Three Reasons Data Managers Need to Join the "C-Suite"

Captivate C-Suite

EDC with Dictionary Coding

eCOA / ePRO

Randomization

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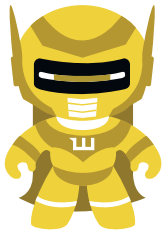
ABOUT CLINCAPTURE

ClinCapture provides a powerful eClinical platform that enables sponsors and CROs to rapidly build and deploy studies, lower clinical trials 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 clincapture.com or follow us at @ClinCapture.

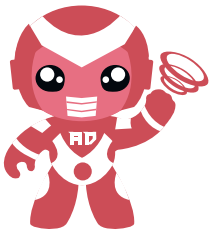
PRIVATRON

Feel the power of Private Cloud



WYSIWYG

What you see is what you get

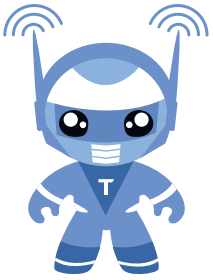


AUTO-DEPLOY

Deploy when and where you want

VERSIONOID

Make mid-study changes by site



TEKONTROL

Get free updates on your schedule

DASHER

Get straight to the data

WHAT IS THE "C-SUITE"?

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You do not need to wear a Brooks Brothers suit or Hermes scarf to be a part of the "C-Suite" (although you can if you choose)! "C-Suite" is the eClinical platform by ClinCapture that makes your EDC experience that much better. While speaking with Data Managers, we are always surprised to learn that many basic features are not included in Electronic Data Capture (EDC) systems. We created the "C-Suite" as the one-stop-shopping option for clinical trials, including all features necessary to capture your clinical trials data. Are you running a smaller study and need a basic EDC? We get it! We created a Light package, to which you can add the "C-Suite" modules a la carte! Remember, Data Managers, you are the boss! To learn more about the "C-Suite" read on…

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1. A QUALITY ELECTRONIC DATA CAPTURE (EDC) SYSTEM

The days of running your study on paper or on a homemade EDC system are over! Your clinical data collection process should work seamlessly with your study, not cause unnecessary issues and slowdown. If you are running a Phase I study, you are probably looking for an EDC system that offers simplicity, speed, and a low monthly cost. If you are running a larger phase II or III study, you will probably need an EDC system that is scalable and has more advanced features. If you are running a Late Phase study, you may be more focused on Outcomes, ePRO, language localization, and of course, long-term cost.

What features should all EDC systems offer?

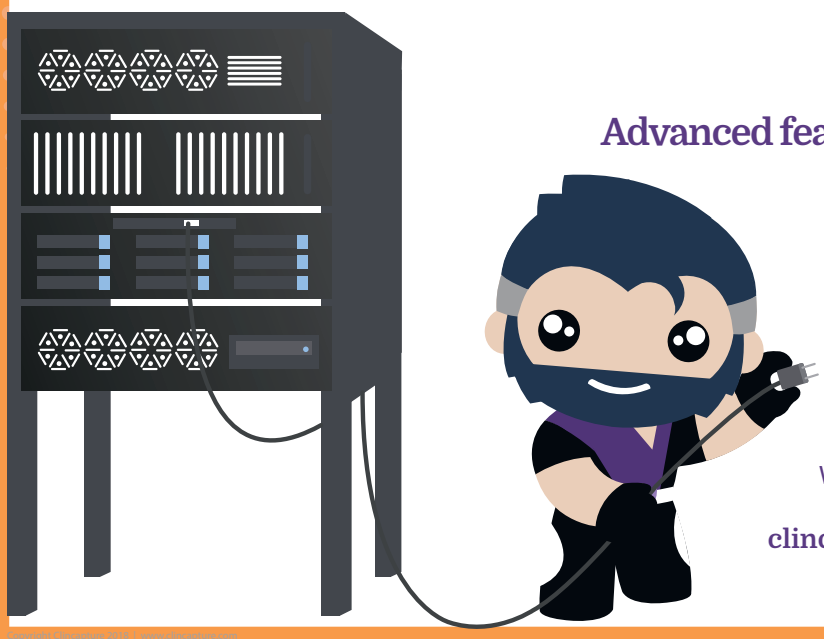
a. Free Build Tool with a User-Friendly Interface
b. Free Training and Support
c. HIPAA, CFR 21 Part 11, and GDPR Compliance
d. No Hidden Costs

Standard features most Data Managers need

a. WYSIWYG Build Tool
b. Programmable Edit Checks
c. Medical Coding

Advanced features most Data Managers want

a. Risk-Based Monitoring
b. Language Localization
c. Form Versioning



Want to learn about each individual feature?
Download Data Manager's Guide to EDC:
clincapture.com/data-managers-guide-to-edc

2. eCOA/ePRO

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In this digital age, having access to Electronic Clinical Outcomes Assessments (eCOA) and Patient Reported Outcomes (ePRO) makes capturing data for a study easier and more seamless.

What is eCOA? Electronic Clinical Outcomes Assessments (eCOA), allows patients, clinicians, and caregivers to use phones, tablets, computers, and other electronic devices to report data.

What is ePRO? Patient Reported Outcomes (ePRO) is a survey of the status of a patient's health that comes directly from the patient, i.e. the patient reports the symptoms directly. These surveys can include pain intensity diagrams, visual analog scales, psychological symptoms, and general quality of life measures, such as how the condition impacts a patient's daily life.

WHAT FEATURES SHOULD DATA MANAGERS LOOK FOR?

- Full accessibility on desktop or mobile device without limitation to only IOS/Android devices
- Supports direct electronic collection of Clinical Reported Outcomes, Patient Reported Outcomes, and Observer Reported Outcomes (collectively eCOA) without requiring special hardware
- Timed-expiration secure token for participants to receive by email to use on any device with internet access and any HTML5 web browser, including Chrome, Firefox, Safari, Internet Explorer, and Microsoft Edge
- Text and scale-based questions, and further custom development from your EDC vendor, if necessary
- Scheduled or on-demand triggers for surveys for maximum flexibility
- Configurable email messages and reminders to alert participants to expected surveys
- Selectable language for surveys/scales which allows participants to complete surveys in their native language
- Progress tracking and completion status in EDC for site monitoring and follow up
- Unifies participant responses with clinical data in EDC to simplify data review and dataset extract
- Compliance report with survey status, dates for survey sent, and reminders

3. RANDOMIZATION

Randomization is vital to a study, since incorrect randomization invalidates clinical study results. A collaboration with an EDC system with randomization, helps protect a study, making the process faster, easier, and truly unbiased. Randomization is a key factor in a study and using the right vendor is crucial.

Below are key points to look for when choosing the right vendor:

- While randomization schemes can be complex (permuted blocked stratification, minimization algorithms, etc.), setup must be easy and intuitive

- Randomization must be fully integrated into the data collection process. The randomization process should be as easy as site users clicking a button, prompting results to automatically save in the database

- Real time reports must be available for early detection of unexpected data/outliers

- The randomization system must be affordable and fully CFR 21 Part 11 compliant

- The vendor must agree to be audited upon request

“

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”

– SCOTT WEIDLEY,
President & CEO at ClinCapture

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