clinCapture

A DATA MANAGER'S GUIDE TO EDC

2019 VERSION

"Greetings, fellow Clinical Data Managers! Welcome to the 2019 edition of Data Manager's Guide to Electronic Data Capture (EDC). In this latest edition, we have added some important updates and features that may be crucial for your upcoming 2019 studies. It's always important to know what to look for in any EDC system!

At ClinCapture, we work closely with Clinical Data Managers every day and continuously focus on incorporating their suggestions and input into product releases, so we can offer a high-quality Electronic Data Capture (EDC) product to help manage clinical trial data.

We look forward to continuing to provide you with timely Clinical Data Management content for your upcoming clinical trials. Whether you are running a simple phase I or a complex phase III study, at ClinCapture we are equipped to handle them all with our #BeyondPhaseI capabilities! Get started learning more by requesting a demo through our website: www.clincapture.com.

POWER UP!
CAPTAIN CAPTIVATE

YOU'VE HEARD THE BUZZ...LET'S GET TO THE FACTS: PUBLIC vs. PRIVATE CLINICAL CLOUD™ EDC?

PUBLIC CLOUD EDC

This software is hosted on the cloud and you share a software "instance" with other customers. EDC systems are generally lower cost; however, you may need to revalidate and retrain your sites with every release. If the vendor cannot guarantee a private instance, then you risk the negative effects of Public Cloud.

PRIVATE CLOUD EDC

ClinCapture's PRIVATE CLINICAL CLOUD™ EDC, offers the affordable benefits of being "on the cloud" without the disruptive interruptions Public Cloud users experience. By being on your own "instance," private cloud users do not have to worry about interruptions to the study for revalidation or retraining.

IS YOUR EDC SYSTEM #BEYONDPHASEI?

#BeyondPhaseI 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 a #BeyondPhaseI system. 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 as low as 20% of the cost of leading competitors with similar features.

DOES YOUR SYSTEM OFFER EASY INTEGRATIONS WITH SYSTEMS LIKE CTMS?

Avoid redundancy in data entry and inconsistency in information, choose an EDC that is compatible with systems like Clinical Trial Management System (CTMS). With your systems integrated, your data will sync in real time. Remember - integrations should be easy with your EDC system!

DOES YOUR EDC PROVIDE CROSS-STUDY REPORTING, ADVANCED ANALYTICS, AND INTERACTIVE DASHBOARDS?

Your Advanced Analytics feature must provide real-time data, constantly changing as CRFs and data evolve, to help drive decisions, resource allocations, and improve operational efficiency. Make sure your EDC gives you the ability to administer key clinical data in real time with an interactive dashboard and provides you with the ability to analyze them across studies and sites with cross study/site reporting.

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.

DOES YOUR EDC OFFER ADDITIONAL MODULES, SUCH AS EPRO/ECOA,RANDOMIZATION, MEDICAL CODING, AND ECONSENT?

Make sure to verify with your provider that they can offer these additional modules, if needed.

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 compliance, it might be time to start shopping around for a new EDC system!

Things to Consider

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!

DOES YOUR EDC SUFFER FROM SLOWDOWNS WITH HEAVY TRAFFIC?

Do not let heavy "traffic" get in the way of your study, switch to Private Clinical Cloud EDC! Since you have your own "instance," you do not have to worry about others slowing you down!
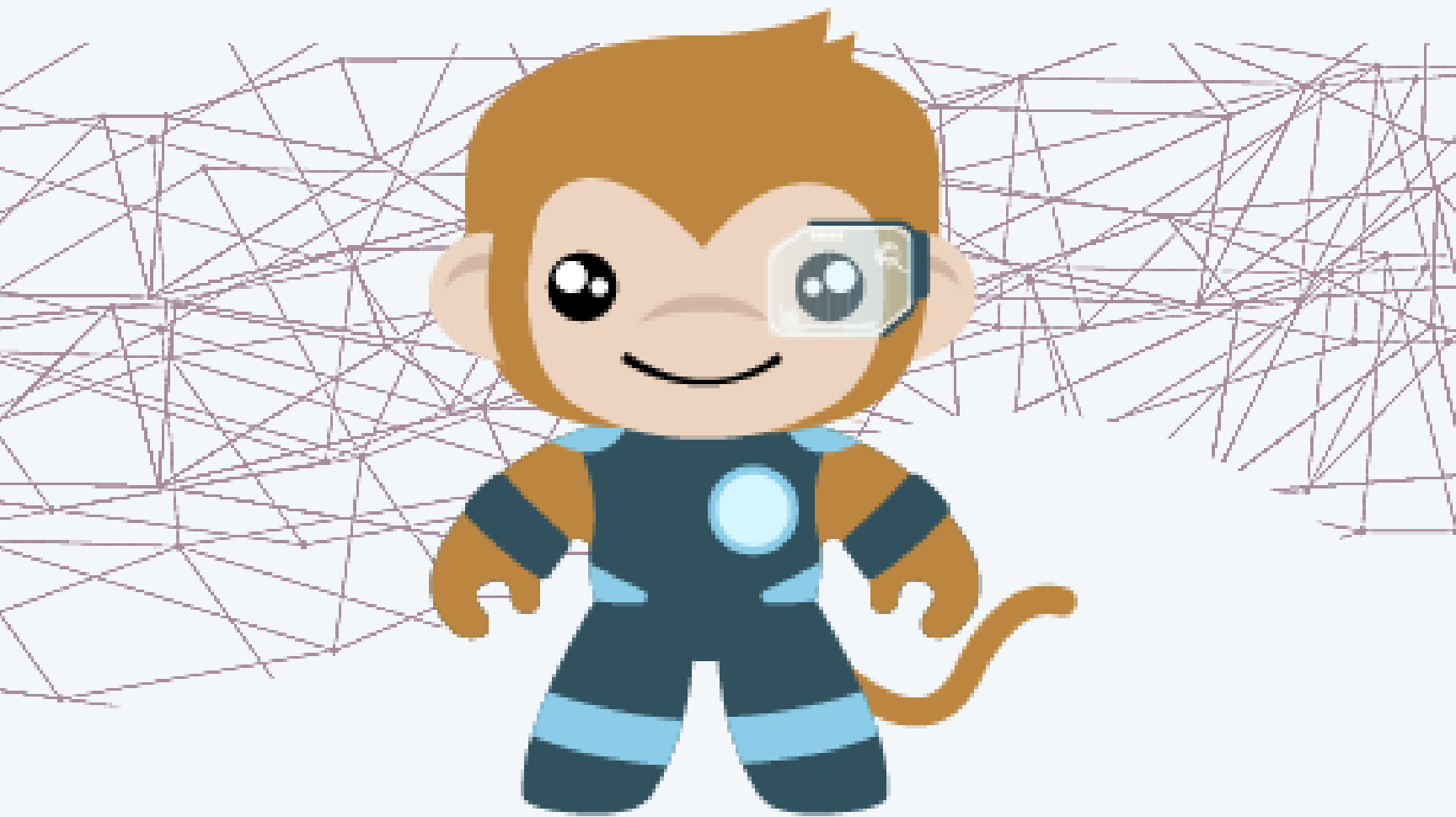
DOES THE EDC SUPPORT MID-STUDY CHANGES WITH DIFFERENT FORM VERSIONS FOR EACH SITE?

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!

IS THE PRICING TRANSPARENT?

When it comes to pricing, you have to take certain precautions when evaluating an EDC system. While some EDC systems charge a simple monthly subscription with low set-up and training fees, others charge for all sorts of things - support, per patient charges, per use charges - it is best to look for an EDC with simple pricing. Avoid hidden fees at all costs!
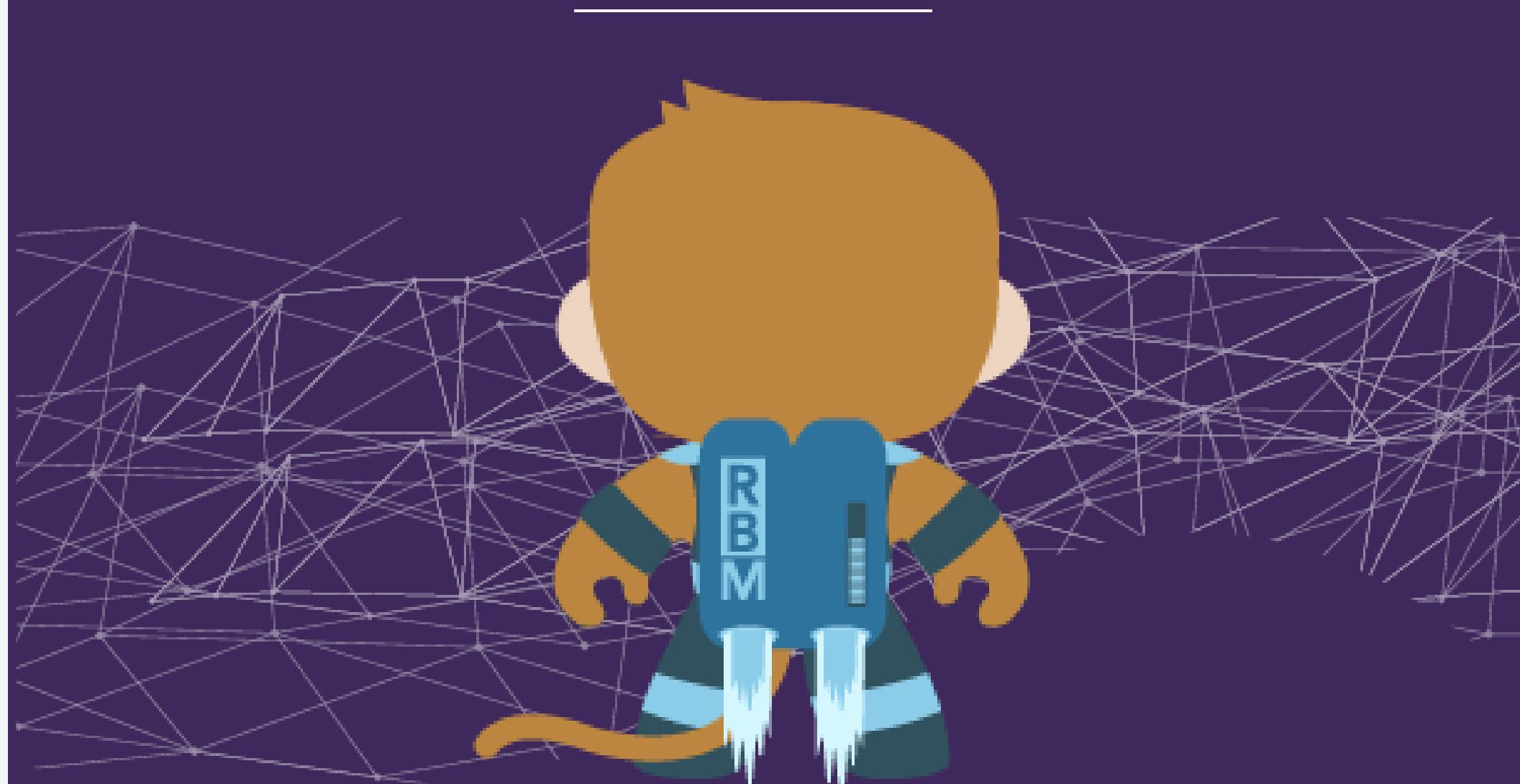
IF RUNNING AN ESOURCE STUDY, DOES YOUR EDC ALLOW YOU TO SEPARATE SUBJECT DATA FROM PATIENT DATA?

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!

DOES YOUR EDC SUPPORT MORE ADVANCED FEATURES SUCH AS RISK-BASED MONITORING (RBM)?

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

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.

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