Why Choose a SITE NETWORK for Your Clinical Trials?

A Bioclinica White Paper

Background

Site selection can affect a study's timeline, budget and data quality. The need to choose sites again for each new study is often time-consuming and inefficient. Moreover, the increase in the number of clinical trials as well as the different exclusion and inclusion criteria across trials have created challenges for selecting sites that perform well. Global site networks can effectively address these concerns, by providing access to multiple experienced sites within a single network, providing cost savings through reduction of the total number of sites used and recruitment of a large volume of patients.

What is a site network?

A clinical investigative site network is a group of clinical sites that are represented under one entity and chosen using specific criteria. These criteria can vary by the type of network that they are involved in but can include qualifications that are suited to conducting clinical trials in a consistent, standardized manner that results in high-quality data. With a site network, you have access to many sites through one central entity, including one point of contact for all site-related communications and for site feasibility assessments over the entire duration of the trial and multiple sites. This provides a more unified, holistic, simplified and efficient approach while streamlining communications, allowing the team to focus their attention on more important areas such as patient care and data quality. Furthermore, negotiations, contracts, budget and providers can be managed once, rather than for each site. Site networks also have the capacity to fill a large majority, if not all, the trial's site requirements, depending on the therapeutic area and protocol.

Types of site networks

When selecting a site network for your clinical trials, it is important to recognize that not all site networks are the same. The available services within a site network can range from "broker" services, where different sites are contacted every time a new study is commenced, to full services, where the organization has control or ownership of the sites. The latter is key to ensuring that you consistently have access to qualified sites suited to your purpose.

Key Characteristics of Quality Sites

- Dedicated, contracted sites
- Specialized clinical research centers
- Standardized training program
- Dedicated patient file
- Standardized SOPs, work instructions and templates
- Dedicated quality control personnel
- Consistent QA/QC processes
- Operational management system
- Dedicated and customized patient recruitment and retention tools
- Broad clinical research experience
- Global services
- Experienced with electronic media
- Broad support network
- Feasibility assessments

When sites are contractually bound to do clinical research only within a specific site network, there are multiple benefits. First, depending on therapeutic breadth and specialist availability new sites do not need to be found for every study; the same network of sites, with a proven track record, is available for consideration for each new study. Therefore, the site network can invest in key opinion leaders (KOLs), research professionals, project managers and outbound patient marketing to engage additional therapeutic experts, providing clients with access to the best research and researchers possible. The extensive resources available from the network help ensure uninterrupted service throughout the entire trial.

Often, these dedicated sites in a full-service site network are specialized centers in clinical research, which represents 100% of the work being conducted. As a result, the staff are experts at clinical research and are allocated specifically to conducting research, rather than dividing their time between research and their daily clinical duties related only to patient care. Patient care remains a priority at site network sites, and they are often able to better engage with the patient/partner/caregiver owing to their understanding of specific patient needs during clinical research.

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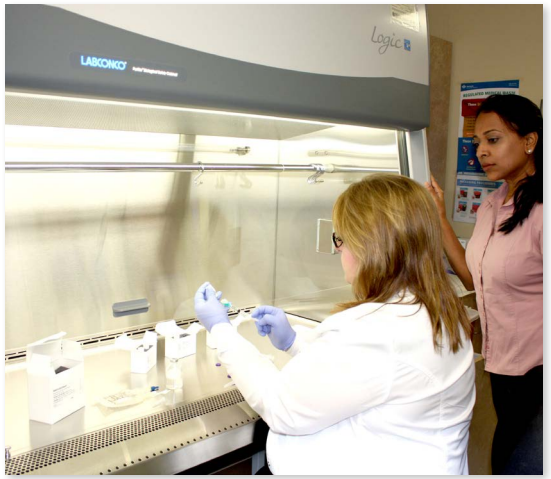
Additional characteristics of optimal site networks

Even within the available full-service site networks, there remain key differentiators. Understanding these can help with selecting the right fit for each study and realizing the inherent benefits of a site network: study completion with fewer sites, improved productivity, streamlined communication and cost savings.

With the increasing global nature of clinical trials, access to sites in other countries is likely to be of importance. The need for specific patient populations and the ability to follow the progress of a seasonal illness such as the flu is often only met by having access to investigative sites in a certain geographic location or on multiple continents. This is when it would be helpful to be able to tap into central global project management that has local regulatory knowledge, the ability to generate reports across all sites and resolve issues, when necessary. However, at the time of this whitepaper, the author is aware of only two site networks that provide global services.

Collecting data across multiple sites, even within the same country, introduces its own challenges for consistent and reliable data collection. To ensure data are collected in the same way at every site, a full-service site network would ideally have a standardized training program, in which all staff is trained to the same

high-quality standards for their position and GCP/ICH. For example, all lab technicians would handle samples and data with the required oversight and level of quality. Furthermore, site coordinators should receive extensive training, and the same dedicated patient file, specifically developed for clinical research, should be used across all sites—to reduce entry errors and missing data.



Data quality is also dependent on the quality systems and extent that SOPs, work instructions and templates are standardized across sites. Having dedicated quality control personnel within a site network facilitates QA/QC processes that are based on the same set of procedures across sites; established, vetted and monitored SOPs; and adherence to compliance standards. Ultimately, this enables thorough trial oversight and clean, high-quality data.

With an established operational management system, the site network optimizes daily flow in the clinics, especially given that the flow is dedicated solely to research-related activities. Study progress is continuously monitored and supported, with the ability to extract the relevant data across clinics and countries (if the site network supports global studies).

During the initial planning phase, site networks that provide feasibility assessments can evaluate the fit with the proposed study, current status of disease incidence and prevalence, competitive trials, past trial enrollment information, country (if provide global services), the study plan and intended sites. Centralized information gleaned from a large number of previous and active trials across multiple research sites is used for this evaluation; global site networks supplement this information with their knowledge of regulatory agencies around the globe. This wealth of information supplements the sponsor's knowledge of the indication and helps with decision-making, which is also aided by the site network's experience with and development of methods, study designs and strategies to overcome challenges or obstacles.

Moreover, dedicated and customized patient recruitment and retention tools help to reduce delays related to slower than expected recruitment and patient drop-out or non-compliance with the protocol. Some full-service site networks invest money and time for advertising and centralized patient recruitment assistance in the form of databases and online communities, from which potentially eligible patients can be contacted. Of particular use is the ability to leverage the data and analytics available in centralized databases to address the greatest needs for patients.

Combined with the sites' broad clinical research expertise, which translates across many therapeutic areas, access to extensive outpatient populations facilitates the building out of a new therapeutic area. This presents

exciting opportunities for quickly aligning with an emerging pipeline or market.

Beyond the services and products provided by site networks, the underlying relationships both internally and externally with key partners are critical to ensuring a stable and effective site network. As already discussed, managing communications and operations across a wide network is challenging and can easily break down. A site network that operates like a close-knit community is able to address issues immediately and effectively. In this community, site managers meet in person on a regular basis, to discuss various topics including patient recruitment ideas. Therefore, each site is not operating independently, but continuing to learn from and problem solve with others.

Because every organization and study have unique needs, it is important to find a site network that provides the required (and desired) resources. Being aware of these differentiating factors for site networks can help when evaluating and selecting the most appropriate network.

Summary

At the most basic level, site networks provide a single point of contact, streamlined communications and quicker site identification. However, more thorough and vetted global site networks a dedicated network of sites that use standardized processes and controls from study start to database lock, which can provide a significant contribution toward program success. Because each organization and study are different, evaluate your site network choices to make sure that you select one that will fit your specific needs.

Bioclinica Research Network

As an example of a global site network, the Bioclinica Research Network remains one of the longest standing site networks, operating for 25 years (since 1992) and supported by key relationships. Bioclinica has databases and online communities comprising >1,400,000 potential patients in a wide range of therapeutic areas, which helps to easily fulfill the site quota and quickly fill the patient population. Therapeutic expertise exists for Alzheimer's disease, mild cognitive impairment, asthma, cardiovascular disease, chronic constipation, chronic obstructive pulmonary disease (COPD), devices, dyslipidemia, endocrinology, hypertension, irritable bowel syndrome (IBS), insomnia, men's and women's health, migraine, osteoarthritis, osteoporosis, outpatient oncology, pain, restless legs, rheumatoid arthritis, smoking cessation, type II diabetes, vaccines and more. Over the last 5 years, more than 15,000 patients have been randomized, with a 93% average retention rate, ultimately saving clients time and money. With the experience of a wide site network to draw upon, the existing blueprint allows new sites to generate high-quality data from the beginning.

Learn more at bioclinica.com.