clinCapture

CHAMPION'S GUIDE TO EDC

You are a champion. That's why you are here, right?

And you are evaluating EDC like a champion, of course!

As all champions know, evaluating EDC (Electronic Data Capture) or VDC (Virtual Data Capture) is no easy task.

As an EDC champion, you will be challenged with various types of lingo, features, and pricing structures.

But not to worry, this guide was strategically written to help you master your EDC evaluation process like the champion you are. So go on, champion, and conquer your EDC evaluation!

Disclaimer: To get the 'full' champion experience, we advise you to read through the entire (short) guide. No skimming allowed - you won't want to miss out on the bonus tip :)

10 'CHAMPION' EDC TIPS

Champion Tip #1

UNDERSTAND THE FULL STUDY REQUIREMENTS

While it's ideal to have the full study requirements planned prior to the EDC evaluation, choose a provider that can make last-minute changes and can help you plan how your protocol fits the EDC model. Some questions you should ask yourself during the evaluation process include: "what special features will I need (ePRO, eSource, eConsent, etc)?" and "what is the size of my study - number of sites, projected enrollment?" Before selecting any EDC software, you have to identify full study requirements. This includes which CRFs will be electronic, the necessity of medical coding, or other special features that might be needed for a successful study build and data capture process. An EDC software should be able to accommodate all clinical trial requirements while expediting the process, including needed software features such as eSource, ePRO, eConsent, and eCOA. It is important to thoroughly understand the requirements in order to successfully choose an EDC partner that meets your study conditions.

Champion Tip #2

ENSURE COMPLIANCE AND DATA SAFETY FROM PROVIDER

Not only should the EDC system be regulatory compliant, but it should also ensure data security. You should confirm that your EDC system is FDA's 21 CFR Part 11 compliant and any features, such as eSource, are fully HIPAA and GDPR compliant. But don't stop there, the EDC system should provide data safety by allowing study administrators to delegate roles with role-based permissions. This will allow users to only have access to data, reports, and forms based on their specific roles. Don't shy away from asking providers candid compliance and data safety questions during the evaluation process. If your provider cannot confidently answer or provide compliance and data safety assurance, it's time to start shopping elsewhere.

Champion Tip #3

CUSTOMIZABLE STUDY BUILDS AND EASY eCRF DESIGN TOOLS ARE A MUST

EDC systems are very complex by nature, but when it comes down to building your study, the EDC system should easily allow for the creation of eCRFs. EDC systems that offer highly customizable study build features, including easy design tools, can also support complex protocols and allow for reports to be easily created and understood. Never settle for a provider that does not offer customizable study builds or easy eCRF design tools. By choosing a provider with these capabilities, you will save time, money, and unnecessary headaches.

Champion Tip #4

MAKE SURE YOU HAVE ACCESS TO YOUR DATA - AT ALL TIMES

When it comes to data accessibility, it is important to make sure that you have access at all times. Whether you want to enter data, sdv, or import/export data - don't let your provider stop you from doing so! Having access to real-time data is crucial for any clinical trial sponsor. An EDC system that provides quick access to data can improve efficiency with minimal time spent on query management. This will overall allow for quicker analysis of your data.

Champion Tip #5

QUALITY AND CONSISTENT SUPPORT IS CRUCIAL

The EDC system should provide sufficient support through a helpdesk. If any questions or issues arise at any moment throughout the study, the helpdesk and support team should be available to walk you through a resolution. Proactive support is equally as important when it comes to consistent quality and service. Many providers are known for excruciatingly long support wait times and inconsistent communication. With time being of the essence in clinical trials, it is crucial to have a provider that makes customer support and communication a priority at all times.

Champion Tip #6

DON'T WASTE TIME ON OLD INTERFACES AND CLUNKY WORKFLOWS

EDC systems with a modern user interface and intuitive workflows will require less time on setup, training, and data entry. With intuitive workflows and user-friendly navigations, your clinical study team will be able to navigate the EDC system efficiently while spending less time onboarding. Never risk your team abandoning your EDC system due to consuming interfaces and workflows. Take the time to choose a provider that will prioritize having a modern user interface and intuitive workflows.

Champion Tip #7

DON'T GET LOST COLLECTING DATA METRICS

Collecting data metrics should be a straightforward process in your EDC system. EDC systems that incorporate an easy-to-use dashboard with quick visibility of site enrollment numbers, SDV statuses, subject statuses, and discrepancies will save your team time. With increased statistical power, you won't have to manually generate tedious reports. There's power in having this information at your fingertips, and your EDC system should help you to achieve this.

Champion Tip #8

IT'S WEB AND MOBILE FRIENDLY...RIGHT?

Having full accessibility of EDC system features (ePRO or eCOA) on desktops, mobile devices, tablets, and other electronic devices will result in a more seamless data capture experience. Investigators and observers will have the flexibility to complete eCOAs in the most convenient way for them. Subjects will also be able to complete their ePROs comfortably from their computer or mobile devices, resulting in higher compliance. In 2021, all providers should be offering various web and mobile-friendly options. If your provider lacks these capabilities, then it's time to look elsewhere!

Champion Tip #9

IT'S NOT JUST ABOUT CAPTURING DATA

An EDC system that comes with randomization of subjects, medical coding, and reporting will help run all phases of a study. A full software phases of a study. A full software provider that offers products adjacent to an EDC will allow your clinical trial team to achieve more with the use of fewer resources. Make sure to pick a partner that will both grow with your study as well as offer the necessary features and add-ons to make your study a success.

Champion Tip #10

MAKE SURE VALUE = COST

The cost of an EDC system should be completely transparent. Regardless of the complexity and needed features of your study, subscription models are straightforward. With subscription models, you can determine the cost of your study without running into unexpected costs or mid-study bills due to changes. It's important to note that not all EDC systems are created equally. Opting for a cheaper system may result in an increase in manual workarounds that end up costing more to implement. In the end, make sure your system equals its worth and that you won't incur an exorbitant amount of fees after implementation.

BONUS TIP:

WHY PRIVATE CLOUD IS NECESSARY

An EDC system with a private cloud model allows customers to experience increased data privacy, enhanced database performance, along with the power to control your databases. With a Private Cloud, customers are given unique databases separate from other customers. Having a separate cloud for other customers will decrease the risk of data corruption while increasing the performance of the database and the power to control software updates released by the EDC vendor. These benefits can only be experienced with the Privacy, Performance, and Power of ClinCapture's Private Cloud EDC.

Now that you have all the tips necessary to evaluate EDC like a champion, what are you waiting for?

About ClinCapture

ClinCapture is revolutionizing the clinical trial industry with Virtual Data Capture™ and is the only provider of VDC™, a leading-edge suite of products designed to expedite remote and decentralized clinical trials. ClinCapture's eClinical products enable sponsors and CROs to rapidly build and deploy studies, lower clinical trial costs, and streamline data capture processes. 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 clincapture.com and follow ClinCapture on LinkedIn.

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