The Voice of the Study Coordinator: Empowering Clinical Trial Sites to Deliver Improved Performance

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The Voice of the Study Coordinator: Empowering Clinical Trial Sites to Deliver Improved Performance

Study coordinators are undeniably central to the successful performance of clinical trials. Yet, despite their pivotal role, their voices are often overlooked; most research into site perspectives is drawn from principal investigators or site managers. A recent series of interviews conducted with study coordinators globally has revealed that many of the pharmaceutical industry's greatest concerns—such as trial timelines and data quality—are felt acutely by study coordinators in their daily work. And, perhaps more significant, the research has elicited insights from study coordinators that can unlock opportunities to actually speed trials and improve data quality.

The following report details the findings of research conducted by the inVentiv Health Site Centricity Unit in conjunction with The Society for Clinical Research Sites (SCRS). The study coordinators' candid responses have uncovered sources of trial inefficiency, and their suggestions for improvements offer a corrective path for sponsors and Contract Research Organizations (CROs)

Executive Summary

When viewed through the eyes of study coordinators, many of the industry's common issues with the effective conduct of clinical trials stem from communication failures. The communication gaps that study coordinators experience are less visible to sponsors and CROs because their internal departments have little interaction with one another on trials, and thus they have few points of conflict. However, study coordinators, receiving conflicting information from these various departments, are keenly aware of where communication is breaking down. And, they then are victims of the resulting inefficiencies.

About the Survey

The research was conducted via interviews between March and April 2017 by representatives of the inVentiv Health's Site Centricity Unit through the company's relationship with The Society for Clinical Research Sites (SCRS) as a Global Impact Partner (GIP).

A Site Advocacy Group (SAG) first met to determine a list of "pressure points" on which to focus. Members then edited and added to the list, forming the basis of the topics discussed in the interviews. The professionals participating in the SAG have extensive experience as study coordinators and an average of more than 12 years of industry experience. The nine SAG members were from a variety of site types representing a wide variety of therapeutic areas and geographies, including: Australia, Canada, France, Germany, the Netherlands, New Zealand, Poland, the United Kingdom and the United States. These nine SAG members were the interviewees throughout the process.

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The communication issues identified were primarily in the following three areas:

- **Recognizing the study coordinator's value during site selection.** The turnaround time for completing feasibility questionnaires hinders study coordinators' ability to answer thoroughly. The questionnaire format is limiting and can result in sponsors drawing inaccurate conclusions about site eligibility. The feasibility process is frequently experienced as disjointed and shouldn't always hinge on the investigator exclusively.
- **Training coordinators effectively.** Study coordinators report that training is difficult for them to access, their available time is often spent on repeat training, and the training they need is sometimes directed toward the principal investigator. Many times, training for study coordinators appears to be treated as an afterthought rather than as a systematic process for all of the study needs. Improvements are, however, being made as most sponsors acknowledge standardized, subject-protection training and maintain central training files on coordinators.
- **Communicating effectively throughout the study.** Often study coordinators don't know who to contact about a study—an issue exacerbated by high Clinical Research Associate (CRA) turnover. Communication is improved with the reliance on startup specialists and site communication specialists.

The research also included further discussion of four technical areas:

- **Budgets, invoicing and payments.** Budgeting appears to be rushed and disjointed, payments don't fully cover costs of patient recruitment and other essential tasks and it's a challenge to be paid promptly.
- **Document management.** The lack of document standards creates inefficiencies. Document management systems are viewed favorably and are improving communications.
- **Vendor management.** Vendors often cause delays that prevent sites from getting started on time. And, sites are sometimes left to resolve vendor issues on their own.
- **Data management.** A host of obstacles—from protocol amendments to unnecessary data queries—frustrate study coordinators and impede their ability to deliver quality data.

All of these difficulties, in the end, present a risk to study quality as well as to the patient, as study coordinators are pulled from their patient focus to deal with other issues. Improving communication pathways by implementing the recommendations of study coordinators below will help them fulfill this most important mission as well as improve the productivity of research projects.

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Feasibility

Study coordinators are essential to clinical trial performance. But, is their contribution truly appreciated? Are the resources they provide properly valued? These questions reflect a core concern for study coordinators. Indeed, the difficulty that they have in effectively communicating their capabilities and the benefits they offer to the industry is often the starting point for a chain of communication issues that can continue all the way through the study.

Although study coordinators are very aware of the various resources available in their sites, they rarely are given the opportunity to adequately communicate the value of those resources during the feasibility process. One main reason is the short turnaround time for completing the feasibility questionnaires (one or two days). Coordinators need more time to understand the study and develop an adequate response.

Another reason is the query format. While the sponsor may be aware of particular difficulties in conducting the study, these issues are not highlighted in the feasibility questionnaire. For example, a key question about how electrocardiography (ECG) is conducted is given equal weight to a routine question about the number of exam rooms. This limits the “getting to know you” aspect of the feasibility exercise that truly determines whether the study is feasible. At the same time, study coordinators may not realize there will be particular expenses associated with how their sites may have to conduct the study. Even worse, they may not realize that a study is not logistically possible for them. As a result, sponsor personnel may conclude that a study is feasible, when in fact it is not.

In some cases, responses may be restricted to check boxes, further limiting the information the study coordinator can provide. For example, if a site’s risk management analysis has determined they must perform a procedure slightly differently than described in the question, answering either “yes” or “no” is problematic. What if the study coordinator answers “yes,” but the study requires the procedure to be carried out a different way, and the site actually cannot perform the study? What if the study coordinator answers “no,” but the variance would have been acceptable? Either way, the sponsor obtains inaccurate information about the true feasibility of the study at that site.

Study coordinators can be a wealth of knowledge about the capabilities of their sites, but when the feasibility process cuts off real communication, that knowledge is not applied. This goes to the heart of the feasibility process: whether the inclusion/exclusion criteria are sufficient for the study to be successful at all. Study coordinators can contribute to developing successful protocols, if they are consulted early in the process with open-ended questions.

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Valuing the knowledge that study coordinators are able to provide also goes to the heart of quality management. Quality can mean a lot of things and is difficult to define, but the process of creating the best possible protocol and making the best match between that protocol and the appropriate sites is where clinical research quality starts.[1]

Study coordinators spoke of the tendency to index everything about a site around the investigator. While the principal investigator as the central figure is an accurate description of some small investigator-owned sites, this perception is not accurate for larger research institutions or specialty research sites and site networks that employ investigators for specific studies. For these organizations, a process that allows the site to project their capabilities beyond focusing on investigators would more accurately communicate the value they can bring to the study. This would mean recognizing the institution itself as the "site," rather than viewing the site as an investigator with ancillary equipment, resources and capabilities. In certain cases, this would mean viewing a site network as the "site."

Study coordinators also reported being frustrated because the feasibility process is disconnected. Site selection visit information is generally siloed by study and the information is not shared between CRAs working on studies in the same program. A clinical research associate (CRA)/monitor may be sent out on a site selection visit for a new study, only days after a visit from another monitor on a current study in the same program. The second CRA often has little familiarity with the program, which is frustrating given that the site already has a relationship with a CRA who is familiar with the program requirements. Then, if the site is selected, the process may be handed off to yet another CRA. With different CRAs coming and going who don't know each other or the research program, a coherent pattern of communication does not develop.

Rather than being trusted partners in clinical research, study coordinators can feel quite disconnected from the research process. If the site is not selected, there is unlikely to be any follow-up. Yet, study coordinators would like to know why their site was not selected. If it was because of a misunderstanding on the feasibility questionnaire, there is an opportunity for the study coordinator and the program managers to better understand how to communicate about feasibility. At present this loop is not closed, allowing misunderstandings in feasibility to persist and continue to present inefficiency.

In order to ensure greater value in the information that the study coordinator provides during the feasibility process, study coordinators recommend:

- Communicating more clearly about the goals of the feasibility assessment

[1] Martin J. Site identification – Standing out by investing in quality. LinkedIn Pulse. 02 June 2017. Accessed from: https://www.linkedin.com/pulse/site-identification-standing-out-investing-quality-martin-mph

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- Providing more nuanced opportunities for the study coordinator to communicate site capability
- Allowing adequate time to complete the feasibility process
- Providing feedback even when the site is not selected

Training

Study coordinators are information athletes. They are asked to cope with a marathon level of information, at the same time as they are running other marathons on other studies. Effectively providing them with startup training and continued access to ongoing instruction is vital to their success. Study coordinators report that training is difficult for them to access, their available time is often spent on repeat training, and the training they need is sometimes directed toward the principal investigator.

Often, coordinator training appears to be an afterthought. For example, CRA visit metrics are commonly based on the amount of data to be reviewed, an approach that disregards the visit time that is devoted to providing the study coordinator with ongoing training. Likewise, study payments are based on patient procedures and may not account for the continued training requirements for the study. If the coordinator is required to learn the material in a secondary language, this likely takes even more time.

This payment shortfall prevents site management from allocating study coordinator time to training. Thus, study coordinators find themselves not having access to the training they need either because it isn't there or because their own site management has not given them the time to access what is available.

The issue of repeat training falls into this same bind. While improvements have been made, study coordinators still find themselves required to complete repeat training that does not improve their ability to perform their tasks. Most sponsors now accept standardized, subject-protections training as sufficient, which dramatically reduces the requirement for duplicate training across protocols. Some vendors also maintain central training files so that coordinators do not have to repeat training.

Despite these improvements, in many cases training has to be repeated even when the same vendor is being used with the same sponsor. Sometimes this training is required of the principal investigator and not the study coordinator, even though it is the study coordinator using the vendor's product. Other procedure-specific personnel involved with the study are generally left out of the training plan completely, even though they are most in need of specific task-related training.

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For example, studies rarely offer a limited training to site phlebotomists on sample labeling or other procedures specific to their role on the study.

Study coordinators noted that the training for a study isn't organized into a systematic process for all of the needs of the study. Rarely do sponsors provide a checklist of the training to be completed, and the training items don't necessarily map to the schedule of events in the protocol. Slide decks may have been pulled from other projects without being customized for the current study. When coordinators have questions about the training, it may take some time to get answers.

Creating a coherent training plan for the entire study would require study management to come together and become aware of what the study coordinators are being asked to do and how that maps to the protocol schedule of events. This would increase communication within the sponsor and CRO and provide an opportunity to improve operations for the entire study.

Study coordinators noted that in-person investigator meetings are often their opportunity for focused training time; however, these meetings are sometimes oriented toward scientific updates for the investigators rather than providing practical information for the study coordinators. Study coordinators point out that thought leader presentations don't necessarily meet their training goals at an investigator meeting. Also, protocols are becoming more complex, but the investigator meetings aren't becoming any longer to allow for the necessary additional training.

Nonetheless, the coordinators prefer the investigator meetings to pre-study visits in which CRAs provide training that would be more beneficial if delivered by vendor experts. Study coordinators noted that vendor demonstrations and practice opportunities are extremely valuable.

Every coordinator interviewed recommended tailoring investigators' meetings to the roles of the different participants. Meetings with breakout sessions were recommended so that study coordinators can focus on learning the tasks for their roles while investigators meet separately. Study coordinators suggested providing other opportunities for breakout sessions, such as, for example, when study coordinators are using a vendor product for the first time. Study coordinators from the same country may benefit from meeting together to discuss issues specific to their country.

To improve training, study coordinators recommend:

- Paying for training time
    - Including additional time for the CRA to provide training at monitoring visits
    - Allowing extra time for language issues
- Organizing all training for the study into a coherent package
- Providing training to the correct site personnel
- Eliminating repeat training

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- Providing adequate training at the investigators' meeting
- Providing hands-on practice with vendor items

Communication

Study coordinators routinely struggle to find the right person to talk to. Simply having an accurate and current contact sheet — a document that could easily be posted and maintained on study portals — is a challenge.

And, having a person to contact is only half the battle. That person also needs to have the necessary training and an understanding of the unique value that sites provide. Adding to the challenge is the fact that the primary communication channels frequently need to be reinitiated through the course of a study due to high CRA turnover.

CRA turnover is a major burden on study coordinators — so much so that the coordinators interviewed were prepared to offer very specific human resources advice to sponsors and CROs to resolve the contributing problems. They observed that CRAs are overworked and that CRA payment models do not necessarily encourage long-term employment.

Study coordinators find that communication is improved when the sponsor or CRO dedicates personnel to specific tasks. Relying on startup specialists, for instance, is particularly helpful during the initial phase of trials when documents are moving quickly and a study coordinator may have a lot of questions. And, coordinators find value in having site communication specialists available throughout the study, since CRAs are often on the road and divided between multiple studies. Site specialists are focused on the study and are always accessible to provide the information sites need quickly when a patient is waiting. Even when site specialists are employed, the CRA needs to be involved in the communication so that study expectations are consistent.

The study coordinators interviewed who had worked with site specialists all held positive views of their roles. One coordinator reported an incident in which a CRA began to make unusual requests of staff. "Our team members were being accused of odd things," the study coordinator explained. "While other organizational models provide a clinical team lead or project manager to speak to, often you don't know that person well enough to easily discuss such a sensitive issue. But our site specialist was someone we knew really well. We were able to bring her into the situation and resolve the issue."

To improve communication across the study, coordinators recommend:

- Maintaining a current contact sheet for the study
- Providing well-trained personnel

- Reducing CRA turnover
- Engaging site communication specialists throughout the study

Budgets, Invoicing and Payments

Study coordinators noted that budgeting was another area that seemed rushed and unconnected. Fees that had been previously negotiated, even on another study in the same program, may have to be renegotiated for a new study. Because of the rush often experienced during the startup phase, the site may be asked to negotiate a budget without a final protocol or the ability to view the case report form (CRF). One study coordinator reported having a checklist of questions to ensure that the site understood how much work a study will entail. Yet, the site is rarely able to obtain answers to those questions in the time necessary to provide comments on the budget.

Study budgets usually do not cover the tasks required for patient recruitment. These funds have been shifted almost entirely into screen failure payments—in other words for visit procedures that were actually performed. Study coordinators noted that when patient recruitment budgets are included, it has the added benefit of requiring the sponsor and CRO to work through the patient recruitment expectations for the study. “Patient recruitment is very different for every study,” explained one study coordinator. “When patient recruitment is part of the budget, the sponsor has to work out how patient recruitment will work for this study and how much study coordinator time these tasks require.”

Patient visit budgets rarely account for the entire scope of the visit. A visit is not simply a collection of procedures, but a process of care to both the patient and the study outcomes. Both regularly require more time than is reflected in the budget. Both also sometimes require unexpected small expenses, yet there is rarely a procedure outlined in the contract for invoicing for these additional items.

Because protocol amendments are common, budget amendments are common. These budget amendments are often rushed, and the contract specialist working on them may have little familiarity with the study. Study coordinators report receiving budget amendments that don’t match the protocol amendment or that just don’t make sense. “I’m not sure sponsors and CROs pay a lot of attention to budget amendments,” said a coordinator. “I’ve received amendments for procedures that aren’t even in the study. When I tried to explain this to the contract specialist, she had never seen the protocol.” Study coordinators recommend treating the budget amendment process as seriously as the original contract.

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Just as in every other area of study coordinator work, communication regarding invoicing is challenging. Billing personnel change, and the new communication information is not provided to the site. Payments that arrive months later and are incorrect eat up coordinator time in reconciling the disbursements.

To improve issues regarding budgets and payments, study coordinators recommend:

- Have as much information as possible available at the time the budget is negotiated
- Provide a project specific budget for patient recruitment
- Include a budget line for patient visit management
- Provide contract language and clear instruction on invoicing procedures for ad hoc expenses
- Provide accurate budget amendments
- Keep payments timely and accurate, in line with previous SCRS advocacy[2]

Document Management

Completing documents at startup and maintaining site files is a major study coordinator task, and so it is no surprise that efficiencies in document management are important to study coordinators. The clarity of document standards, document management systems, and the accuracy of documents received by the study coordinator have an outsized impact on how efficiently study coordinators are able to complete their tasks.

Clear communication of document standards and due dates makes the task of the study coordinator easier. Document standards are often developed ad hoc from department to department, resulting in diverse standards within the same study for items such as the data format. Study coordinators note that the process of creating standard documents for the study allows them to plan their workflow. It also surfaces — and perhaps allows them to resolve — discrepancies in standards. Where discrepancies remain, such as from regulatory agency requirements, at least having a standards document from the beginning of the study will reduce the number of documents that have to be corrected.

Furthermore, as sponsors and CROs develop standards for study documents, they will be in a position to communicate more about standardizing documents across projects and across companies. The more that documents are standardized, right from the start in the feasibility process, the easier it will be to complete them correctly the first time. “I envision standardized documents including a ‘site CV,’” said an experienced study coordinator. “We shouldn’t have to

[2] SCRS. Site Payment. October 2016. Accessed from: http://myscrs.org/shop/site-payment-white-paper/

type in the exact same information over and over into a different format for every study. When it is a feasibility questionnaire we're completing, that's something we only recoup if we are selected for the study."

Document management systems, often called "portals," are frequently criticized for problems they introduce, such as the added number of passwords a study coordinator has to use. Despite these criticisms, the study coordinators interviewed were overwhelmingly positive about portals. Portals improve communication about documents. They go far in overcoming some of the issues created by personnel turnover, especially CRA turnover. And, they provide evidence of the difficulties study coordinators may have in receiving inaccurate documents.

Inaccurate documents (such as those that are out of date or that bear the wrong information) are high on the list of frustrations for study coordinators. Some documents may be required in a local language, and the study coordinator expects the study management to be aware of local laws and to remain in compliance. Instead, they find themselves requesting the required translated documents as well.

Coordinators are also frustrated when study documents arrive with incorrect site information merged into the document, or with no information, requiring the site to retype information into each document that was already provided. Most studies have a process where site information is collected early in the startup process specifically for the creation of these documents. Despite this information being provided, study coordinators find that some of the burden of document creation continues to fall back on them.

To improve document management issues, study coordinators recommend:

- Communicate document standards and due dates clearly
- Use an electronic document management system
- Format documents correctly, in line with local regulatory requirements
- Pre-populate site information within document templates, where available

Vendor Management

Vendors are not always ready for the study to start, and their delays cause sites to fall behind in enrollment from day one, despite their having done everything right. Study coordinators expressed frustration about completing the site initiation visit but being unable to proceed because the vendor materials aren't available. Emails with login information can take some time to arrive, and when they do, they may not clearly indicate which study they are for.

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“Really, the vendor should be ready to start the study well before site initiation,” explained a coordinator. “They need to be ready at the investigators’ meeting. When I return to the office from the investigators’ meeting, the materials I just practiced on should be available to me. I have a lot to remember, and if I don’t receive the materials for weeks or months, I just have to learn everything all over again.”

A vendor relationship manager (who may also serve as the site specialist) can be helpful. It is more efficient to coordinate vendors centrally than to leave every site to deal with vendor issues on their own. Study coordinators report having to resolve problems with vendors that they didn’t select and that don’t answer to them.

In a study program, the vendor relationship manager may oversee communication between those sites and vendors that are used across the entire program. The vendor relationship manager can log vendor issues, a practice that should help bring sites and study managers into alignment on vendor assessments. Sites are sometimes surprised when problematic vendors are selected for additional studies, only to find that study managers never became aware of the problems the sites were having with the vendor.

This issue reflects a fragmented approach to vendor management in the industry. When sponsors were asked who selects vendors, negotiates their contracts, and then manages them, survey responses returned a tic-tac-toe board of options. A quarter (24 percent) of sponsors reported that CROs “don’t do a good job managing third-party vendors,” meanwhile 14 percent reported not having enough staff to manage the third-party vendors themselves.[3] As the number of vendors per study grows, effective management of the vendors remains a difficulty for sponsors, CROs, and sites.

When it comes to vendor equipment, study coordinators are largely positive. If a vendor provides a tablet that patients can use to enter survey information so that the coordinator doesn’t have to type the CRF data from a paper form, no one is going to argue with that. However, when every study has a different tablet, some of which require dedicated printers to create paper records for the patient chart, the pile of devices becomes its own problem. It may seem like the devices don’t cost anything to have on site, but when an entire extra room is required to store study equipment, it actually results in a significant site expense.

Despite their difficulties with vendors, study coordinators do appreciate the services they provide. To improve vendor management, study coordinators recommend:

- Vendors be ready before the study starts (preferably at the investigators’ meeting)
- Vendors provide login information promptly

[3] Atlas L & Sobotka P. Third-party vendor management. Applied Clinical Trials. September 01, 2013. Accessed from: http://www.appliedclinicaltrialsonline.com/third-party-vendor-management

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- Vendors clearly mark their communication with the protocol identification
- Sponsors and CROs provide centralized coordination of vendor communication
- Sponsors consider the actual increased expense of the vendor product to the site

Data Management

Study coordinators see data as their final deliverable. Everything that they do at the site leads up to delivering quality data. However, a lot of obstacles are thrown in their way. Protocol amendments and data entry changes may make source documents and procedure checklists outdated. The CRF pages may not be available when visits start, and if they are available, they may be in the form of printed screen shots that do not include the drop-down options. CRAs don't have time to review queries with the study coordinator during their site visits, and data management systems may require the coordinator to flip through several screens to process a query, which may not work when Internet connections are slow.

Coordinators recommend doing more before the study starts to reduce changes after site initiation visits begin. They have the sense that protocols are rushed through to meet deadlines, requiring later amendments. In fact, sponsor organizations report that more than half of all protocol amendments are avoidable.[4] In addition, CRFs are released and queries loaded without a final review. Coordinators recommend including sites in that review process.

Fully documenting a data set to stand on its own sometimes results in unnecessary queries of coordinators, and they question the need for documentation to fall entirely on them. For example, one coordinator reported a query confirming that a time entry of "1105" meant "11:05." Of course, one way to avoid this query would have been to provide better data entry specifications. But in the absence of that, was it necessary for the study coordinator to complete this clarification?

When a query is meant to further document an explanation in the CRF rather than to correct a data entry error, other individuals such as the CRA are capable of documenting these explanations. In complex cases, the CRA has the added advantage of being able to communicate directly with the data management team to provide the documentation they seek.

To improve data management issues, study coordinators recommend:

- Avoiding protocol amendments

[4] Tufts Center for the Study of Drug Development. Protocol amendments improve elements of clinical trial feasibility, but at high economic and cycle time cost. January 14, 2016. Accessed from: http://csdd.tufts.edu/news/complete_story/pr_ir_jan_feb_2016

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- Providing complete CRF information before the study starts
- Allowing the CRA enough time to review queries on site
- Reducing documentation queries

Conclusion

Communication is clearly the primary concern of study coordinators. They're asked to do an enormous number of tasks that rotate through studies as they ramp up, continue through maintenance, and go through study lock and close out. Their work involves not just the sponsor and CRO but many vendors, and they need training and a continuous flow of current information in order to be successful.

Study coordinators feel communication failures within and between sponsors, CROs and their vendors acutely when they're unable to get the information needed to do the study. The study coordinator has a unique, firsthand perspective on the communication inefficiencies that can harm not only the site, but the sponsor and CRO.

The knowledge and expertise that study coordinators bring to the clinical research enterprise place them in a key role in quality management. The path to good data quality begins with the best protocol design and the best feasibility process.

While these issues can be seen broadly across the study, they also impact specific technical aspects of the protocol. The multiple products, vendors, and systems with which a study coordinator must engage in each study indicate that the drive to create efficiencies with these products is simultaneously creating inefficiency. This inefficiency is most clearly seen by the study coordinator who has to attempt to bring all of these systems into a coherent deliverable.

"The study coordinator has a unique, firsthand perspective on the communication inefficiencies that can harm not only the site, but the sponsor and CRO."

The difficulties in communication present a risk to study quality as well as to the patient, as study coordinators are pulled from their patient focus to deal with other issues. Improving communication pathways by implementing the recommendations of study coordinators will help the return their focus to their primary role of caring for the patient and delivering quality data.

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This improvement will also ensure greater efficiency within the sponsor and CRO, ultimately improving the quality and productivity of the entire clinical research project.

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