The CLIN CHRONICLE

BECOMING A CDM FORCE

DATA MANAGER'S GUIDE TO REPORTING *WHAT ARE CEOS LOOKING FOR IN ECLINICAL SYSTEMS?* CDM WORD SEARCH *WHAT'S YOUR PHASE* WHAT'S IN YOUR DM SATCHEL? *JOINING FORCES TO FIND CURES FOR RARE DISEASES* AND MORE...

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LETTER *from* CLINCAPTURE

Meet the CEO

Greetings, fellow Clinical Data Managers! Welcome to the first-ever edition of The Clin Chronicle, a magazine for Clinical Data Managers, featuring insightful articles written by Clinical Data Managers, ClinCapture staff, and industry professionals. 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.

In this issue of The Clin Chronicle, we will showcase a new product release we are very excited about, Advanced Reporting with Business Intelligence Tools! This highly anticipated winter release provides real-time actionable data that can help lead teams to improve organizational efficiency and resource allocations, as well as make other timely decisions to improve the outcome of clinical trials. In this magazine, you can find more information about this release, as well read other interesting and timely articles!

We hope you enjoy the first edition of The Clin Chronicle! Are you interested being featured in our next The Clin Chronicle? Please email marketing@clincapture.com for more information. We look forward to continuing to provide you with timely Clinical Data Management content. You can access more resources, or request a demo, at www.clincapture.com.

Power Up!
Scott, CEO of ClinCapture

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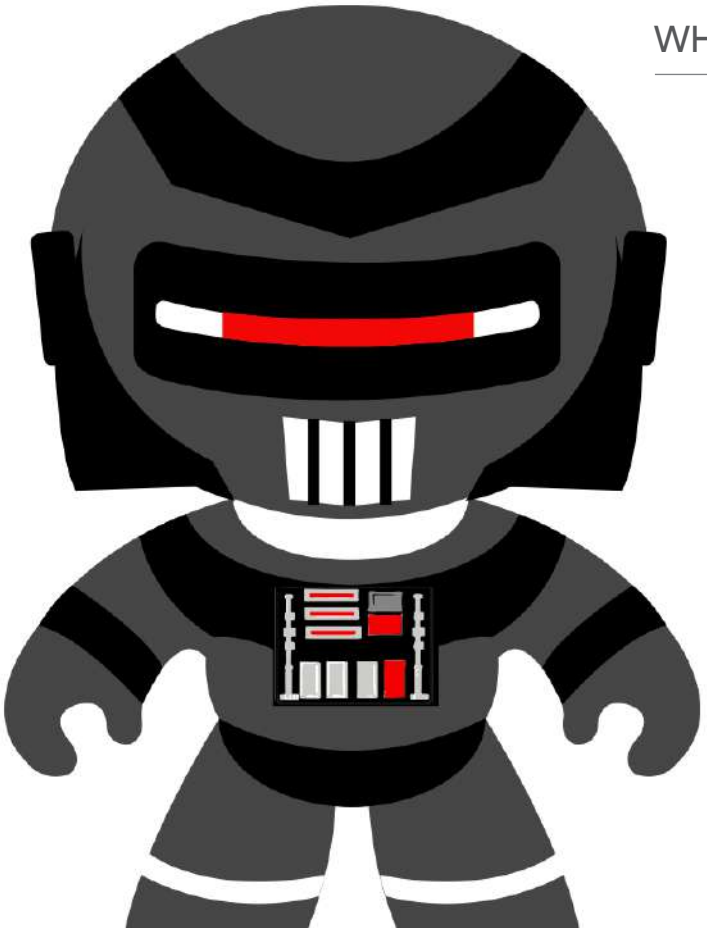

MEET OUR FEATURED CAPPY AWARD WINNERS

Holly Simonton DATA HYGIENE

My favorite thing about being a Data Manager is that the work I do helps others all around the world. I'm proud to have won this Cappy Award because this motivates me to continue pressing on and teaching others data management!

Jim Carter FORM FANATIC

My favorite part about being a Data Manager is being in a field where I get to meet a lot of new and exciting people! I'm happy to be recognized with the "Form Fanatic" Cappy Award and continue to build a strong relationship with ClinCapture!

Brandi Blount TIRELESS TESTER

My favorite thing about being a Data Manager is that data is like a puzzle. I love piecing it together, finding the inconsistencies, discovering the relationships between different pieces.. I'm proud to have won this Cappy Award because it's an award given by my peers in Data Management.

SEE YOU NEXT YEAR!

MARK YOUR CALENDERS:

SEP, 2019

#CAPPYAWARDS2019

captivate

Advanced Reporting with Business Intelligence Tools

Easy to use: Graphical, drag and drop interface.

Self-Service: Users can explore and analyze clinical data on their own with ad hoc reports and dashboards. There is no need for expert assistance.

Real time: Provides users up-to-date reports instantly, as their CRFs or their data change. Unlike other EDC systems, there are no additional steps or time wasted to generate data warehouses or business views before users can analyze their data.

Cross study/site reporting: Key clinical data can be analyzed across studies and sites.

Embedded: Users can access the tool from within the Captivate Live application.

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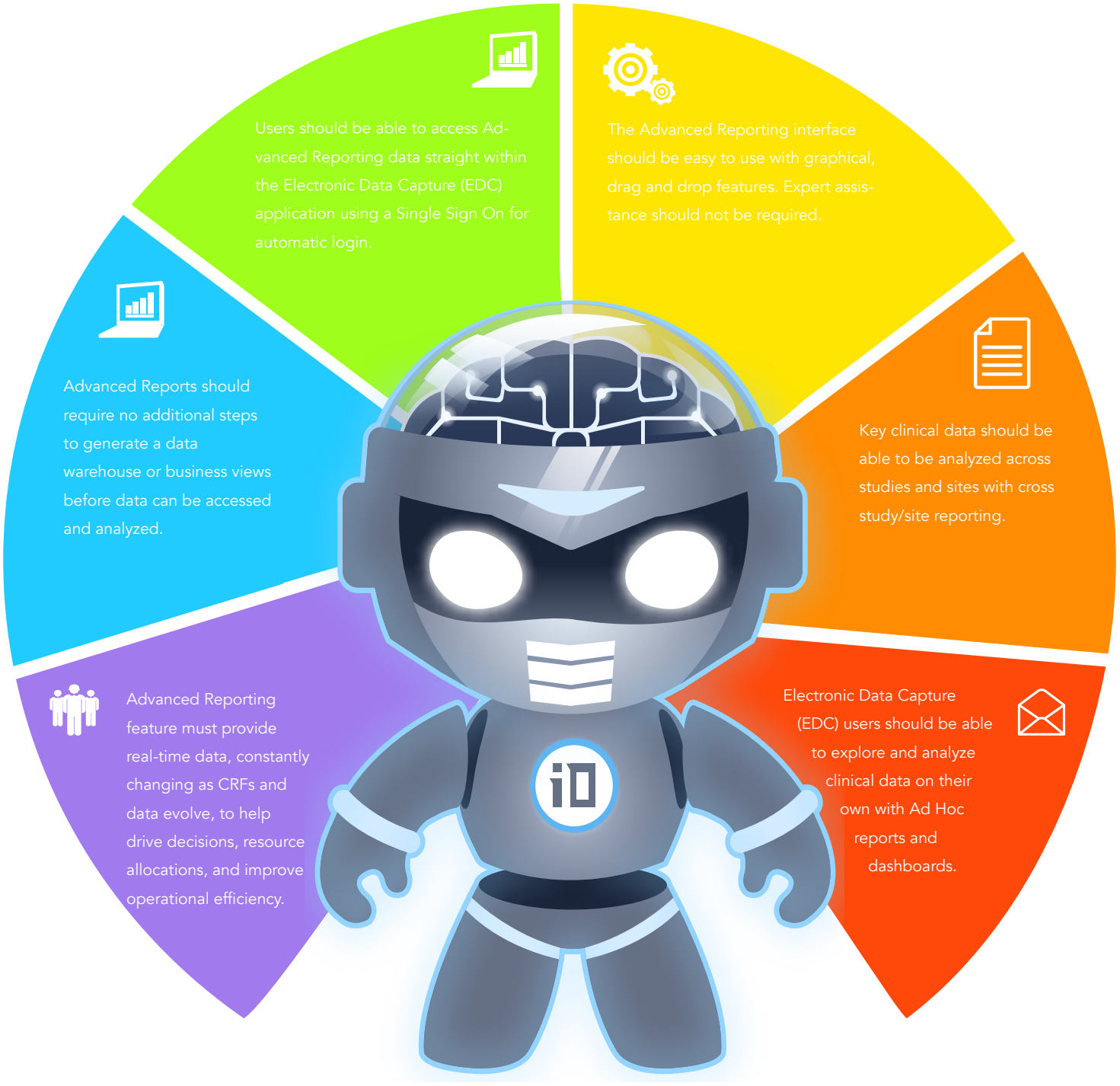
Data Manager's GUIDE TO REPORTING

As a Clinical Data Manager, having access to clear Ad Hoc Reporting with Business Intelligence (BI) Tools is crucial. This real-time actionable data can help lead your team to improve organizational efficiency and resource allocations, as well as make other timely decisions to improve the outcome of your clinical trial. Below you will learn what Advanced Reporting features to look for in an EDC system.



leaders of the force

What are CEOs looking for IN AN ECLINICAL SYSTEM?

When it comes to Electronic Data Capture (EDC), all vendors seem to promise the same things: low cost, fast, easy to use. As a CEO (or a member of upper management), how do you know if an EDC system is truly optimal for your study? As you know by now, an EDC system is an investment -- sometimes for a long term. As a CEO, you have to look at the big picture and past the same basic features every vendor claims to provide. By being equipped with the right information, you can work better to meet the goals of the data management team while maintaining overall business goals.

First, when evaluating an EDC company, consider their track record of helping companies receive regulatory approval. Ask potential vendors about recent companies that used their EDC product and achieved regulatory approval. Second, how easy is it to scale with the EDC system? Many EDC systems only offer basic features and are difficult to scale, forcing customers to switch to another system when their study calls for more advanced features. In addition, some EDC systems do not have the ability and features to run multi- site studies. Consider going with an EDC company that offers both basic and advanced features and can easily scale as the study grows.

Besides offering transparent pricing and fees, EDC companies must be trustworthy and innovative and offer a short and long-term product roadmap. If you plan on being with a vendor for a longer term (more than 3 months), ask the vendor for a product roadmap. This will give you an idea of what upcoming features can benefit your study. Above all, partnering with an EDC company is a commitment, make sure the company is trustworthy, helpful, and available to assist you throughout your study.

JOINING FORCES TO FIND CURES FOR RARE DISEASES

Olivia Montaño, Pathways for Rare and Orphan Studies

Olivia Montaño is the Senior Director, Program Management. Her innovative leadership and emphasis on standardization over the past 25 years has received recognition with multiple industry awards. She specialized in clinical trials administration, vendor management and clinical data management and is an active contributor to the Society.

Patient Organizations play an important role in the development of treatments for rare diseases. They can help in the design of the right study, increasing its likelihood of success, as well as expediting the drug development process.

When a "Sponsor" embarks on a clinical development program for a common disease, there is a wealth of information in the literature and trials conducted previously to use in designing a trial. With a rare disease, there is often very little information available to aid in study design. Patient organizations that are able to collect data from patients over time prior to the start of a clinical development program can significantly increase the chances of success of a drug development program.

Pathways for Rare and Orphan Studies (PROS) works with rare disease patient advocacy groups, focusing on strengthening the groups' ability to work towards clinical trials in the hopes of treatment discovery. PROS works to help prepare them for the clinical phase, including starting or participating in a patient registry – a crucial first step.

One of our projects involves working with the Rare Disease Ghana Initiative. Since the patients served by this organization are located in rural areas, a non-traditional solution is needed for a patient registry. A sustainable and user-friendly EDC system is necessary. As part of its Weidley's Wish initiative, ClinCapture offered us complimentary access to Captivate EDC, as well as free training and support. This initiative which grants nonprofits free access high-quality EDC, gave us piece of mind that the data could be entered from anywhere and safely stored in the cloud. For 2019, we are looking forward to the successful launch of the initial patient registry for undiagnosed patients as well as subsequent databases furthering the rare disease progress of Ghana.

WHAT'S YOUR PHASE?

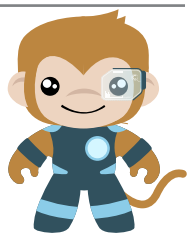
Data Manager's favorite EDC features per phase

There is a wide-array of Electronic Data Capture (EDC) features to choose from for a clinical trial study. Depending on the type of study and phase, various features will be more important than others during the selection process. Check out "What's Your Phase" to see what features fit best for your next study!

PHASE I

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. This phase also benefits from fast study building tools, such as Drag and Drop and XML.

PHASE II/III



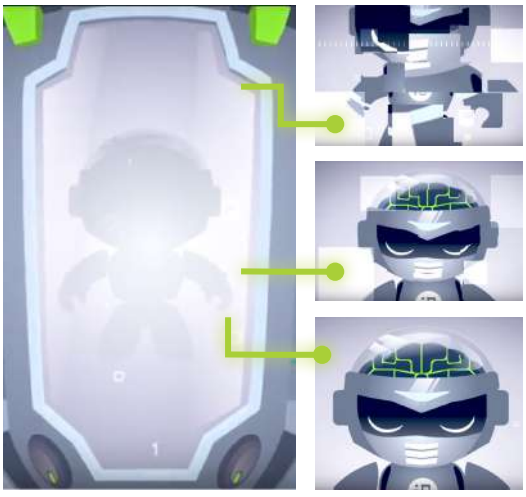
If you are running a larger phase II or III study, you will probably need an EDC system that is scalable and has more advanced features, such as Risk-Based Monitoring (RBM) and Advanced Reporting with Business (BI) Intelligence Tools.

PHASE IV/LATE PHASE

If you are running a Late Phase study, you may be more focused on Outcomes, ePRO, language localization, Advanced Reporting with BI tools and of course, long-term cost.

THE STORY OF MACHINE LEARNER

Captain: "Welcome to my lab, Data Managers. Today we'll give life to my latest creation, a new addition to the feature fighters."



"I have been listening to your frustrations and I built an advanced reporting tool with BI capabilities to provide you with real-time data, which stays up-to-date as your CRFs and data evolve. You won't need expert assistance anymore to explore and analyze your clinical data."

"Did I mention that you will be able to run cross-study/site reporting? Now join me in celebrating the birth to our new CDM hero, Machine Learner!!"

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

Scott Weidley, President & CEO at ClinCapture

INTRODUCING MACHINE LEARNER

In early 2019, Machine Learner will join ClinCapture's feature fighters. Packed with essential knowledge and skills, Machine Learner brings Advanced Reporting with Business Intelligence tools to ClinCapture's leading EDC, Captivate. Are you eager to learn more about this amazing feature? Visit www.clincapture.com/demo to request a thorough walk through with one of our helpful team members.

SUPERPOWERS

Machine Learner was built to take "uncontrolled data" and turn it into real-time reports, featured on the Captivate EDC dashboard. This feature is easy to use with a graphical, drag and drop interface and no expert assistance required.

JOINING FORCES WITH DATA MANAGERS

Unlike other EDC systems, Machine Learner makes it easy for Data Managers by requiring no additional steps to generate a data warehouse, or business views before they can analyze their data. Did we mention cross-study/site reporting is available?

THE BIRTH OF MACHINE LEARNER

Machine Learner is very excited to put his powers to use by bringing Advanced Reporting to your clinical trials! Are you ready to meet him and learn about Advanced Reporting? Visit www.clincapture.com/demo to request a demo with our team.

WHY CLINCAPTURE LOVES WORKING WITH DATA MANAGERS

VINCENT D'ALOIA *SOLUTIONS ENGINEER A.D.*

I love working with Data Managers because they are often the most tech savvy members of their organization. Data managers are not afraid to get their hands dirty when learning how to use software such as Captivate. They often ask the most insightful questions, and are constantly coming up with new ways to get things done.

When collecting feedback from Data Managers, they often have great new ideas for product features, and these sometimes even wind up being in future releases of the software. Mostly, Data Managers are passionate about their work, and an integral part of any successful clinical trial. Working with them makes me feel like I'm making an impact as well, and helping bring new medicine and treatments to patients.

AMANDA MCLEAN *ENTERPRISE ALLIANCES MANAGER*

Clinical Data Managers are critical in ensuring data integrity throughout the clinical trial process. They are wonderful to work with because they deeply care about the quality of their work. ClinCapture takes pride in creating a product that caters to Data Managers. We work very closely with our Data Manager customers and use their feedback to shape our product releases. It is very important to us to create a product that allows Data Managers to work efficiently so they can continue to expand their key role in bringing potentially life saving drugs to the patients who need them.

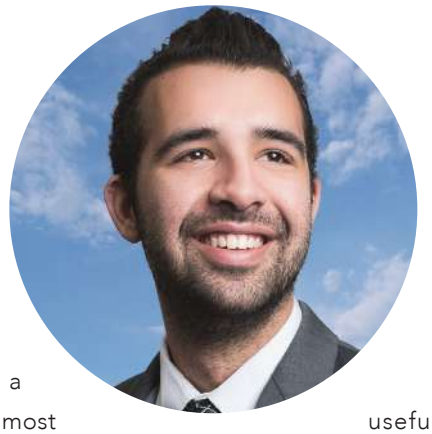
VICTORIA TRUMBULL

SR. SALES DEVELOPEMENT REPRESENTATIVE

From my conversations with data managers, it is evident that the universal goal in the healthcare industry is to save lives efficiently. Common characteristics of a Data Manager include strong will, enthusiasm, and one finger on the pulse of clinical research at all times.

GRANT KAPLAN

CUSTOMER SUCCESS MANAGER



Since Data Managers are in charge of technicalities, standards, and protocol of a study, they provide the most useful feedback on how to improve our software and workflow. Working with Data Managers to help them accomplish their goals has been fulfilling, rewarding, and incredibly useful to learn from.

NICK NEWTON

SR. SALES DEVELOPMENT REPRESENTATIVE

I love working with Data Managers because I learn something new from each conversation. Like clinical trials, no two Data Managers are the same, so I'm constantly exposed to different points of view from brilliant minds in the industry. Data Managers have such a passion in their voice when talking about their work and demonstrate the significance of clinical trials in saving lives. They're natural problem solvers, and their insight is invaluable when figuring out what matters most in an EDC platform.

CALEB SAVALA

ACCOUNT EXECUTIVE

Data Managers are the best because their work changes the world. Without their commitment and attention to detail, innovative, safe therapeutics would not enter the market. I enjoy working alongside Data Managers since they are always looking to be more productive and efficient in their endeavors. This includes sharing feedback about their workflows and the challenges of collecting data from a clinical site. Their attention, effort and involvement in product feedback is crucial to supporting ClinCapture's efforts to develop software that saves lives.

DATA MANAGERS ARE THE BEST BECAUSE THEIR WORK CHANGES THE WORLD

WHAT'S IN YOUR CDM SATCHEL?

As a Clinical Data Manager, you keep your satchel packed with necessities to help you during a study. From Electronic Data Capture (EDC) with Medical Coding to Advanced Reporting, let's take a look at popular items Clinical Data Managers keep in their CDM satchels! Learn more about these items at www.clin-capture.com.

1

Electronic Data Capture (EDC): This CDM item is a must for all Clinical Data Managers running a study. It's safe to say: not all EDC systems are created equal! The best EDCs are hosted on a Private Cloud and have the ability to run both simple and complex clinical trials!

2

Advanced Reporting with BI Tools: This item is offered by only the top EDC vendors. Users can explore and analyze real-time clinical data on their own with ad hoc reports and dashboards without expert assistance! The best EDC systems allow cross study/site reporting and provide a seamless interface straight on the EDC dashboard!

3

Randomization Module: This CDM satchel item is necessary for any randomized clinical trial. The best systems should support simple randomization, permuted-block randomization, stratification, and dynamic randomization algorithms. System should also offer full support for double-blinded trails, including kit management, kit replacement, and emergency un-

4

eCOA/ePRO: This CDM satchel item should be easy to set up and user-friendly. Patient Reported Outcomes (ePRO) and Observer Reported Outcomes (eCOA) should allow participants to use any device/web browser, unify answers with EDC systems, provide compliance reports, and should not require any special hardware.

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C	I	O	C	A	I	E	E	O	O	C	R	P	E
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FIND THE WORDS

1. SOPs
2. Edit Checks
3. Randomization
4. MedicalCoding
5. PrivateCloud
6. Captivate
7. eCRFs
8. RBM
9. eSource
10. EDC
11. Performance
12. Power
13. Privacy
14. Studies
15. Phases
16. Pharma
17. MedicalDevice
18. Biotech
19. CDM
20. DataManager

LEARN MORE

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