Worldwide Clinical Trials

Guide

Effective Site Relationships: Creating a Successful Site Network for Oncology Clinical Trials

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Effective site relationships are essential for any clinical trial, amplified in oncology, characterized by nuanced study protocols and niche patient populations that warrant extra care in establishing and maintaining strong relationships with the right sites. While most CROs have site networks that facilitate rapid feasibility and pre-study site visit (PSSV) for efficient trial startup, partnering with a CRO with expertise explicitly suited to your needs is pertinent. The goal of an effective site network should be to optimize site strategy and ultimately relieve the time, effort, and financial pressure otherwise necessary to establish sites from scratch.

This guide explores crucial factors in creating a successful site network, focusing on the importance of clinical oncology trials and associated complexities.

Site Network Benefits

Site networks, independent clinical research centers that collaborate under a single entity, function as a team, and work with the right site networks can reduce site startup times, costs, and associated paperwork across all trial stages. The efficiencies allow the site, sponsor, and CRO to focus on what matters most: the patients and intervention. Oncology covers a wide range of indications and unique treatment modalities that are all associated with nuanced protocols for safe and effective production, storage, patient administration, monitoring, and reporting, including complicated IP handling (which could involve radioactive radioligand therapies), storage, and tight timelines for administration. Therefore, having a trusted support team at the site with whom you've previously worked and developed a relationship forms a unified delivery team with a shared mission. Beyond, engaging with a site network forms a web of centers, providing options to support any unique components of a novel therapeutic by engaging with associated sites optimized to a given trial's needs or particular patient focus.

Site networks bring trial access to a broader patient population, creating higher volumes of interested and qualified participants. Often, a therapeutic requires a specific patient population, or the population most affected by a diagnosis may be in distinct geographic pockets, making a site network highly valuable when optimized and intelligently employed.

Site networks typically benefit from efficient quality assurance due to the developed and clearly defined partnership, where all parties are aligned, making it easier to support high-quality operations fully.

Initiating the Conversation — Finding the Right Sites

> At a site-by-site level, a network provides more consistent trial exposure without requiring additional work from the site staff in securing new investigations.

A site network is only as strong as the sites that collectively encompass it, making site selection an essential component. When building a network, a strategic and balanced approach becomes imperative to finding the right sites for study purposes. For example, a large general hospital may not be ideal in some contexts, as multiple studies compete for attention. However, smaller sites may have less experience setting up complex oncology trials, which could result in bottlenecks that negatively impact trial activation. Attending meetings and conferences facilitates direct discussion and interactions with potential new sites, particularly if the site staff attending are interested in the clinical trial space. International conferences facilitate these interactions with sites across the world, including areas in Europe outside of the E.U., that may have quicker startup times, a better mix of subjects, and are more cost-efficient when used in addition to high-traffic sites in higher-traffic locations.

Curating the Right Site Blend

Ideally, a network would consist of leading centers in the respective oncology indication along with others that are smaller yet effective at patient recruitment and may be more engaged in the trial operations than a larger center running multiple large clinical trials. Realistically, many of the leading oncology centers globally are at capacity, making trial execution difficult, further supporting the role of a branched network approach. Depending on interest, a highly motivated yet relatively inexperienced site can also serve as a significant yet untapped resource for oncology trials, and following some minor additional front-end effort, one can turn a previously inexperienced site into an influential team member for current and ongoing trials. In addition, site management organization networks can facilitate patient search and recruitment efforts and should be considered an additional component of a successful site network.

Public vs. Private Sites

The public and private sectors are associated with different startup timelines, where the private sector is often much quicker to get running than the public sector. The timeline differences are partially because the private sector dedicates infrastructure focused on streamlining trial processes, adequate technology, and a strong financial incentive to keep the trial process moving. However, it becomes important to consider the cost-to-benefit ratio when looking at prospective sites, as it can be a lower financial burden when operating in the public sector.

Site Fit Determination

When determining if a site is a fit, ensure that the prospective site understands there will be a dedicated team working with the site staff to become a partner on their side and with their interests in mind. When mapping out the network, it is crucial to determine sites that may need more versus less oversight based on site-specific strengths, previous experiences, and overall capacity; tailoring the oversight engenders the partnership mentality and helps all sites feel met where they are while optimizing resource allocation. In discussing the potential to join a site alliance, guarantee that a site has adequate resources, not just investigators and study nurses but in the support departments that are essential for efficient study conduct — pharmacy, medical imaging, or nuclear medicine so that all parties understand they are supported and positioned for success. Ensure a clear discussion of the efficiencies associated with a partnership and how it creates a more straightforward pipeline of studies for which the site can bid and benefit from patient access to care and revenue perspective, compared with awaiting feasibility from a sponsor directly.

> Ideally, an effective CRO should curate a balanced array of sites to meet various study needs and ensure smooth operations.

Maintaining the Relationship – Key Aspects for a Successful Long-Term Partnership

Sites in an alliance enter an exclusive partnership instead of a transactional interaction. As such, it becomes vital to structure the interactions to foster this ongoing relationship. One important approach involves keeping the same dedicated CRAs at a working site for subsequent trials, which increases familiarity, trust, and efficiencies in working with the site on multiple studies over time; this essentially positions the CRAs as an extension of the site staff.

Some methods for maintaining a positive partnership include the following:

- **Establish feedback loops** to ensure clear communication across all members of the team.
- **Assign a relationship manager** who holds monthly or quarterly calls with feasibility and site management leaders to discuss current progress and upcoming plans.
- **Maintain consistent, clear, ongoing communication** about current and upcoming trials. Discussing upcoming trials can gauge site interest, depending on the study and each site's unique qualities, preferences, and staffing.
- **Develop clear and transparent protocols** and regular updates to improve compliance and reduce potential deviations.
- **Making regular recognition announcements for site efforts,** including performance reviews and public recognition in study newsletters, helps maintain motivation and builds camaraderie across the network.
- **Plan site visits beyond audits** to facilitate fully and proactively addressing and supporting site needs; this is bolstered by ensuring continued education and protocol check-ins.

Collectively, these actions can keep sites and staff happy, interested, and engaged, even between trials. Moreover, it prevents the perception of being ignored or forgotten and makes sites more likely to respond positively to future trial opportunities.

Increased Efficiencies Expedite Trial Timelines

The site network framework should ensure that sites receive all legal paperwork, contracts, and agreements at the outset, creating less paperwork during subsequent trials and increasing efficiencies from startup time to database lock. For example, establishing a general NDA, common contractual terminology, or a master services agreement eliminates the additional administrative wait time for processing agreements on a trial-by-trial basis, making it easy to get a site up and running as soon as a trial becomes available.

> A sound site network strategy should build rapport with the site and provide CRAs who are well-versed in oncology protocols, including complex IP handling procedures at partner sites.

When necessary, drafting new contracts or updates is more likely to be approved rapidly compared with an entirely novel site, sponsor, and CRO triad, where a lack of familiarity could delay discussing wording and details with additional back and forth before finalization. Moreover, previous experience fosters better predictions for upcoming study timelines, and a successful CRO should approach this relationship with a pre-determined plan to avoid delays and the trial on track. This level of detail is essential to prevent costly or harmful delays, especially in oncology trials, where treatments are highly complex, yet timing and accuracy are vital for patient quality of life and survival.

Ideally, the site network strategy includes a breadth of geographical coverage, spanning sites and studies under FDA and EMA regulatory monitoring, as well as sites in APAC and Australia, collectively networking global patient populations necessary for a wide array of cancer indications and ensuring diverse and representative patient data.

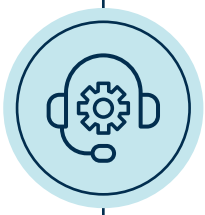
Streamlined study procedures reduce administrative burden, including the following:

Carefully structured contracts

Work with sites to develop agreements encompassing multiple study locations. Doing so fosters rapid progression into the site assessments and expedites the trial timeline.

Rapid feasibility assessments

Perform the assessments within days, not months. This lowers the barrier for sponsors and simultaneously reduces the site burden otherwise incurred from multiple PSSV and feasibility assessments.



Full technical support

Provide full support for all parties involved, including the sponsor and sites. This should include eDiary management for patient-reported outcomes, an integral component of any oncology therapeutic's pathway to market, aligning with FDA and EMA guidance, and better positioning the product for payer acceptance should the intervention go to market.

A collaborative approach becomes critical for problem-solving. Involving sites, sponsors, and the CRO in the decision-making process, recruitment and retention strategies, and adjustments to the protocol as the study progresses optimally positions any clinical trial for success. It helps to create patient retention plans that include resources such as access to transportation, digital follow-ups, and participant education materials, which historically keep enrollment and retention numbers higher.

When properly positioned, sound site relationships can significantly improve clinical oncology trials across all phases, improving efficiency and reducing trial operation costs, effectively bringing potentially life-saving therapeutics to those in need.

For an in-depth discussion about how you can leverage these techniques to improve your oncology trial operations and outcomes, contact us today.

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