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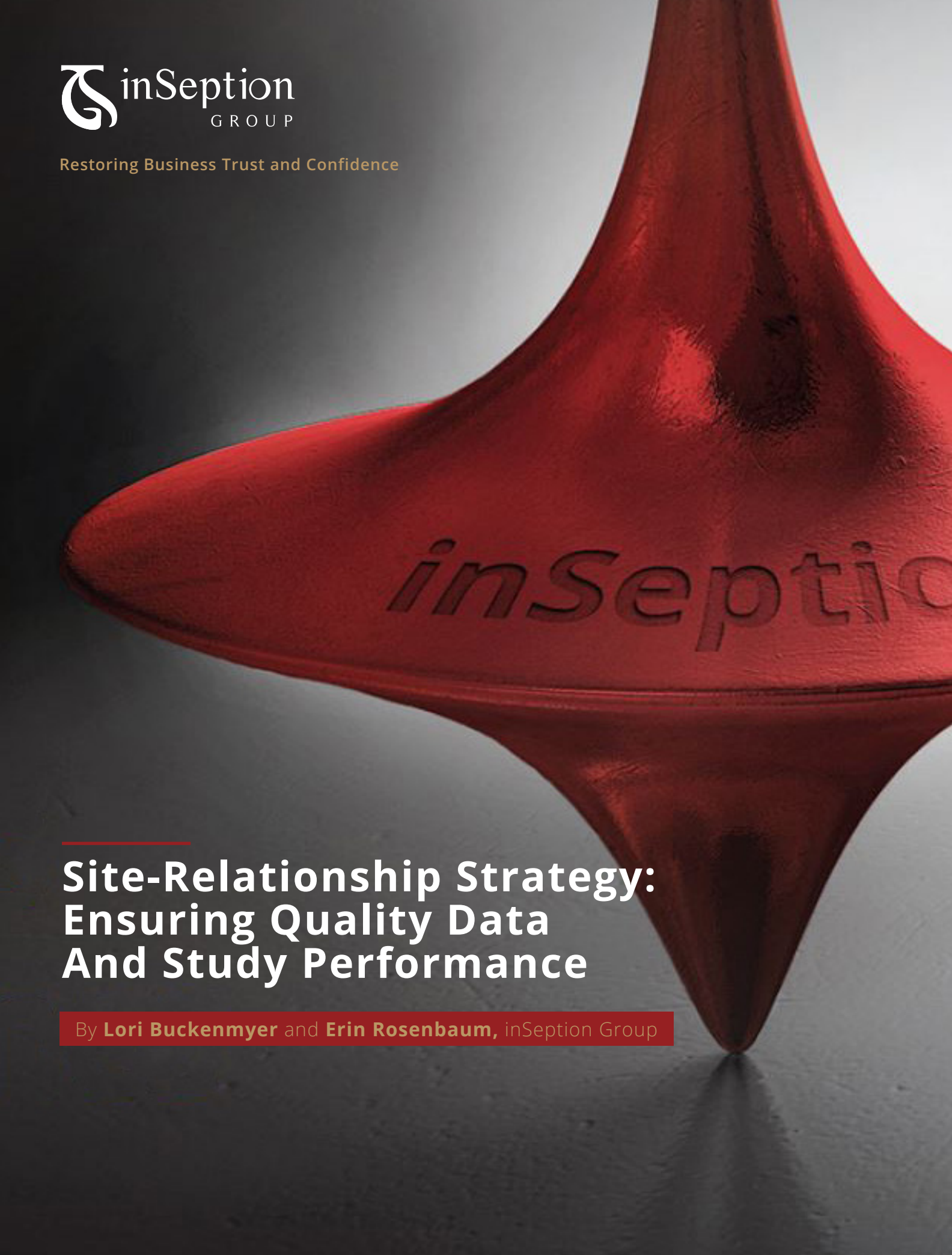

Site-Relationship Strategy: Ensuring Quality Data And Study Performance

By **Lori Buckenmyer** and **Erin Rosenbaum,** inSeption Group

Effective site monitors drive the open communication, information-sharing, and mutual understanding of the other party's challenges conducive to fruitful site relationships.

Site-Relationship Strategy: Ensuring Quality Data And Study Performance

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Strong relationships between a sponsor's CRO and its clinical sites are instrumental to study success by any metric: ensuring patient safety and privacy, meeting ambitious timelines, assembling thorough documentation packages, along with others. The lynchpin of such productive relationships is the CRO personnel assigned to manage and monitor sites — called CRAs or monitors, but referred to at inSeption Group as Regional Site Managers (RSMs).

Clinical sites generally expect a monitor/CRA to act as the study conductor, working with them to ensure high-quality data capture and the completion of relevant documentation. inSeption strives to go above and beyond in this role, wherein clinical sites can rely on their RSMs to shoulder a multitude of responsibilities, empowering each site to concentrate on treating patients. Critically, engaging an adept RSM before study start-up allows sponsors to reap maximum benefit from that individual's expertise and effort.

SITE EVALUATION AND START-UP

Involvement in the site evaluation process gives a RSM a more holistic understanding of each site they monitor. An accurate picture of the site's situation and operation is vital if a RSM is to work closely with, and be accountable for, a site through the life of a study.

Many CROs utilize a separate internal feasibility team and/or study start-up team, which works with the site until it secures Institutional Review Board (IRB) approval to conduct the study, then

hands management of the site to the monitor. Monitors who enter at this point, after a site has been approved, rely heavily on information drawn from feasibility reports and other documentation to determine tasks the site may or may not be capable of doing.

Conversely, at inSeption, a RSM who is part of the site evaluation process has greater insight into details unlikely to be captured in a database or a spreadsheet. inSeption RSMs are able to dive into the processes, procedures, and resources behind the responses captured by typical feasibility questions (research staff experience, facility capabilities, presence of in-house storage or labs, number of patients the site can treat and/or recruit, etc.). Each answer gets "the tires kicked and hood lifted" by the RSM to ensure that the site truly understands its responsibilities, the patient population, the sponsor expectations, and their capability to put it into practice during the study conduct. This context is difficult to glean from a questionnaire.

The site's ability to identify its strengths and shortcomings, and to accurately answer these questions, varies based on its experience. Sites also may embellish their capabilities to be chosen to participate in studies, whether deliberately or inadvertently. Consider remote monitoring as an example. Many sites had no knowledge, pre-COVID-19, of the time required to meet remote monitoring expectations through redacting information, posting information, and transferring files to a secure location accessible by monitors when they are not on-site.

Whether a site has lots of experience in clinical trials or very little, collaboration with a RSM during the selection process will provide transparency within site responses and sponsor expectations. If the site is struggling to provide answers or provides an answer that does not seem feasible (based on the site's resources or personnel), the issue can be caught and addressed prior to study implementation, rather than corrected through remediation later. The RSM's presence prior to initiation eliminates the transition from study start-up teams to a CRA or a monitor.

SITE PROCEDURES AND DOCUMENTATION

Sites that do not have a relationship with a monitor often have difficulty identifying where the RSM can contribute and its benefit. For example, sites can become overwhelmed in assembling and submitting regulatory documents (e.g., Form FDA 1572). RSMs can complete many of these documents on the sites' behalf so the sites only has to review and sign off on them, removing a significant portion of that burden.

This is not an area where monitors traditionally are utilized, because they usually are assigned to a site well after site start-up or the site simply does not think to involve its monitor in the task. Assisting a site in the creation of site-specific informed consent or site-specific source documentation is another duty in which inSeption RSMs actively participate.

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In terms of site SOPs and investigational product (IP), consider cell & gene therapies: most of the time, patient or donor material is used to produce the outcome (the IP). Its basis is taken from the patient, processed, and reintroduced to the patient — a process that requires tracking every touch point and step along the way. The same is true of tracking laboratory samples. Sites that conduct research frequently have SOPs in place designating who handles certain materials or tasks, as well as the required credentials and certifications. Sites newer to research may not understand the expectation for established procedures. In such scenarios, RSMs can help with SOPs, establishing a process chain and identifying people who might be able to complete certain steps.

VENDORS AND LABS: COMMUNICATION AND ISSUE RESOLUTION

Sites work with numerous vendors over the course of a study; some may include EDC providers, central laboratories, and supply chain partners. If management of those vendors is not centralized, the site must maintain communications and be ready to intervene, if issues arise, with a multitude of contacts. inSeption RSMs act as a liaison for sites' vendor management.

For example, if the site is having difficulty getting an image to a centralized imaging vendor, the RSM can guide the site through the process to facilitate a resolution and prevent future issues. In many similar instances, the RSM manages vendor communications directly, so the site can rely on one person to procure those answers and solutions.

RSMs also can assist with lab sample tracking and timing (i.e., critical sample time points). An RSM who is provided direct access to all samples going to the lab can examine lab reports and inform the site of upcoming milestones or missing samples immediately. This proactive approach helps to reduce errors and improve data quality. At some sites, the RSM has daily contact with investigators, ensuring patient visits are running smoothly, data is entered as soon as possible after a visit, and that data is promptly reviewed. Some RSMs even work with sites to assist in data entry requirements and expectations, over the phone or video conference, to avoid queries.

Also, while it usually is not necessary, RSMs can assist with query response. For example, the response or data entry update requested by a manual or automatic query may confuse the site. The RSM can help expedite query closure by essentially translating the query and its requested data entry update for the site.

A "ONE-STOP SHOP" FOR SITE RELATIONSHIP MANAGEMENT

RSMs earn their moniker by helping to properly manage all aspects of a site's study implementation within their capability. From the start of a study, they collaborate with the site, supporting site coordinators and investigators to focus on the patient and study implementation. The strategy pays immediate dividends by eliminating miscommunication and omission of information between study start-up teams and site monitors.

Proper site management also eases day-to-day monitoring because data review is optimized; the RSM has helped establish efficient ways to collect data and shares or removes administrative burdens. RSMs even can help sponsors and sites to prioritize work requirements when conflicting deliverables exist. Most sites with whom inSeption works participate in multiple studies. ISG does not always monitor all those studies but, when they do, the RSM can work with the site to outline when specific deliverables are due. For

example, if one study has a database lock next month, versus another study having a database lock three months from now, the RSM can help the site prioritize based on those timelines.

"HOORAY, THE MONITOR IS HERE!"

The goal of inSeption is to foster a relationship where sites look forward to a monitor's insight and assistance, versus a reaction of, "uh-oh, the monitor is coming tomorrow." Helping organizations to change that mindset, building a familial relationship versus a transactional one, is a process rooted in kindness, flexibility, and understanding. For example, inSeption has RSMs who work on the weekends or at night to meet study timelines by accommodating the schedules of the study coordinator and investigator. If the site is busy with clinic and/or research visits during the day, then visit data and query resolution may be required during evenings. Additionally, an investigator may be on rounds three weeks out of the month, requiring the RSM to coordinate visits around this schedule.

inSeption RSMs understand these hurdles as a result of initial involvement with sites. They have developed relationships with the site coordinator, the investigator, and understand the patient population, so every monitoring visit is not simply a source-to-data comparison, but includes a holistic review of the study visits. Equally important, inSeption hires RSMs with expertise in the specific therapeutic areas being researched. This grants RSMs with knowledge and understanding of the nuances of implementing these studies. The sponsor may also benefit from the RSM's suggestion of sites not originally considered for a study.

Successful oversight and monitoring of a study involves managing expectations, setting milestones, and making sure monitors have enough time with each site. Historically, monitors have had responsibility for up to 10 or even 20 sites. A monitor cannot effectively manage an individual site's study implementation when they are responsible for such a high volume of sites. The monitor's time becomes limited while on-site, which restricts their ability to support the site with data quality improvements or SOP implementation. Effective site management (not just monitoring), particularly in the relatively complicated indications in which inSeption operates, requires that RSMs have ample time to spend with each site.

> **A monitor who cares about the site's success and invests in a relationship allows them to identify errors, and then helps them to develop processes and procedures to avoid them in the future.**

The flexibility to accommodate site coordinators' and investigators' hectic schedules, as well as emergencies that may arise, stems from the fact that inSeption RSMs generally monitor and manage four to six sites. A site is better served with a monitor who works with them as a team and is invested in the site's success, rather than a monitor who simply carries out their required on-site tasks but does not help to facilitate site success.

Sites want to do the right thing by generating high-quality data while protecting the safety of research subjects. They want to help patients by contributing to an unmet need. A monitor who cares about the site's success and invests in a

relationship allows them to identify errors, and then helps them to develop processes and procedures to avoid them in the future. This proactive process can cut weeks, if not months, from the study timeline (e.g., by completing documents for a site, rather than relying on a site to complete those docs and return them to the CRO, or addressing queries in real time, versus waiting for the next monitoring visit).

To learn more about RSMs and end-to-end site monitoring, visit www.inseptiongroup.com.

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ABOUT InSEPTION GROUP

Unified in our passion to bring therapies and an improved quality of life to patients around the world, we will only provide solutions that increase speed and efficiency in making available life-changing treatments to the patients we serve.

We build the foundation for success by assembling an elite team for every client, every time. Every team member has a mutual passion and an insatiable desire to share in offering hope and making a difference for the patients we serve during their fight for a better, longer life.

We believe that only teams of functional experts, who share personal attributes of excellence and grit, can deliver transparency, precision, and certainty to an industry that is rife with complexity and disappointment.

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