clinCapture

DATA MANAGER'S GUIDE TO
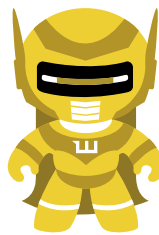# ELECTRONIC DATA CAPTURE

www.clincapture.com

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.
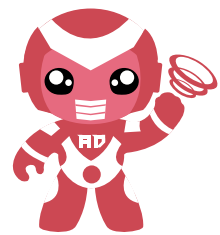
PRIVATRON
Feel the power of
Private Cloud

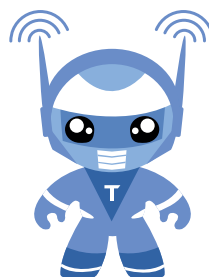### WYSIWYG
What you see is
what you get

AUTO-DEPLOY
Deploy when and
where you want

VERSIONOID
Make mid-study
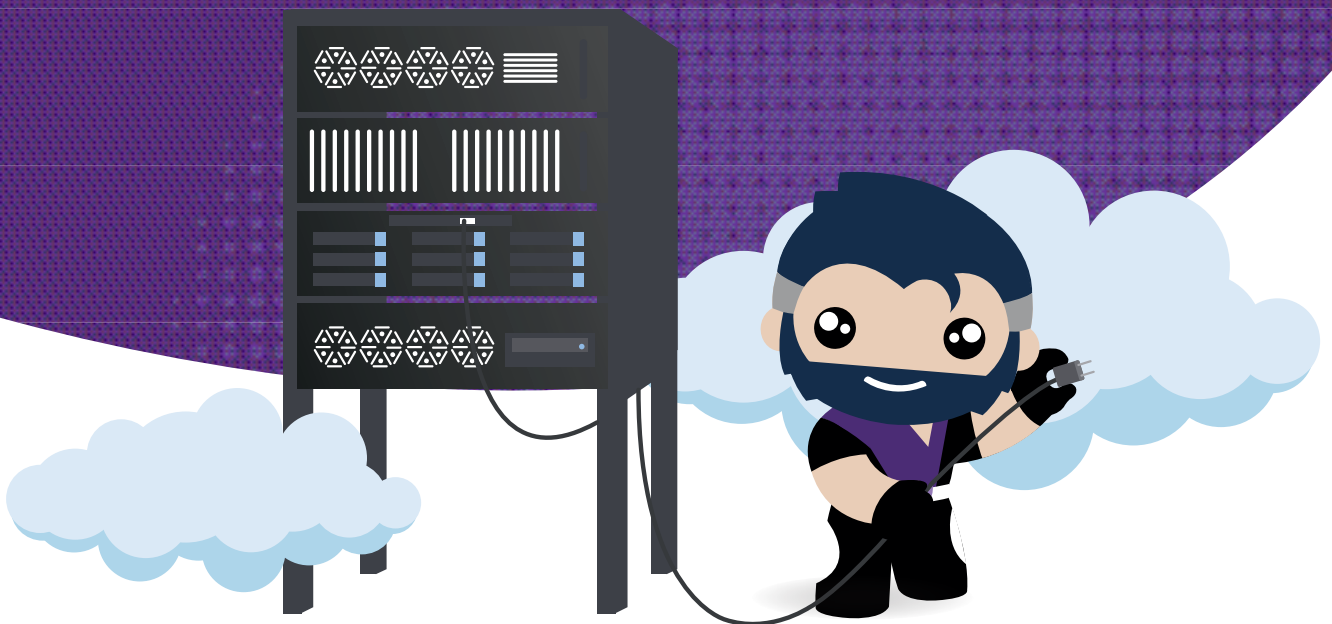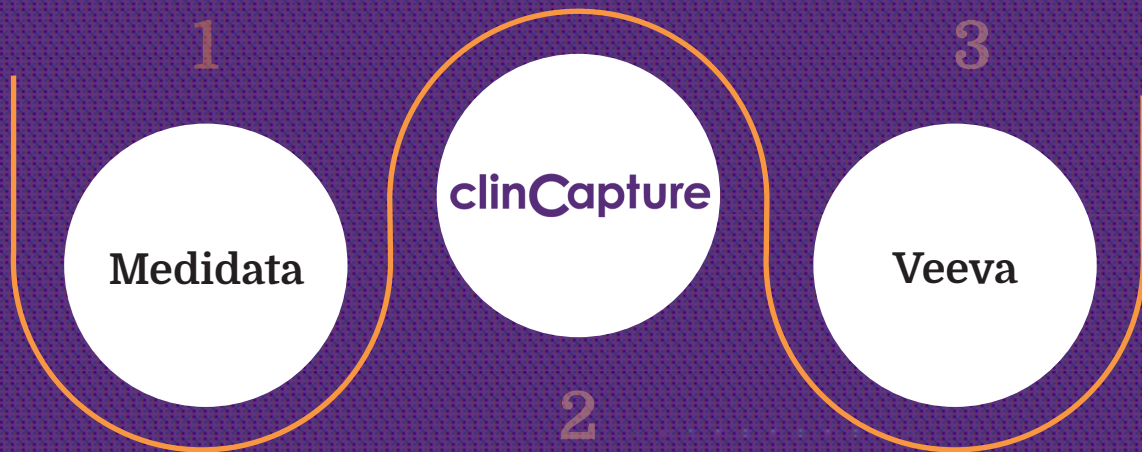changes by site

TEKONTROL
Get free updates on
your schedule

DASHER
Get straight to the data

1. IS THE EDC ONE OF THE "BIG THREE"?

clinCapture

What are the "big three" companies of EDC? These frontrunners of EDC are ClinCapture, Medidata, and Veeva! These companies are known for their ability to run complex trials of all types (e.g. Pharma, Phase I-IV, etc.). Other EDC systems may be limited to certain types of studies, such as Phase I or Academic. Don't limit yourself by using an EDC that is not one of the "big three." Choose one of the big three! Please note - these applications can run simple studies AND complex studies, so there is no need to upgrade to another application during more complex phases of the study or opt for a cheaper option in the early stages. ClinCapture proudly offers Captivate EDC at a fraction of the cost of leading competitors with similar features.
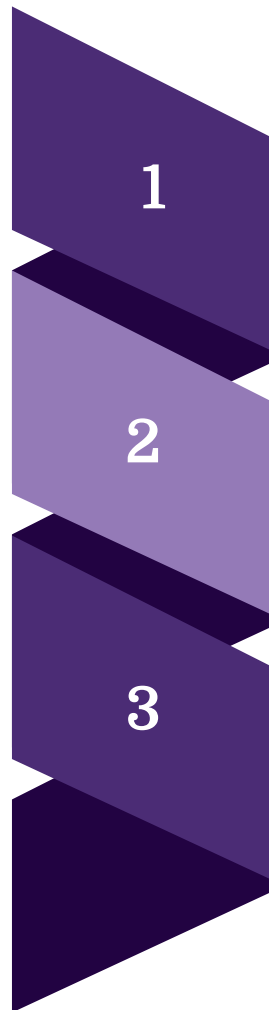
1

Medidata

clinCapture

3

Veeva

2

2. HOW IS THE EDC HOSTED?

1. PRIVATE CLOUD

This is the best of both words. The software is hosted in the cloud, making it more affordable and easier to support. As opposed to public cloud, private software gives each customer their own "instance," meaning there are no interruptions to the study for revalidation or retraining. Always choose a Private Cloud EDC when possible!

3. ON PREMISES

EDC software is hosted locally at your company or at 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, it is also the most expensive type of software and the most difficult to support.

2. 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); however, you may need to revalidate and retrain your sites with every release. Public Cloud software vendors rarely identify themselves as "Public Cloud." Make sure you ask the question: "Will we be getting 100% private instance of your software or will 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.

3. HOW DO YOU BUILD A STUDY IN YOUR EDC?

clinCapture

There are two ways to build eCRFs (electronic Case Report Forms) in EDC.

1. Programming using XML - This method can be more difficult for entry- level users, but is necessary to build complicated edit checks and form rules.

2. WYSIWYG or "Drag and Drop" - This method is faster and easier, especially for entry-level users; however, you can only build very simple edit checks and form rules this way.

The best EDC systems allow you to build your eCRFs both ways. The WYSWYG builders are usually easier for designing the forms, while the programming method allows more complicated edit checks and form rules.

4. DOES THE EDC ALLOW INTERACTIVE FORMS?

Some forms in your study may contain diagrams that a patient or clinician would write on if the study were conducted on paper. In EDC, these are called "clickable forms". If you have these types of forms, e.g. pain diagrams, visual analysis diagrams, etc., then you will want to ensure that you have clickable forms!

5. DOES YOUR EDC HAVE TRUE LANGUAGE LOCALIZATION?

Almost any EDC will allow you to use different languages in the eCRF, but only the most powerful EDC systems allow you to change the language in the user interface. This is essential for localizing the EDC for different languages.

6. DOES YOUR EDC SUPPORT RISK-BASED MONITORING (RBM)?

If you plan on using RBM, then you should make sure your EDC supports site-level Source Data Verification (SDV).

7. IS THE PRICING TRANSPARENT?

This is a special place for caution. While some EDC systems charge a simple monthly subscription, others charge for all sorts of things - training, support, per patient charges, per use charges - it is best to look for an EDC with simple pricing. Avoid hidden fees at all costs!

8. DOES THE EDC SUPPORT MID-STUDY CHANGES WITH DIFFERENT FORM VERSIONS FOR EACH SITE?
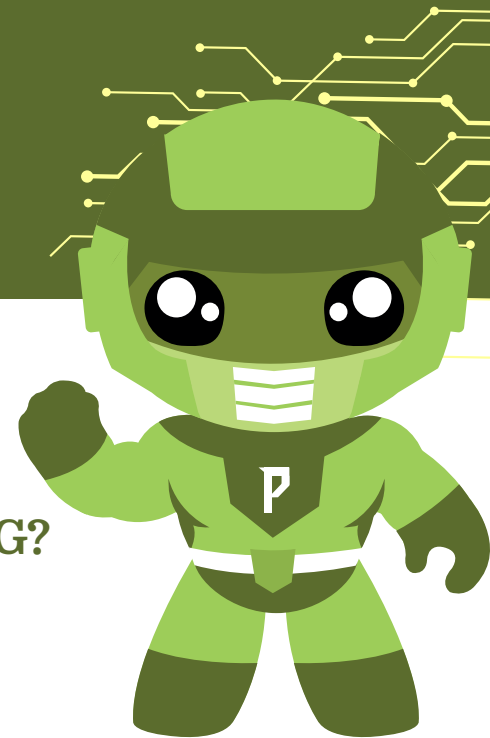
Unless you are running a simple single site study, you will want to make sure that your EDC not only supports easy mid-study changes (most of the newer ones do), but that you can manage different form versions for different sites (many EDC systems do not!). Otherwise, all of your changes have to be the same at every site!

9. WHERE IS YOUR STUDY GOING TO BE DEPLOYED?

It is always good to know where your study is being deployed, i.e. where are the servers. The best EDC companies will allow you to choose your server locations, including servers in Europe for EU studies.

10. DOES YOUR EDC HAVE ADDITIONAL MODULES, SUCH AS ePRO (ELECTRONIC PATIENT REPORTED OUTCOMES), RANDOMIZATION, AND MEDICAL CODING?

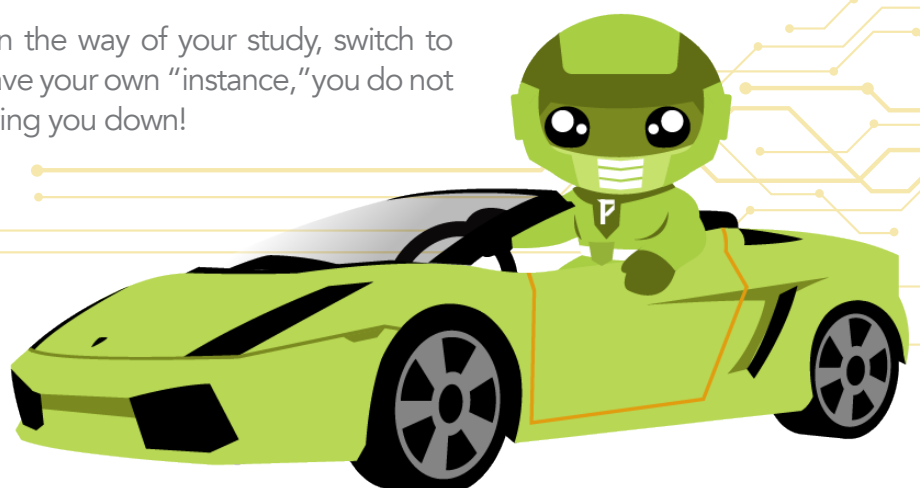These addional modules make it easier for you to run a study and should be included in your EDC system!

11. IS YOUR EDC VALIDATED, CFR PART 11 AND HIPAA COMPLIANT?

If you are not sure, ask your EDC vendor! It is very important to be compliant. If your vendor cannot assure compliancy, it might be time to start shopping around for a new EDC system!

12. DOES YOUR EDC SUFFER FROM SLOWDOWNS WITH HEAVY TRAFFIC?

Do not let heavy "traffic" get in the way of your study, switch to Private Cloud EDC! Since you have your own "instance," you do not have to worry about others slowing you down!

13. ARE YOU ABLE TO ATTACH LARGE FILES TO THE eCRFS? HOW LARGE?

This is an important question to ask, as sometimes you need to attach large picture files to the CRFs. Public Cloud EDC in particular can have difficulty supporting large files, since all of their customers are sharing the same database!

14. IF RUNNING AN eSOURCE STUDY, DOES YOUR EDC ALLOW YOU TO SEPARATE SUBJECT DATA FROM PATIENT DATA?

This is crucial if running an eSource study. Many EDC companies confuse the notion of mobile with "eSource". Just because an application is mobile, does not mean it can be used for eSource. Make sure patient data and subject data are treated differently!

15. DOES THE EDC HAVE AN INTERACTIVE DASHBOARD WITH ANALYTICS?

Most users prefer to be able to administrate their study with an interactive dashboard. Make sure your EDC has this feature!

"
**ONLY WHEN
THE POWER IS IN
THE HANDS OF THE USERS
CAN ENTERPRISE SOFTWARE
BECOME TRULY POWERFUL**

"

– SCOTT WEIDLEY,
President & CEO at ClinCapture

clinCapture