

Acurian on...

Bolstering Clinical Trial Enrollment with Site Support Services – It's All about Relationships

Within the patient enrollment continuum, when a candidate for a clinical trial attends their First Office Visit (FOV, or consent visit), the study is explained to them in detail and they can ask any questions they want. If they decide to proceed further, the study coordinator or nurse will review the informed consent form with them and ask for their signature and permission to continue with screening.

For Acurian, the FOV is perhaps the most important inflection point in the enrollment process, as it is the biggest driver of enrollment cost and time. While primary responsibility for following through on the FOV falls to the assigned research site, we believe the Patient Recruitment Organization (PRO) still has a key supporting role to play. We can't just "walk away" at that point and say, "We've generated interest and pre-screened the respondents, so our work here is done." On an ongoing basis, the PRO should also provide sites with **people, processes, and technology** to support the enrollment and retention goals of the trial. We call this **Site Enrollment Optimization**, or SEO.





People Power

Because we have found that on average across all clinical trials, only 17% of referred patients get beyond the FOV, Acurian architects a variety of SEO services to improve that percentage. In our view, SEO has several goals:

- Building a lasting, focused relationship with each clinical research site. This starts with establishing direct contacts at the site, followed by regular in-person visits with site decision makers and stakeholders.
- Positively impacting the sites' FOV and consent rates, referral conversion (from candidate to randomized participant), and patient retention, all by encouraging development of site-patient relationships.

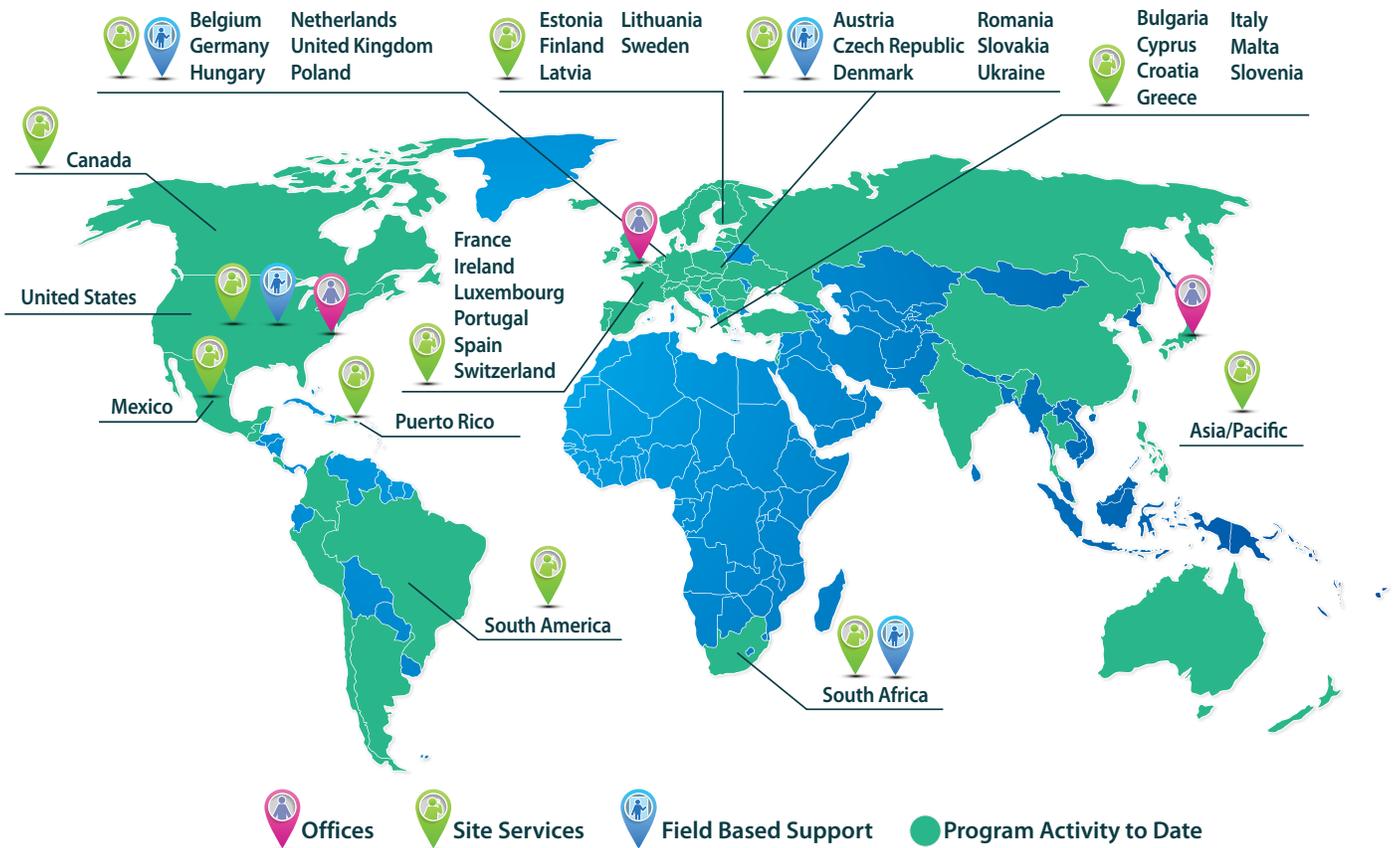
In support of these crucial relationships, a team of Acurian SEO specialists, including in-house Site Services Associates and field-based Site Strategy Consultants (SSC), constantly works to:

- Provide educational orientations and best practices to optimize conversion of pre-qualified referrals
- Reinforce the value of referrals to the sites and keep the trial "top of mind" for their staff (since the sites' understanding of the campaign and their role in it is critical to the success of the project)
- Set expectations, establish urgency and priority with the sites, and tactfully hold them accountable.



Operating under a regional model, the Acurian SEO program assigns a dedicated contact to each site to provide personalized attention and services. This geographical alignment allows the SEO specialist to build a 1:1 relationship with each research site, leading to improved long-term site performance and better site intelligence.

SSC and Global Site Support Capabilities

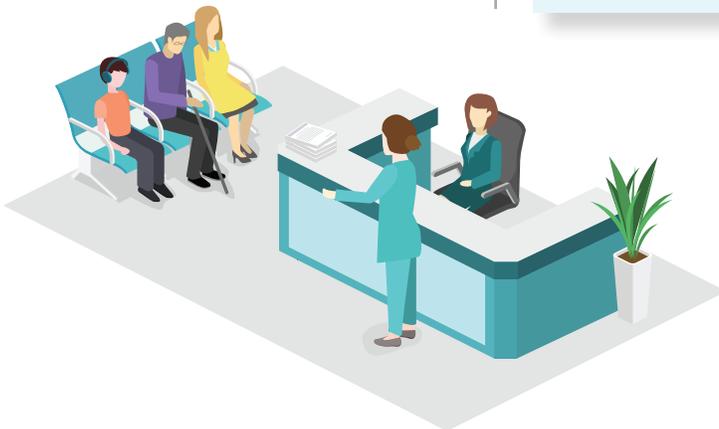




Processes Overview

A well-managed SEO program can influence the enrollment workflow with the sites in various ways:

- Modifying or influencing site behaviors and overcoming obstacles to make the process more efficient and productive (in terms of referral conversion)
- Gathering site intelligence (For example, a site may be misinterpreting the protocol or screening procedure. SEO specialists would quickly share that information with the project manager, who would communicate it to the sponsor or the study monitor.)
- Addressing issues directly or escalate them to the sponsor's clinical team; e.g.,
 - Site inability to screen
 - Site Good Clinical Practices concerns
 - Site unwillingness (to engage referrals, provide updates, or implement best practices)
- Providing referral load balancing (On a weekly basis, Acurian compares the volume of patient referrals versus the sites' ability to screen them, and adjusts the patient flow accordingly. This avoids overwhelming the sites, while also coordinating more resources around the best-performing ones to optimize the overall program.)
- Overseeing patient reimbursement, messaging and travel services
- Recommending sites for study selection (see next section)





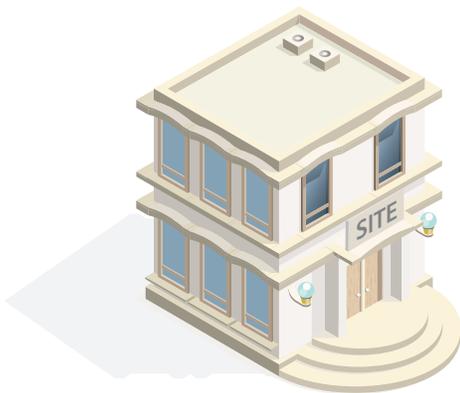
The ForSite Network

In addition to its field-based and in-house site support personnel, Acurian has developed an affiliated group of clinical research sites called the ForSite Network. These sites recognize the importance of enrollment performance as part of a successful research business, as well as the value of central enrollment support.

ForSite represents a business relationship between Acurian and the site that is independent from any individual sponsor trial. Currently, over 1,500 sites are members. These network members typically have a 30% higher FOV rate and a 16% higher referral-to-consent rate than non-ForSite members. (A network site's willingness and ability to process externally sourced referrals are essential to enroll at peak efficiency.)

Under a ForSite Network agreement, Acurian provides each site with fair market value reimbursements for staff training time, hosting visits for local Acurian representatives, providing timely updates on Acurian referral statuses and most significantly, FOV performance. There is no cost to the site, and no contractual obligation to achieve a certain FOV percentage. Sites that decline membership are still eligible to participate in the Acurian recruitment program.

The network is constantly growing through Acurian's own efforts and via project work with sponsors. We carefully monitor which sites in the network are top enrollers when supported by our recruitment services. Therefore, if a sponsor is still in the site selection phase, or wishes to augment its current site footprint, we can provide the sponsor with access to recommended ForSite Network sites as part of an existing contract.





Medical Records Retrieval

When prior documentation is required to screen an Acurian referral (a patient not known to the clinical practice), a medical records retrieval company contracted by Acurian obtains the patient's medical records and sends them directly to the research site. We coordinate with the vendor to make sure a signed, HIPAA-approved authorization form is received from the patient prior to retrieving the records.

Technology Backbone

Staying connected with sites around the globe requires advanced technology. Acurian Recruitment Manager® is a proprietary application we use to track referral processing performance at sites. By accessing this user-friendly portal a few minutes per week, sites can provide updates that allow the SEO specialists and project managers to have timely views of what's going on. Continuous improvement is supported without creating a burden on the sites.

A major pain point for sites is having multiple systems and logins for managing site-related data entry functions. Acurian works with the providers of Clinical Trial Management Systems (CTMS) to integrate the flow of our data to sites, while retrieving updates on the status of our referrals without requiring sites to enter the data via a separate system. We also employ a Customer Relationship Management (CRM) application to coordinate messages between site contacts and our field-based teams, to avoid bombarding the sites with too many communications.





Conclusion

Acurian's technology infrastructure facilitates the integration of site intelligence and real-time referral conversion performance to help optimize our recruitment campaigns. The systems support the balanced distribution of referrals within a local market to the sites demonstrating the capacity and performance history for successful conversions. Identifying a motivated pre-qualified candidate and connecting them to a site that has the ability to see them as quickly as possible provides a better experience for both the study patient and the site.

In instances where sites have the capacity to screen patients, but lack the resources to conduct secondary screening and scheduling, Acurian can leverage additional services to conduct these activities in partnership with the site. These add-on support tools (such as secondary referral screening by medical trained personnel, direct scheduling, and on-site staff support) can keep sites productively screening, regardless of resource limitations.

Acurian works with each clinical research site as if they are our customer, because relationships with the sites are critical to our business. Different sites have different needs, motivations, capabilities, and decision makers, so we tailor our SEO interactions accordingly to create mutually beneficial partnerships. And for our sponsor customers, Site Enrollment Optimization leads to greater efficiencies and better cost performance per patient.