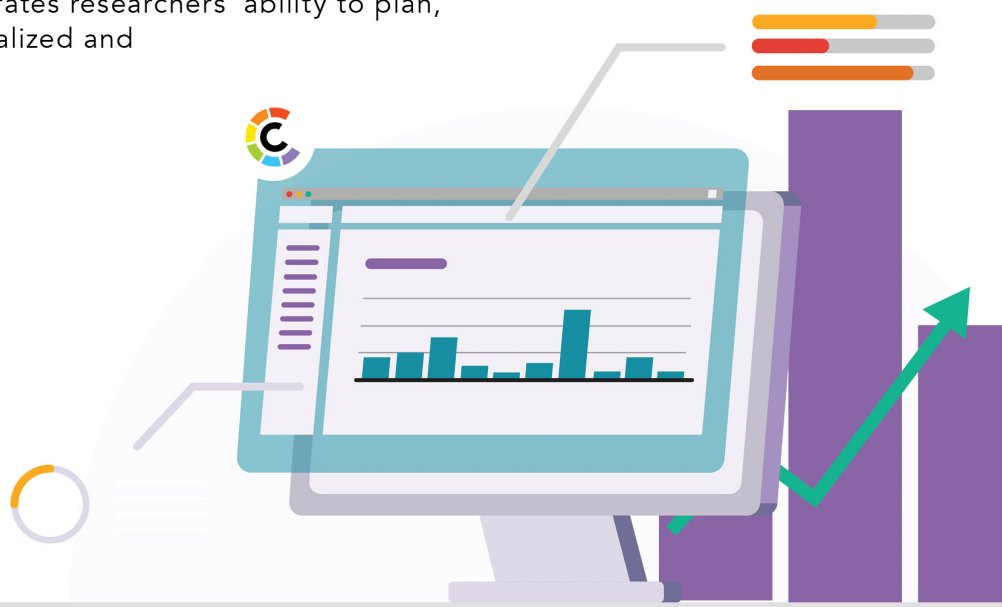
Ensure that your EDC system has the products needed to run complex studies. Many EDC systems do not offer this. ClinCapture offers a suite of products in addition to our fully featured EDC including Captivate™ Coding, Captivate Randomization™, Captivate™ Reporting, and more.



03 Conducting Remote & Decentralized Trials

Is your company conducting a remote or decentralized trial? You will want to ask EDC vendors about the capabilities to conduct remote trials. Which features do they offer? What is the startup time and cost for this?

At ClinCapture, we are the only company to offer Virtual Data Capture™, which combines ClinCapture's powerful platform with electronic Patient Reported Outcomes (ePRO), electronic Consent (eConsent) and electronic Clinical Outcomes Assessment (eCOA) utilizing electronic Source records (eSource) technology. Virtual Data Capture™ accelerates researchers' ability to plan, execute, and manage decentralized and remote trials.



04



What Type of Cloud Is Your EDC Vendor Using?



Private Cloud

EDC software is hosted in the cloud, making it more affordable and easier to support. As opposed to a public cloud, private software gives each customer their own “instance,” meaning there are no interruptions to the study for revalidation or retraining. It is always best to choose a private cloud EDC.



Public Cloud

EDC software is hosted on the cloud and you share a software “instance” with other customers. This type of software is generally lower cost (with some exceptions). The downside with a public cloud is you may need to revalidate and retrain your sites with every release. Public cloud software vendors rarely identify themselves as “public cloud.” So, make sure you ask the question, “will we be getting a 100 percent private instance of your software or will we be on a shared instance with other customers?” If the vendor cannot guarantee a private instance, then you risk the negative effects of public cloud.



On-Premises

EDC software is hosted locally at your company or the provider’s location. This type of software is good when you do not want any interruptions to your study, as you are not forced to revalidate for software updates. However, this is the most expensive type of software and the most difficult to support.



05

Transparent Pricing & Fees

Understanding the cost of an EDC system should be simple and transparent but that's not always the case. Some systems may be reasonably priced, but once you get the first bill you might be shocked by the buildup of small fees from add-ons. Here are some fees to avoid while selecting an EDC:

Support Costs

It is easy to underestimate the number of support hours needed. If an EDC vendor charges by the hour, this can add up fast! Choose a vendor, like ClinCapture, that offers a free support program.

Training Costs

It is also common to underestimate the cost of training. Training costs are common among EDC vendors and can be very expensive. Try going with a vendor with affordable training, if possible.

Subscription Costs

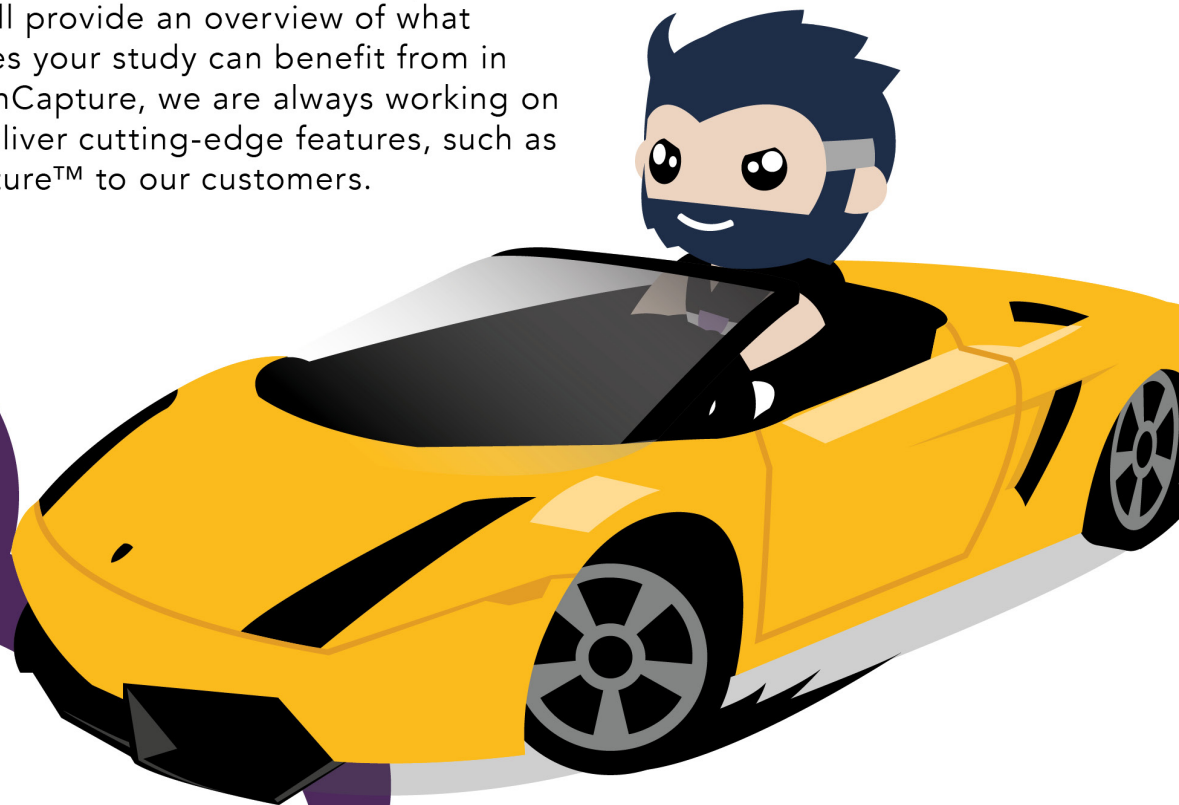
Paying month-to-month can be very expensive. You can often save money by taking advantage of annual subscription plans.



06

Product Roadmap

If you plan to use an EDC system for a longer-term (more than 3 months), ask the vendor about their product roadmap. This will provide an overview of what upcoming features your study can benefit from in the future. At ClinCapture, we are always working on innovations to deliver cutting-edge features, such as Virtual Data Capture™ to our customers.



07

Trustworthy & Innovative

Rock Health

ClinCapture is proud to be backed by prominent Venture Capitalists who believe in our product and mission. Research your EDC vendors to ensure the company is trustworthy and ask the following questions: Who supports them? What are their success stories? What new features are on their roadmap? By conducting your research, you will be able to understand their trustworthiness and credibility.



Weidley's Wish

Weidley's Wish is a program started by ClinCapture CEO Scott Weidley with the mission of facilitating clinical research in the discovery of orphan drugs and the treatment of rare diseases. We've offered our eClinical software (EDC) application for free for certain types of clinical studies and most recently, COVID-19 related research. In 2020, Weidley announced ClinCapture's EDC at no cost for specific clinical trials investigating COVID-19. This initiative was provided through Weidley's Wish.





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