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Why the Regional Site Manager

Is the Swiss Army Knife of Clinical Trial Monitoring

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By inSeption Group

Efficiency and accuracy are fundamental tenets of clinical trials. So why do most clinical trial teams handle key tasks like a game of “telephone”? In this game, a phrase is passed from person to person and the message often becomes unintelligible by the time it reaches the last person. Similarly, when critical information and context pass through numerous people throughout a trial, each handoff lessens efficiency and risks jeopardizing the accuracy of data and communication.

inSeption Group’s Regional Site Manager (RSM) model eliminates these risks by leveraging efficient, start-to-finish clinical trial site management by a single expert point of contact. This experienced individual’s oversight ensures seamless communication, promotes data accuracy and integrity, and drives proactive problem-solving—streamlining processes that traditional siloed roles often complicate.

Jack Of All Trades, Master Of All Trades

An RSM provides the convenience of a single contact point, intimately familiar with each clinical trial site and its resources/challenges. Typically, an RSM fulfills the following duties for a clinical trial site:

Feasibility/Site Selection Associate/ Study Within a Trial (SWAT) CRA

A range of factors can impact a research site's ability to succeed in conducting a clinical study. Assessing each possible site and selecting those with the necessary capabilities and readiness to participate in a study is an essential role of an RSM in the early stages of clinical trial planning. For each potential research site, the RSM completes a feasibility questionnaire in collaboration with on-site personnel.

The clinical trial sponsor then reviews and responds with approval (or not) for the site's ability to move forward in the process. If a site is approved, the RSM schedules and conducts a site qualification visit (SQV), then subsequently completes an SQV report, providing any additional commentary they believe will aid in the sponsor's decision. The sponsor uses this documentation to guide its final approval decision.

The SQV is usually the RSM's first face-to-face meeting with site staff and thus the first step of the team-building process—a major differentiator from the traditional CRA process. Consider that, after completion of site SQVs, many CRAs report that site staff are disappointed and frustrated to learn the CRA will not remain the site's assigned monitor throughout the trial. In the RSM model, the SQV is the beginning of the site/monitor relationship, not the end.

Site Startup (SSU) Specialist/ Site Activation

During SSU, an RSM provides the full regulatory package to each site, pre-filling documents as much as possible prior to sending. The RSM also assists in creating site-specific informed consent forms (ICFs) and ensures compliance with the ICF checklist, which helps protect the rights, safety, and well-being of all clinical trial participants — one of the RSM's most essential responsibilities.

An RSM also assists each site with vendor qualification and training, as well as coordinates with the site and ISG's contract department to facilitate completion of the budget/contract. The RSM's documentation duties include reviewing and completing the regulatory greenlight checklist/investigational product (IP) release checklist, per study requirements. The RSM's final site activation task often is scheduling and performing the site initiation visit (SIV), although sometimes the SIV is completed prior to greenlight approval and IP shipment.

Main Site Manager/ Clinical Trial Liaison

As main site manager, an RSM oversees each of their trial sites' daily operations, ensuring compliance with study protocols and regulatory requirements. The RSM acts as a liaison between clinical trial sites, investigators, and the central CRO while also fostering collaborative dialogue between site and study team/sponsor/CRO/study groups.

The RSM ensures data integrity and quality by monitoring site performance and conducting regular visits. They also provide training and support to site staff on study protocols and procedures and are responsible for investigation and resolution of any issues that arise during the conduct of the trial, including patient recruitment and retention challenges.

This problem resolution extends to corrective and preventive actions (CAPAs); RSMs partner with sites to create and execute a CAPA for identified chronic issues, especially those that affect the safety and well-being of patients. A typical CRA will often only review and provide feedback/check progress, rather than assist in development and actions toward resolution. RSMs help the site to identify the problem and gauge its risk, then work with site staff to investigate the issue and determine the root cause. As part of this process, RSMs document the CAPA analysis and the proposed road map to mitigation, which includes validating findings and creating a list of action items for the site to address. They also provide training or retraining to site staff before closing out each CAPA after it has been implemented.

Monitor/Main Site Source Data Verification (SDV) CRA

As part of their monitoring duties, RSMs perform SDV to ensure that data collected during the trial are accurate, complete, and verifiable (i.e., correspond to information reported in CRFs). The RSM queries any data discrepancies or missing information, ensures all discrepancies are resolved, and documents those resolutions, plus any follow-up actions.

The RSM also contributes to the development of the clinical monitoring plan (CMP), which lays a road map for the timing of visits—a critical factor that can significantly enhance accountability and patient retention in a trial. RSMs then provide further support by scheduling visits according to the CMP and proactively taking other study needs into account. During each visit, the RSM's annotated report is used as a guide to ensure they are capturing all relevant and requested information that can then be processed into a monitoring visit report. At each step, the RSM continues to build relationships with sites and participants, leading to greater focus and detail in visit reports and higher quality touchpoints throughout the process.

The RSM Role Rewards Initiative

An individual who understands activities across all major site elements provides study sponsors with a general sense of security built on a stable reference point. Justifying this confidence, ISG ensures RSMs are well supported and capable of exercising critical thought and initiative in all their duties. Due to the complexity of the trials—and our inSeption philosophy of establishing RSMs as a "one-stop shop" for full site management—RSMs are typically only assigned four to six sites on average; industry monitors are frequently assigned up to 20, leading to burnout, overutilization, and eventually, a higher incidence of disruptive turnover. Additionally, siloed roles or groups that can speak only to their part of the process are confined by the guardrails on their duties, stymied from contributing more meaningfully to the trial.

Often, companies hire new graduates into these siloed roles. Although their work is focused, they lack understanding of their colleagues' duties, particularly when they are just starting with the company. It is easy for accountability to falter as the baton is passed from person to person before it arrives at the site monitor around the time the study begins enrollment. Even then, most sites are not guaranteed a consistent monitor for extended periods of time. That monitor could be juggling a multitude of studies across several therapeutic areas at once, all in different phases.

Teach an RSM To Fish...

RSMs are unique to ISG, hired by virtue of their broad experience across medical and clinical trial roles — nurses, coordinators, CRAs, and more — as well as an inherent ability to quickly internalize information and then act on their own initiative. So, they understand challenges across the clinical trial not just in general but in terms of the specific burdens and challenges confronting specific roles. Site personnel appreciate that empathy and perspective.

RSMs receive mountains of information they are expected to understand, consider critically, and then quickly apply to tasks at hand. Accordingly, it is ISG's organizational responsibility to prepare RSMs to succeed in this gauntlet. We support RSMs by providing as much trial and site information as possible before assigning an RSM to a site, ensuring that even tasks with which they were formerly unfamiliar are well understood before they engage. In fact, ISG sets a high standard from the start by hiring RSMs with relevant indication experience, providing them with a strong foundation to build client-specific context—a philosophy consistent across every ISG department.

While site responsibility rests on the shoulders of each individual RSM, they are backed by a constant behind-the-scenes team effort. ISG works hard to collaborate daily and to keep open lines of communication with each RSM, helping them to be confident and effective. This dynamic also breeds an environment where, if a personal emergency or other major disruption pulls an RSM from duty, a fellow ISG team member can step in seamlessly to ensure the team, sites, and sponsor are not negatively impacted. We consider this continuity paramount to not only data integrity but also to the well-being of patients.

Because of the high expectations placed on RSMs and the high bar ISG sets for hiring into the role, larger CROs are unlikely to return to this single-champion model. For many CROs and the large-scale studies they oversee, specialized roles serve as a training ground for personnel; the startup group, SWAT teams, etc., serve as a focused means for their new hires to begin learning clinical development and eventually grow into monitoring roles. ISG will never be that training ground; we hire only senior monitors who have proven themselves across multiple trials and duties.

This philosophy aligns well with the smaller and midsize pharmaceutical companies and biotechs we serve. When they hire internally, they seek out people whose skillsets check multiple boxes, not teams of junior associates whose key value is cost savings. In fact, that model can be frustrating and disappointing for sites because, just as they begin to like and trust someone, such as the individual performing the SQV, that person hands them off to someone else.

Do As I Do...

Abraham Lincoln is credited with the statement, "Give me six hours to chop down a tree and I will spend the first four sharpening the axe." The takeaway is that successful execution of a task follows diligent preparation. This mindset embodies the RSM role. Every RSM is an integral, valuable part of our team, expected to be intimately involved in all clinical trial steps and to contribute their voice to solutions.

This expectation, combined with ISG's commitment to supporting our RSMs, leads directly to enhanced service for each clinical trial site. The RSM is an advocate for the site who helps to facilitate patient enrollment, site staff training, and timely source data entry. The RSM's deep expertise and constant presence throughout the study duration also drive efficient resolution of issues and queries. They are known and trusted by the principal investigator and site staff.

Clinical trial sponsors and sites have consistently praised the RSM model and its start-to-finish relationship. RSMs support each site and drive results in ways other monitors cannot match. To learn more about how to transform your clinical trial teams' culture and proficiency, visit https://inseptiongroup.com.

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About inSeption Group

inSeption Group is a full-service, global outsourcing organization built on a foundational culture of exceptional service and quality. This culture attracts a subset of people who take a personal responsibility to deliver on what has been promised. inSeption Group's ability to custom-build teams with these experts, while providing valuable continuity, distinguishes our approach from traditional outsourcing options. In the changing landscape of clinical research, inSeption is building a new kind of future—one where transparency cultivates trust, integrity outweighs self-interest, and people deliver on their promises.