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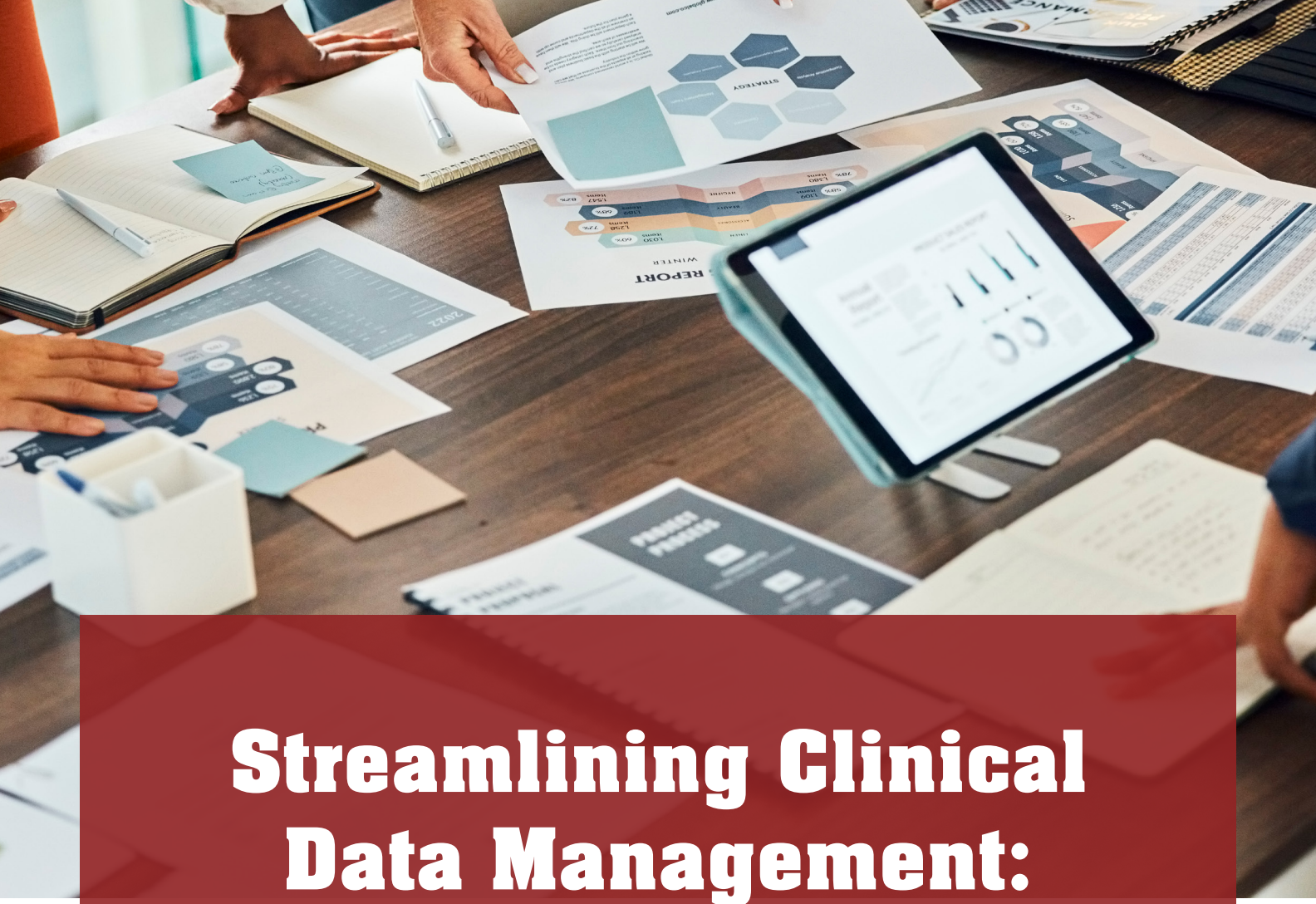

Streamlining Clinical Data Management: Eliminating Redundancy to Increase Efficiency

By Ashlee Curtis, inSeption Group

Clinical trial data processes are paradoxical by nature. Some data points are absolutely critical in terms of when and how they are collected; other data is seemingly important, but it is not leveraged during or after the study, making its collection and management an unnecessary burden. Therefore, it is in the best interest of study sponsors, CROs, sites, and patients to streamline clinical trial data processes by ensuring this type of redundant or extraneous information is not collected by the electronic data capture (EDC) system. By concentrating on raw data early, trial runners can ensure a more efficient and effective interpretation process on the study's back end.

Improving clinical data management, though, requires an understanding of the root issues, which includes identifying which data points are essential, how those data points are used and coded for interpretation after they are entered by the site, and then determining which data-centric tasks can be completed by data management personnel, statisticians, and clinical scientists.

Identify Extraneous Data Collection Early

Enabling sites to focus solely on critical data facilitates faster data entry, reduces queries from data management, CRAs, and regulators, and fosters better relationships between sponsors, CROs, and sites. But how can clinical teams and data teams determine which data is essential and which is not? EDC systems typically demand a staggering amount of data at the outset of a trial, with no indication of what is most or least important.

Part of the reason is that EDC templates often are carried over from one trial to the next, and until somebody pushes back on a data point, it continues to be needlessly collected. Accordingly, catching some redundancies and unnecessary burdens early in a trial reduces the clinical team's data entry burden, improving overall study efficiency and, by extension, reducing costs. Enabling clinical professionals to look over the system and the protocol can help ensure its stipulations align with their understanding.

For example, CRAs looking over a protocol may realize that two tests are scheduled too close together, because the patient will not have enough time to walk from one end of the site to the other. Or, they may realize a particular data entry request is not part of a routine lab, so it is in danger of being overlooked or misinterpreted. Unfortunately, an up-front approach is not always logistically possible because the study team usually drafts the protocol and the data team builds the EDC before any clinical team has been assembled.

Involving clinical teams at the beginning of the study, when creating electronic case report form (eCRF) pages, also helps solve this problem. Moreover, establishing comprehensive eCRF completion guidelines (CCGs) helps the site and CRAs understand how each page should be entered, as well as how solutions should be implemented if issues arise with any page. inSeption Group is differentiated from competitors in assigning a Regional Site Manager (RSM), i.e., CRA, before sites even have been chosen, ensuring their expertise and experience is available to inform all critical elements of study start-up. In any case, setting clear expectations for data entry and issue remediation is paramount.

Otherwise, many problems that could be fixed in advance of study kickoff are not discovered until sites are active and CRAs begin to recognize data shortcomings or trends: for example, the same protocol deviation might keep occurring. So, the protocol must be amended or the situation leading to the deviation must be reported upward. Either way, addressing these problems after the study is active takes more time, money, and effort.

Creating an open forum before a study kicks off, driving discussion about the protocol and the EDC, is another effective way to overcome some potential issues between the clinical team and the sponsor/CRO. CRAs can otherwise be siloed, performing the same tasks and discovering the same anomalies without realizing it. Ideally, those CRAs would talk to their team leader, who then would make the appropriate connections to confirm the CRAs' reporting before dispersing that information to the rest of the team. Nevertheless, the desire to constantly make things better must be present on the collaborating teams.

Carefully Build Tracks in Front of the Moving Train

In addition to scrubbing unnecessary data points from a study protocol and EDC system before the trial starts, data collection and management can be streamlined by addressing issues throughout the study. Under most studies, the data team asks the site for interpretation, or the sponsor asks the CRA for feedback on the build, and that collective feedback contributes to modifying the study build.

Such collaboration helps to eliminate the cycle of data hoarding and can spare sites significant work: If it requires 45 seconds to enter data on a particular document, rather than two minutes, that small amount of time adds up over hundreds of pages. At times, this task can place a site and the data team at odds, since the site often sees events and instructions in shades of gray; interpretation has an element of ambiguity. Conversely, for the data team, everything is black and white. Again, establishing clear CCGs is vital to accuracy and efficiency.

In this data management scenario, the RSM reviews and verifies the collected data, after which the data team looks over that information and issues queries to the site based on its findings. Sometimes, those data team queries are unclear, ambiguous about what precisely they want the site to review or update.

This impasse kicks off a discussion between the RSM and the data team to clarify the information being sought. Collaboration through a liaison also clarifies the data team's overall preferences around how well datasets match and how they like communication to occur. The same is true of clarifying clinical scientists' preferences.

For example: if patients are receiving potassium on a sliding scale over four days, should the data be entered per dose and patient, including volume, or as a total equivalent dose for the period? Whatever the decision, there should be constant discussion between teams around the rigidity of what is recorded and the language used to describe it. Additionally, this information should be recorded in the eCRF, helping the next coordinator enter the same data the same way.

Passing the Data Management Hot Potato

Another way to streamline clinical trial data management is to shift more interpretation and contextualization responsibility to the data team and statisticians at the back end of the study. Sites still will enter some data that ultimately will not be used, but the data team may have to run only a report on the data that filters out extraneous details, which is not necessarily burdensome to the data team.

For example, consider adverse events (AEs) during lab work. A site has to enter lab values during a patient visit and, if the findings are clinically significant, they enter an AE. Sites may think the logged AEs are used to confirm the patient had anemia from date A to date B, but in reality, study investigators entered lab values to track how long patients had platelets and to grade the condition of those platelets. The AE log is utilized so investigators/sponsors know the relationship to the study treatment, if any therapies were given, or any changes to the therapy were needed. So, sponsors and CROs need to be cognizant of asking sites to do unnecessary work because they are unaware how investigators are using those data points.

The simpler element of data management is matching data: for example, confirming whether the data entered into the system about the patient's vital signs matches the patient's chart. Higher-level thinking is required to make some of the "judgement calls." Perhaps a patient had a slight fever for two hours, but the fever spiked during hour three. Even though the EDC does not request hour-three data, that fever spiking and its timing could be relevant and should be recorded.

Connectivity and causation can lead to even slipperier slopes, too. For example: a patient is changing the oil in their car but neglected to set the jack properly, and the car fell and broke their toe. Is the broken toe an AE? Should it be reported to the sponsor? Could some element of the study have affected the patient's judgement or impacted their bone density? The point is that studies generate a tremendous amount of data and determining relevance requires trained eyes and a team effort.

Unfortunately, as a study winds down, the time available for data management starts running out. Depending on the study phase and how many patients are enrolled, the data management load can become overwhelming: an RSM might have 400 pages to review at a site but can squeeze only 40 pages into each day (assuming the site is well-organized and the RSM does not need to hunt down scattered data). They can only work so fast, and safety pages, which tend to take longest, generally are the top priority.

Some data simply are relegated to the trash bin. The sponsor determines the data's importance and whether it is worth the time and cost to correct associated issues or if the answer simply is to filter those data out of final findings/results.

Early in a study, that cost/benefit equation is more forgiving: Changes to a system query might be pushed through immediately or an update to the protocol may be put off until annual reviews.

Ultimately, a team that works well together and feels comfortable communicating is vital. It should be as simple as the RSM reaching out to a data manager or medical monitor, or vice versa, to screen-share with them and review questionable data in real time. When these parties are aligned before bringing an issue to the site, it avoids having to amend a data point multiple times.

Conclusions

Streamlining data collection is not just a boon to the sites tasked with collecting a plethora of information. Improving the timing of some tasks, assigning them to different parties, and fostering team communication promotes better operating conditions for the entire study team. The way the teams are built and how they work together is the linchpin of how a study proceeds. To learn more about minimizing the burdens of data collection and interpretation, contact the author and , visit https://inseptiongroup.com.

About the Author

With a degree in Organizational Behavior Management and Psychology, Ashlee began her career in research in 2016 as a clinical/data coordinator at an academic hospital. Her passion for teaching and clinical trials led to a career change and becoming a Clinical Research Associate (CRA) in 2019. With a blend of academic knowledge and practical experience, she is committed to advancing the field of clinical research and making meaningful contributions to research.

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