Worldwide Clinical Trials

Guide

# Tactical Planning:
## A Guide for Tapping into Inexperienced Sites in Clinical Oncology Trials


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## Expanding Your Oncology Trial's Enrollment Potential

Large, experienced research centers within major healthcare systems traditionally participate in oncology trials. However, these centers often partake in multiple studies, leaving limited opportunities for running additional trials, leading to issues regarding available patients and site capacity. Furthermore, healthcare professionals at these institutions may be too occupied with existing responsibilities to engage with new clinical trial protocols and can struggle to meet their agreed enrolment rates. Alternatively, these sites may decide to take on new studies but struggle to meet the recruitment timelines or provide adequate attention and resourcing. Regardless, securing access to such experienced sites often depends on luck and timing, with ongoing competition for open space.

In contrast, less experienced sites, including smaller or community hospitals or trial naïve cancer centers globally, represent a relatively untapped opportunity. Granted, running an oncology study at inexperienced sites is associated with several challenges, including staffing, operational limitations (e.g., aseptic services, clinical trials staff, or pharmacy), and insufficient expertise in regulatory documentation or executing complex protocols. Regardless, inexperienced sites have associated benefits; despite being new to the clinical arena, untapped sites can generate higher patient interest and enrollment potential if the CRO and sponsors effectively handle site engagement, training, and setup. This guide provides important considerations for working with inexperienced sites in your upcoming clinical oncology study.

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# Find Hidden Gems Through Strategic Site Identification

Smaller hospitals or those in less prominent regions may not be easily identified or well-known in the clinical oncology research community. Still, they can offer great potential for enrollment, patient diversity, and overall trial success. Some solutions listed below facilitate better site detection.

## Effective Site Identification

### 1 Conferences & Networking

Conferences, such as the European Society for Medical Oncology or the American Society for Clinical Oncology, are excellent for networking and identifying prospective sites. Smaller regionally focused networking events or research days are also good places to meet clinical research staff participating in academic clinical research but wishing to venture into industry-sponsored clinical trials. A physical presence at these meetings, such as a booth, can often be a rallying point for clinicians seeking information about trial involvement. Thus, equip your sales teams to respond to such inquiries and ensure the teams know where to refer interested site staff internally.

### 2 Research Prospective Sites

Establish a list of potential investigators and sites interested in trials. Some of them may already have the necessary team and facilities from working in academic trials.

When selecting a CRO, consider those with an existing investigator database or site list serving as a bank of prospective and receptive sites. Cultivate strong relationships with the principal investigator (PI) and their team to foster loyalty and pave the way for studies. New sites are often eager to learn and adhere strictly to protocol timelines and data entry requirements, increasing their potential appeal. Plan what you and your CRO can offer these new sites regarding learning materials, guidance documents, and contact points to ensure they remain engaged and value the relationship.

### 3 Go Global

International searches outside the “usual suspect” countries will provide many possible sites with more diverse populations and can lead to broader agency acceptance of trial results. Do not discount larger hospitals in traditionally underrepresented countries, as a single hospital with an oncology center might provide access to a large proportion of the potential patients in the country, opening a considerable venue for competition-free enrollment. Sponsors may be able to expedite regulatory pathways due to lower volumes of research, and the costing and contracting processes may also be faster than those of more established research centers.

### Site identification avenues:

- Academic trial publications
- National working groups or expert panels
- Recommendations from existing PIs that are consistently well-performing
- Targeting geographical locations and then visiting hospital websites to gauge potential interest

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# Proactive Site Feasibility Assessments Reduce Risk

## Site Feasibility Takes Additional Attention to Detail

Evaluating the feasibility of naïve sites involves supplementary considerations, such as ensuring sufficient patient access, availability of necessary equipment, the engagement of other support services within the hospital, dedicated staff, and site willingness to dedicate the resources needed to support the trial (**Figure 1**).

Sites without the necessary equipment, staff, or a sufficient patient base for a specific study may be adequate for a different trial, making it essential to diversify site usage depending on the protocol and capabilities. Those without adequate equipment would incur substantial costs to provide the required equipment. However, it could be a relatively modest investment to provide a controlled refrigerator and freezer to a site and set them up for trial success, for example. While hospitals have pharmacies, those less familiar with clinical trials may need to increase pharmacy staffing, skills, storage, tracking, and security to the necessary level. Anticipating these challenges upfront via a simple check box document before feasibility fosters a smoother, more effective feasibility assessment and, if completed, facilitates a productive in-person selection visit.

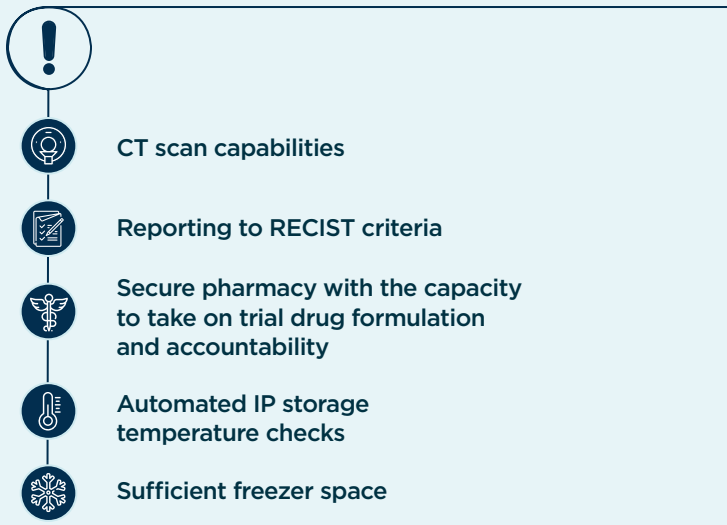



**Figure 1.** Necessary capabilities that an inexperienced site may lack.

## Upfront Attention Reduces Risk

- **In-depth feasibility visits:** A naïve site may require more pre-site and site monitoring visits than standard to confirm a sufficient patient pool, justify additional time and resources, and assess the site's pharmacy capabilities. Communicating and fostering access to appropriately trained staff, and positive relationships with the site encourages openness in their interactions with the CRO and the sponsor.

- **Regulatory documentation and training:** Naïve sites may require additional support in obtaining necessary certifications, such as CVs, ICH GCP training, and local research approvals. Ensure your CRO provides value for developing a relationship with the new site by facilitating training to the required standard and within a reasonable timeline. Ensuring the locations have a good understanding of their country's ethics and regulatory authority requirements and a good understanding of the role a site plays in that process is also critical.

- **The right trial for success:** Matching the proper study to maximize individual location's capabilities, patient population, and facilities will set the site up for a more successful experience. A Phase I study is a suboptimal starting point for a naïve site's research journey. A less complex Phase III study, where the drug's safety profile is better understood, the patient sampling requirements will be fewer, and the study design is more pragmatic, is a more suitable place to start. The naïve locations could also be a part of a cluster with many other sites, and under these conditions, they become more appealing to everyone because of the design's risk-spreading nature.

**With careful planning and proper execution, these challenges do not create substantial delays.**

# Take the Leap & Overcome Hesitation in Using Naïve Sites

## Resistance to Naïve Sites

When preparing for an oncology trial, naïve sites may elicit several concerns (**Figure 2**).

Without previous oncology commercial trial experience, sites may encounter difficulties establishing efficient patient enrollment in line with regulatory and protocol requirements. These difficulties result from many factors, including strict eligibility criteria, geographic limitations, referral issues, and trial complexity. Similarly, a naïve site may appear risky because data quality (ALCOA+ principles), data collection, and accurate recording may be unfamiliar to them initially. However, with careful planning and intelligent partnerships, working through these hurdles successfully with the sites is possible.

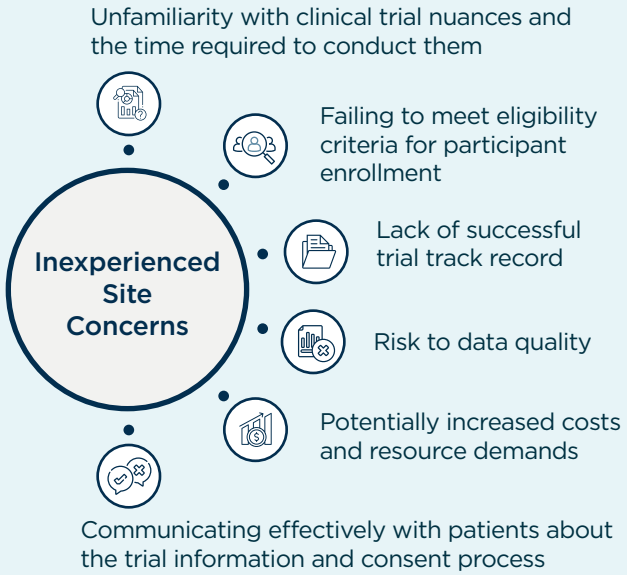



**Figure 2.** Common concerns around a naïve site.

## Partner with an Experienced CRO

### 1 Collaborate with an Experienced CRO

Select a CRO with a proven track record of selecting and working with naïve sites to ensure they can dedicate the time and resources for success. It is essential to understand operations in the given geographical region, including a deep comprehension of local and national ethics, regulatory expectations, and financial and legal requirements. The CRO is your primary resource for education; it must work closely with the site staff, highlighting the substantial requirements required for oncology trial conduct and how they can help the site gain essential knowledge and develop experience. A reliable CRO must demonstrate clear, open, and transparent communication, as they will be your trusted partner and lend confidence in rapidly anticipating and clearing challenges.

### 2 Promote Supportive CRA Engagement

Confirm that your CRO provides experienced clinical research associates (CRAs) to support site staff and ensure adequate education on adverse event reporting, recognition of dose-limiting toxicities, specific protocol requirements around inclusion and exclusion criteria, and electronic access to training modules. It helps to include learning outcome assessments to ensure competency at the beginning and throughout the trial. Finally, during the pre-study site visit, trialists must thoroughly check the previously received feasibility information to ensure the site has the required patients, infrastructure, and interest to justify participation in the study.

### 3 Draft an Adequate Clinical Monitoring Plan (CMP)

CMPs always require careful attention to detail, regardless of location, but clarity and exactness are even more essential when you factor in the participation of naive sites. For example, the CMP should plan for extra site visits during the trial. Along similar lines, plan to front-load CRA visits and include additional site and remote monitoring in the CMP to safeguard successful study completion.

# Steering Away from Staffing Pitfalls

## Staff Inexperience & Unique Protocols

Smaller naïve sites may lack the necessary team support for conducting clinical trials, which could hinder the study's progress. Even with ample staff, any naïve location is vulnerable to more staffing issues than an experienced site. Additional reviews and points of contact for proactive deficiency identification can help circumvent the friction points.

Oncology trials require specialized knowledge in cancer biology, treatment regimens, and patient management when trying a new therapeutic compared with standard patient care. Along with specialized expertise, inexperienced sites may yet to have engaged with regulatory bodies for commercial studies, adhering to all the requirements, particularly adequate documentation, is critical. Trialists will need to cover all these aspects during site training. Furthermore, oncology trials may require intricate dosing regimens and patient-specific assessments requiring substantial education to facilitate proper protocol compliance. It is often complicated to handle the investigational products (IP), which can have unique storage needs, specific compounding requirements, or patient delivery methods, underscoring comprehensive education.

### Potential staffing challenges associated with an inexperienced site:

- Depth of staff (e.g., sufficient to cover for sickness or holidays) or a lack of specialized expertise in clinical staff and support services, including pharmacy, medical imaging, and laboratory teams
- Complicated IP handling and dosing could require the use of a specialist or specific equipment
- Comprehensive training requirements
- Inadequate staff time
- Document management and storage — the importance of the investigator site file and its contents

## Plan for Proactive Education & Additional Attention

### 1 Engage Hospital Staff

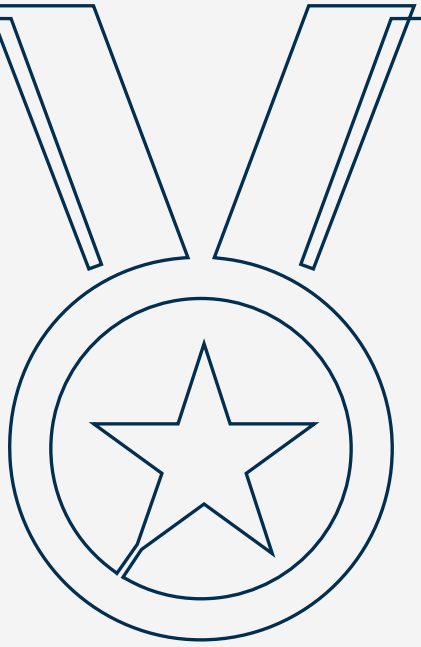
The site investigator must identify hospital staff interested in participating in clinical research who are qualified to form a successful team. These individuals are often motivated by the opportunity to elevate their professional knowledge and standing and contribute more actively to the study. Hospital staff with some experience and fewer ongoing trials may have more time to dedicate to the study. Consider creating a CRO-mediated forum for direct PI-to-PI interaction to allow experienced PIs and sites to exchange ideas with those less proficient.

## 2 Explain the Benefits to the Hospital & Patients

The sites may not initially understand the benefits of running a trial at their location, making it helpful to emphasize that both the PI and the patient will gain access to innovative treatments and information about novel medicines. Explaining that patients get more in-depth care while in a research study and the networking opportunities to share information with other staff running the trial in different centers across the world can further reduce hesitation.

## 3 Plan to educate

To make the most of the existing staff, prepare a comprehensive education plan covering relevant and manageable information; an experienced CRO can provide full support. It is advisable to transparently discuss the additional workload with the staff while ensuring they feel comfortable and capable of managing it. Failing to fully inform the staff might result in burnout and unexpectedly falling short-staffed mid-trial.



# A Little Challenge for a Big Reward

When properly scoped, planned, and implemented, conducting trials with naïve sites provides a new avenue to enroll patients into trials that otherwise could face enrollment challenges. Operating in conjunction with experienced sites, incorporating naïve locations could open opportunities to a proportion of the local cancer population, providing access to previously unavailable and potentially lifesaving care. Further, working with a new site creates a new network of professionals and support staff. Thus, taking a strategic, trusting, and collaborative approach with an experienced CRO to properly execute an oncology trial with inexperienced sites can open new pathways for success.

Contact us today to speak with experts about optimizing your subsequent oncology trial with an inexperienced or naïve site.



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