



ClinCapture Academy
Presents
EDC Study Building
Playbook

2018 VERSION



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.



PRIVACY



PERFORMANCE



POWER



Fight for Your Right to Features



FREE BUILD



DASHBOARD



WYSIWYG



**RISK BASED
MONITORING**



FORM LIBRARY

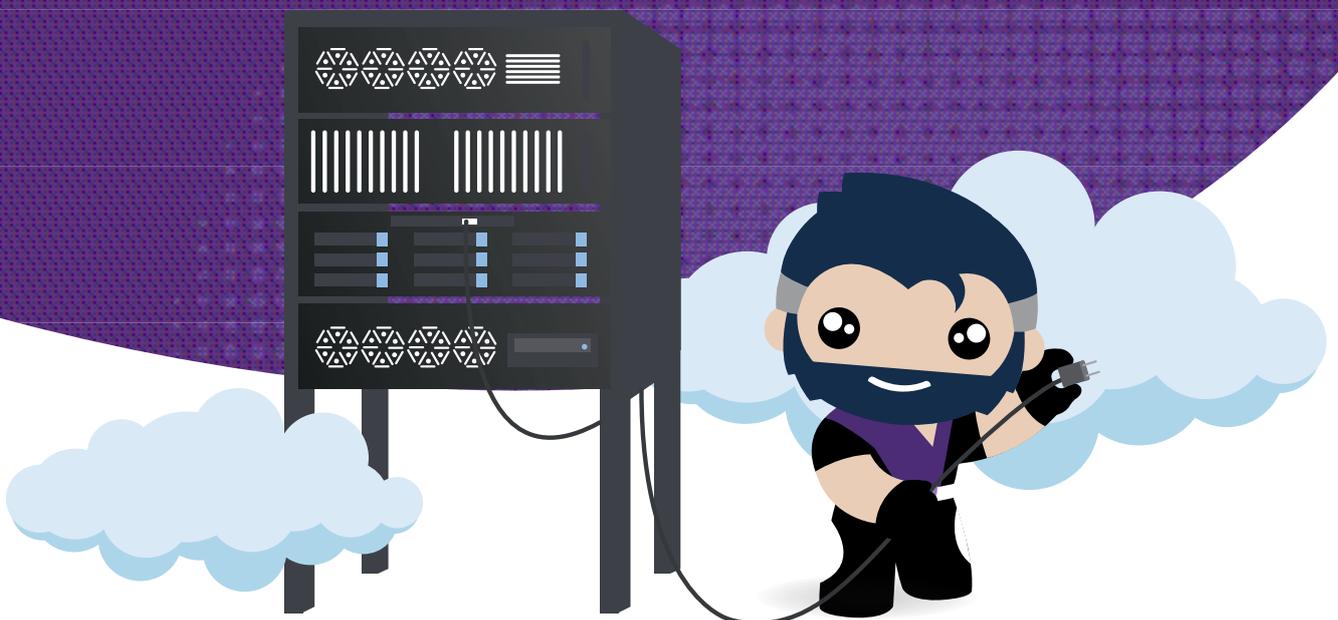
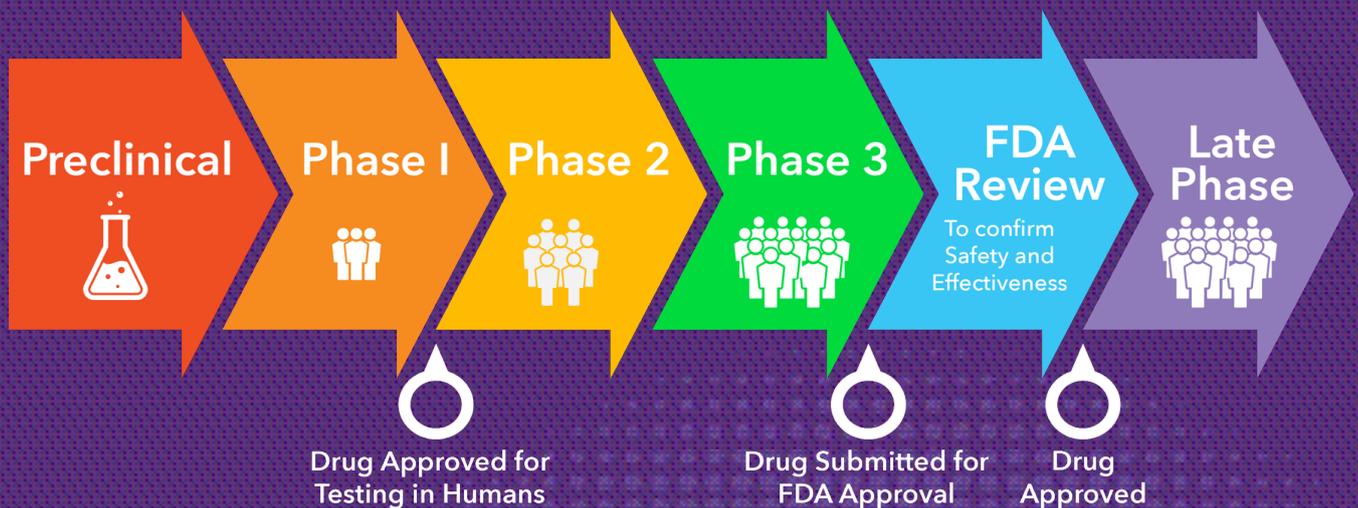


VERSIONING

Welcome to our 2018 EDC Study Building Playbook! This playbook will show you five *Playbook Rules* that will make your study building more efficient and easier for your data entry users. These rules apply to all EDC systems, although we will also share with you how to take advantage of ClinCapture's advanced features when building your study. We hope you enjoy our EDC Study Building Playbook! We update our guides annually to reflect the most up-to-date techniques. Do you want to receive the latest versions when they become available? Contact marketing@clincapture.com to be added to our mailing list.

NO MATTER WHERE YOU ARE IN THE PROCESS,

FOLLOW THESE FIVE RULES WHEN BUILDING YOUR STUDY...



PLAYBOOK RULE #1 EFFICIENCY IS KEY

When building studies in an EDC system, it is important to keep in mind that efficiency is key. Keep your form builds as simple as possible and only collect what is necessary per the protocol. Ask yourself the following question: "If a user enters data, would they find this process easy?" If the answer is no, it may be time to simplify your study build! This simplicity will help minimize confusion and unnecessary steps for your data-entry users. At ClinCapture, we offer free training and support to make your study-building experience a positive one!



PLAYBOOK RULE #2 MAKE IT USER-FRIENDLY

It is crucial to consider data entry users when designing forms. Are they easy to understand? In addition, utilize tables when appropriate for log forms, such as adverse events and concomitant medication forms. Do not over-use edit checks and required fields, as this can become a burden for data entry users. Again, try to envision using your study build from the perspective of the user.



PLAYBOOK RULE #3

**TAKE ADVANTAGE OF
EDC FEATURES**

Utilize EDC advanced features, such as form versioning, to make the study building process more efficient and easier for your data entry users. If your EDC system allows it, think about utilizing repeating forms or visits, and building dynamic groups. It is important to take advantage of these EDC features to better your study building process and end result. Do you have a particular feature in mind? Your EDC vendor may be able to add in this feature or have it available to you for future studies. It is important to speak to your vendor about their upcoming releases! At ClinCapture, we like to stay innovative and release new features twice a year.

**PLAYBOOK RULE #5
REMAIN FLEXIBLE**

It is important to remain flexible as you build your studies. There are going to be protocol amendments, so it is best to always expect them! When you are initially building your study, make sure to keep everything simple and avoid adding unnecessary rigidity into your system. This simplicity will help if amendments need to be made at a later time. Making changes takes time and effort so only make changes to your study when necessary.



**PLAYBOOK RULE #4
UTILIZE STANDARDS
AND TEMPLATES**

Implement standards and templates into your study, such as variable names and export names. Make sure to put thought into using a naming convention before you start building. Ask yourself questions like: "What's the database name for each of the items on the page going to be?" It is always optimal to have a thoughtful system and plan for how to name items in the study when building forms. In addition, if your system allows you to design generic forms, like a standard demographics or basic adverse events, to use multiple times, take advantage of this feature! This will help you be more efficient by providing you with a starting point when building new studies. ClinCapture's Private Cloud EDC allows users to re-use forms both within a study and across studies. This is a big time-saver.





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



**– SCOTT WEIDLEY,
President & CEO at ClinCapture**

clinCapture



SAN FRANCISCO

1428 Bush St. San Francisco, CA 94109

NEW YORK CITY

311 W 43rd St. New York, NY 10036



800-987-6007



contact@clincapture.com



www.clincapture.com