



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. For more information, please visit www.clincapture.com and follow ClinCapture on [LinkedIn](#).

Rock Health

ClinCapture is excited to be partnered with organizations who believe in our product and mission. Rock Health supports entrepreneurs working at the intersection of healthcare and technology.



Weidley's Wish

ClinCapture CEO Scott Weidley created Weidley's Wish with the mission of facilitating clinical research in the discovery of orphan drugs and the treatment of rare diseases. Through the Weidley's Wish program, ClinCapture offered its eClinical software (EDC) application for free for certain types of clinical studies including COVID-19 research in 2020.

Overview

As of April 4, 2021, the National Institutes of Health (NIH) reported 373, 298 registered Clinical trials. That is an increase of more than 200 percent over the past 10 years. Clinical trials continue to transition from a paper-based data collection method to Electronic Data Capture (EDC) system. An EDC system allows clinicians to collect and manage trial data on a digital platform.

An EDC system is an investment, sometimes for the long term, for your company. As CEO, you need to understand how an EDC system will help your company be successful. In this guide, we will share the benefits of an EDC system and questions you should ask before selecting a vendor.



Background of EDCs

Before the use of EDC systems, clinical trial information was collected on paper. Now, more trials are moving to EDC systems and replacing paper records with electronic records. The move to EDC systems offers many benefits for clinical trials including the following:

Data Privacy/Security

EDC systems are hosted online or on a server and because of the nature of these systems, vendors ensure privacy and security. EDC systems provide an extra level of security by offering select permissions depending on the role of each user.

Cost-effectiveness

An EDC system will save your company time and money in the long term. However, the cost of an EDC system varies depending on the vendor, so it is important to understand different pricing structures. Some vendors may charge additional fees for services and other items. We will take a look at pricing structures later in this guide.

Compliance

EDC systems must be regulatory compliant because it supports the accuracy and integrity of the study for FDA clearance. You will want to ensure your EDC system is 21 CFR Part 11 compliant. The EDC vendor should also have technical controls in place to ensure data integrity and have standard operating procedures, or SOPs, in place.

Quicker Access to Data

EDC systems will save you time from start to finish. Intuitive EDC systems require less time on training and setup, whether your team builds the study or you enlist the vendor to build it for you. During the study, the EDC system should allow you to see data in real-time, spend less time on query management, and allow for quick analysis at the end of your study.

Now that you have an understanding of the benefits of an EDC, let's move onto questions that will help you differentiate vendors.

Data Hosting

Where is your data being hosted?

EDC vendors have a few options for where they store clinical data for customers. Those options include on-premise storage, or cloud hosting, which is offered on both public and private cloud.

On-premises hosting is a remnant of a previous generation of network computing, in which data is typically stored in a server room in the same physical location that it is originally captured. Although this made access fast and convenient, advancements in networking have made the need for local storage largely irrelevant. Moreover, on-premise hosting may require additional costly resources to ensure the safety and security of data, such as fire suppression systems, additional security personnel, and more.

On the other hand, cloud-hosted data is usually kept in large facilities dedicated solely to data storage. Companies such as Amazon Web Services (AWS) have facilities located all over the world containing data from companies of various industries. These facilities often have advanced disaster protection and recovery technologies, and allow for data backups and redundancies to reduce downtime and improve efficiency.

With cloud-based hosting, vendors will offer either a public or private cloud. If your vendor is hosting data on a public cloud then you are sharing a database with other customers. While your data is kept completely separate, other customers' usage of the database may affect the speed and performance of your study. With a private cloud, you receive an exclusive database that is not shared with customers.

Data Hosting (con.)



	On-premises	Public Cloud	Private Cloud
Competitive Pricing		✓	✓
Data Privacy	✓		✓
Upgrade Control	✓		✓
Automatic Upgrades		✓	✓
Does not require dedicated maintenance staff		✓	✓
Great database performance			✓
Easy Scalability			✓
Does not require on-site hosting		✓	✓

EDC Features

EDC systems can be classified into three categories for which we will reference as simple, legacy and ideal. Here is a breakdown of the differences between each system:

Legacy Systems

- High Cost
- Reliant on professional services
- Reliant on vendor
- Very Customizable
- Older Technology
- Robust Feature Sets



Ideal System

- Competitive Pricing
- Modern UI/Intuitive Workflows
- Extremely Customizable
- Offers all features needed for complex protocols
- Private Cloud Infrastructure

Simple Systems

- Lower Cost
- Easy-To-Use
- Rigid Structure
- Not Customizable
- Missing Features

What else should you consider with an EDC?

CEOs should also be aware that in order to run all phases of a study, you'll want a vendor that offers more than just an EDC. You'll want a vendor that is a "one-stop-shop" or full software provider.

Products adjacent to EDC:



Randomization

This feature allows your team to conduct randomized controlled trials, which are regarded as the gold standard trial for evaluating the effectiveness of interventions.



Medical Coding

This feature standardizes medical terms in the clinical trial, so results can be submitted to regulatory authorities. MedDRA and WHO Drug are common dictionaries that may be offered by EDC vendors.



Reporting

Reporting tools may offer real-time data, various reports and/or customizable options.



CTMS

CTMS or Clinical Trial Management System is a system used to manage clinical trials.



eTMF

eTMF or Trial Master File is a content management system.

Can your EDC collect data in the COVID-19 era and beyond?

The COVID-19 pandemic accelerated the adoption of EDC because it allowed trials to continue with remote work. Studies that continued or were related to the pandemic underwent protocol amendments to conform to remote or decentralized trials. With the use of EDC, it was easy to amend protocol changes with electronic Case Report Forms (eCRF). The convenience of an EDC allows for seamless remote site monitoring, data verification and reporting.

These are the functions that you should look for in an EDC in the COVID-19 era and beyond:



eSource

eSource or electronic Source allows you to collect clinical data directly within the EDC, bypassing manual paper data entry.



ePRO

ePRO or electronic Patient Reported Outcomes empowers patients to contribute to research by providing timely data through electronic questionnaires that can be answered from the comfort of their home. Patients can view the surveys on a smartphone, desktop, laptop, tablet or other electronic device.



eCOA

eCOA or electronic Clinical Outcomes Assessment enables healthcare workers and caregivers to provide clinical information about their patients through electronic surveys. The electronic surveys can be viewed on a smartphone, desktop, laptop, tablet or other electronic device.



eConsent

eConsent or electronic consent simplifies and accelerates the subject enrollment process by allowing consenting to occur remotely.

Pricing Structures and Fees

The cost of an EDC system should be transparent to the customer, unfortunately, that is not always the case. Some vendors will provide a reasonable price for their system but shock customers once fees from builds, service charges, and other items are added on.

Here are common pricing structures that you will see when searching for an EDC:

Legacy systems

With a legacy system, you will discover multiple limitations and added costs. Legacy systems require a large amount of professional services for the build, mid-study changes, customizations, database lock, and more. Plus, legacy systems may also charge per subject or site, so as the trial grows, so does the cost.

Subscription Models

Subscription models are straightforward. With this type of model, you can determine the cost of the study without running into unexpected costs/mid-study bills for unexpected changes.

Simple Systems

Simple systems nickel and dime for just about everything. You will find that simple systems put caps on sites, users, subjects, CRFs, data points, customer support and more. So, if you need additional sites, users, or other variables then you will see the cost of the EDC increase.





clinCapture

San Francisco
Las Vegas

800-987-6007
contact@clincapture.com
www.clincapture.com