10 GOLDEN RULES OF CLINICAL DATA MANAGEMENT

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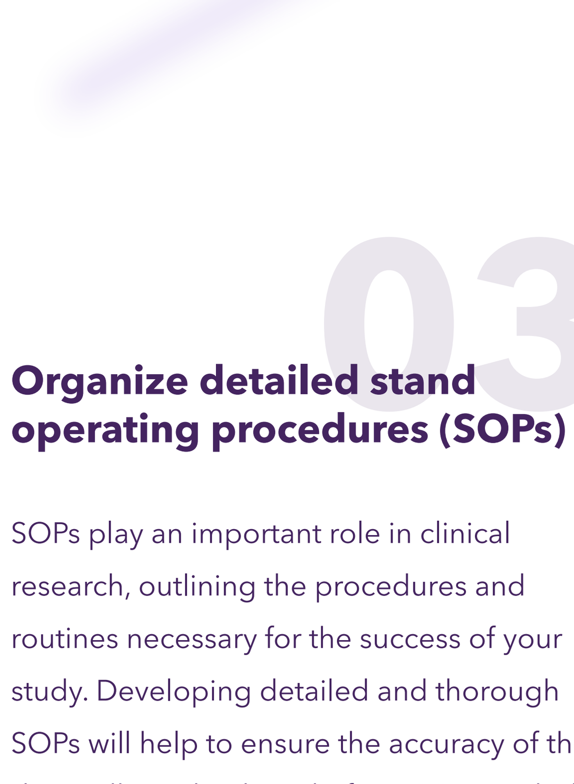
Clinical data management (CDM) requires the utmost attention, especially with all the details to consider and protocols to adhere to. Overseeing data collection and ensuring accuracy throughout a study comes with its own set of challenges and rules to remember, but don't worry - we wrote them out for you.

Whether you're in the early stages of a study or in the middle of seeing one through, here are 10 golden rules of clinical data management to keep in mind.

01 CDM starts at the beginning

Although the bulk of CDM responsibilities happen after the data is collected, don't hesitate to involve the CDM early and throughout the entire study. Early involvement allows the team to identify critical data points and to ensure all efforts work towards a quantitative end goal. This helps to maintain the integrity of the data collected as processes are maintained.

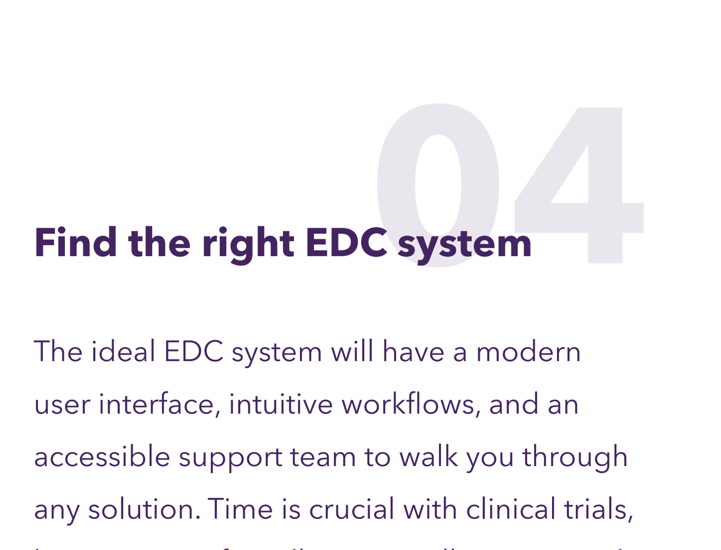
02 Implement "fit for purpose" and "end to end" data strategies



The Society for Clinical Data Management (SCDM) advises the implementation of "fit for purpose" and "end to end" data strategies to prevent the critical risks of emerging study designs. A "fit for purpose" strategy enhances the quality of data by ensuring that data is more targeted towards study objectives. This way, non-critical data points are removed. Additionally, an "end to end" strategy ensures the thoroughness and accuracy of the data collected.

03 Organize detailed stand operating procedures (SOPs)

SOPs play an important role in clinical research, outlining the procedures and routines necessary for the success of your study. Developing detailed and thorough SOPs will help to ensure the accuracy of the data collected. When drafting SOPs, include all relevant staff in the conversation. Keeping your team members in the loop will communicate expectations and practices related to data collection. With your staff all on the same page, you reduce the risk of errors in data collection and reporting.



04 Find the right EDC system

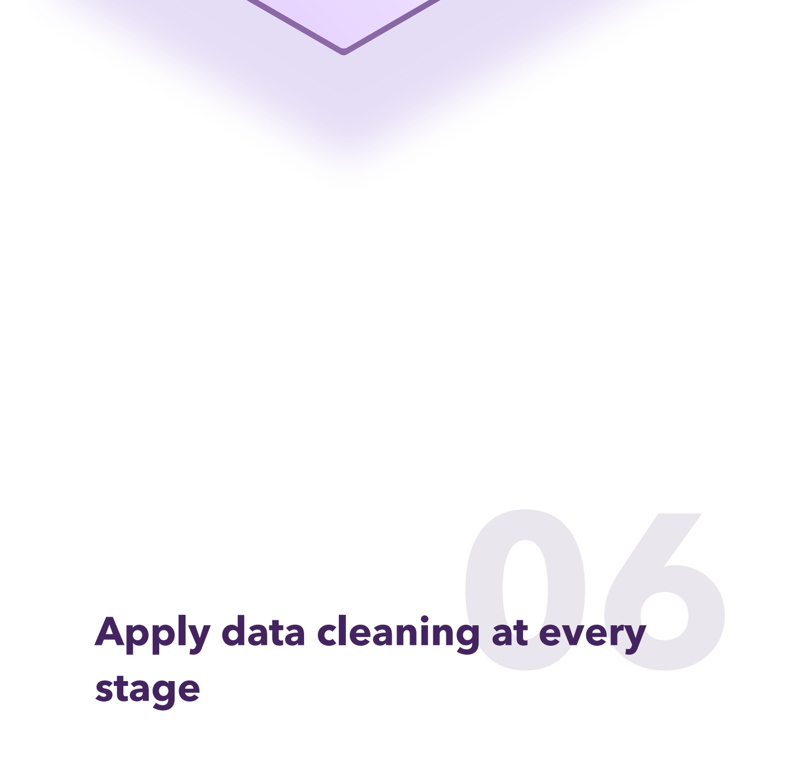
The ideal EDC system will have a modern user interface, intuitive workflows, and an accessible support team to walk you through any solution. Time is crucial with clinical trials, having a user-friendly system allows you and your team to spend less effort onboarding and more effort on other priorities. You should also have full accessibility to your EDC system -- whether it's from a desktop, a tablet, or a mobile device. This allows for a more seamless experience.

When you run into any EDC-related issues, a proactive helpdesk should be available to you as soon as possible. Long wait times and poor communication from support teams will hinder your productivity, and it is just plain frustrating to deal with.

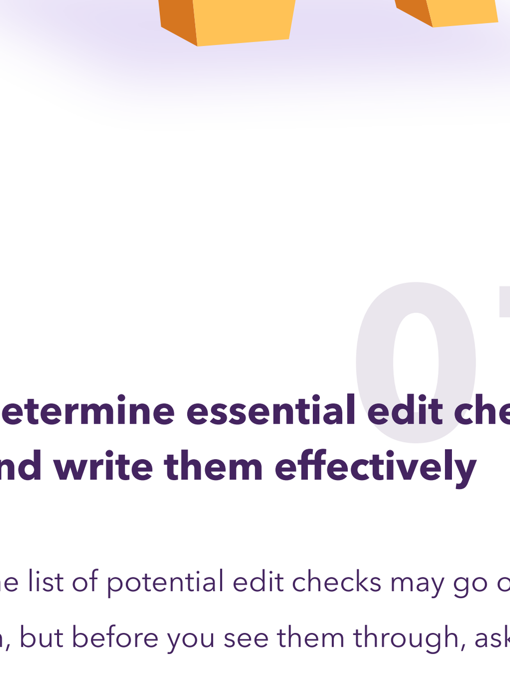
05 Develop a clear Data Management Plan (DMP) and let it evolve with the research

From the get-go, having a clear, concise DMP will help organize clinical data as it's added to your EDC. While it may seem like a no-brainer, having specific answers to questions like "What work is to be performed?" or "How can data be analyzed?" will prevent any confusion as research is conducted.

At the same time, it's also important to let your DMP exist as a living document. Research is all about discovery, and as new information arises, shifting gears at a moment's notice may be necessary. When study plans change, remember to reevaluate your DMP and revise it so that it consistently meets your needs.



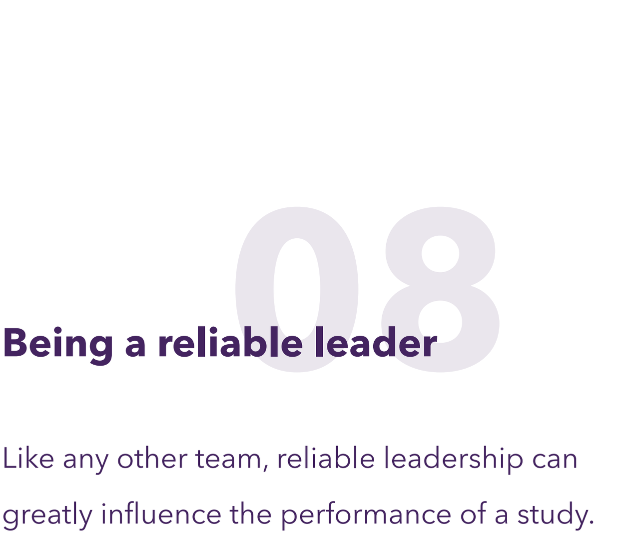
06 Apply data cleaning at every stage



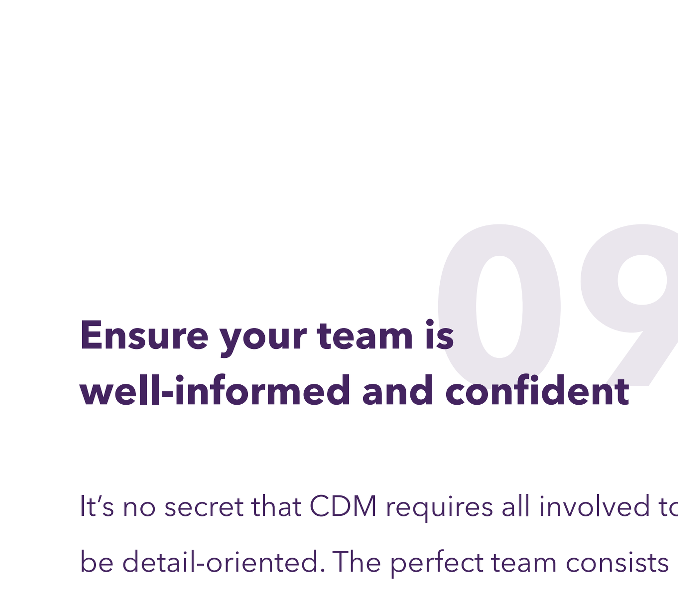
Although EDC systems prevent most discrepancies in data collection, paying close attention to the process at every stage will ensure quality control. One way to remain consistent with data cleaning is by running standard data cleaning reports. This will help not only the accuracy of the data but also the effectiveness of later analysis.

07 Determine essential edit checks and write them effectively

The list of potential edit checks may go on and on, but before you see them through, ask yourself: How many are actually likely? When deciding on which edit checks to pursue, consider only the most relevant ones so that you can avoid wasting time and energy on developing them. After you've determined essential edit checks, develop them in a way that is as clear and unbiased as possible. Define the issues, explain potential errors, do not set narrow ranges, and prompt action without leading the site. Doing so will provide the clarity your staff needs.



08 Being a reliable leader

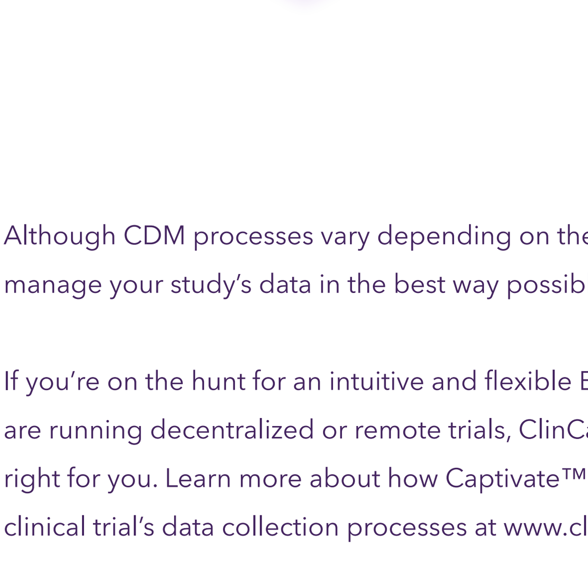


Like any other team, reliable leadership can greatly influence the performance of a study. Data managers are key players in all things data collection -- from supervising the CDM process to coordinating relevant tasks. With that in mind, it's all the more important to stay updated on industry practices, understand SOPs like the back of your hand, and consistently work towards a quantified goal.

09 Ensure your team is well-informed and confident

It's no secret that CDM requires all involved to be detail-oriented. The perfect team consists of people who not only know what they're doing, but they're also confident in their responsibilities. Train your staff on the best industry practices and provide them with the necessary tools to succeed.

10 Consistency is key



Clinical trials involve many moving pieces. With multiple staff members and multiple sites to keep track of, the quality of the data depends on the consistency of the work produced. From data collection to data cleaning, it's important for all team members to follow procedures and protocols from the very start until the very end.

Although CDM processes vary depending on the situation, these 10 golden rules will help you stay on track and manage your study's data in the best way possible.

If you're on the hunt for an intuitive and flexible EDC system, ClinCapture's Captivate™ is the way to go. If you are running decentralized or remote trials, ClinCapture's leading Virtual Data Capture® (VDC®) solution might be right for you. Learn more about how Captivate™ or Virtual Data Capture® (VDC®) can streamline your next clinical trial's data collection processes at www.clincapture.com.