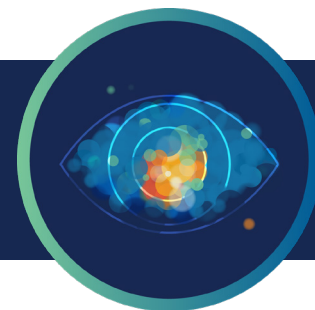


EXPERT INSIGHTS: BUILDING STRONG SITE RELATIONSHIPS - KEY TO SUCCESSFUL OPHTHALMOLOGY CLINICAL TRIALS



How do sites play a key role in ophthalmology research?

Sites play a pivotal role in clinical research, acting as the critical link between the Sponsor and the patients. They are responsible for identifying and enrolling eligible patients, administering the treatment, collecting study data, and most importantly retention of patients. The Sponsor and CRO rely on the site to follow the study protocol, minimizing protocol deviations to ensure high-quality data. Without sites having strong patient relationships and producing high-quality data, the studies cannot be successful.

Clinical trials offer patients access to new treatments that may not otherwise be available, and sites have the ability to identify patients that would benefit from a new drug or device. Sponsors and CROs depend on the sites to recruit patients who would be good candidates for the study, ensuring enrollment goals are met, patients are reliable, and timelines are maintained.

Additionally, sites are experts in standard of care and are integral in ensuring patient safety. Principal Investigators (PIs) treat the patients and have a strong understanding of the therapeutic burden. They know how patients are typically treated with the indication, providing an important perspective in the trial.

What challenges are sites facing in ophthalmology?

Oftentimes, clinical research exhibits trends in therapeutic indications, so sites frequently participate in multiple studies of the same disease. When competing studies are involved, one of the key challenges is patient recruitment. Investigators must carefully determine which patients are best suited for each protocol. Additionally, the limited patient pool for a particular indication can lead to enrollment shortages, further complicating recruitment efforts.

Patient retention also poses significant challenges for sites. In studies where patients are on a placebo or do not perceive immediate benefits, there is a risk of patients dropping out of the study. The occurrence of adverse events, depending on the investigational product (IP), can also impact patient retention. Long-term enrollment can be challenging in certain studies, especially for gene therapy studies where the patients are often dosed at the start of the study with 5 or more years of follow-up. Sites must navigate these complexities and leverage their relationship with their patients to keep patients engaged over a long period of time.

Rare disease ophthalmology trials present additional challenges for sites when identifying patients, due to the smaller patient population. Referrals may be limited in rare disease trials due to physicians being reluctant to refer patients to other sites for fear of losing connection with their patient. Long distance travel may be necessary to meet enrollment goals. Coordinating patient transportation can be logistically challenging, especially for patients with difficulty traveling to a different city, those with limited mobility, and individuals with varying sensory challenges. The wide diversity of patients in ophthalmology trials requires customized accommodations tailored to meet individualized needs.

Furthermore, certain studies demand specific machines and infrastructure for assessments that may not be routinely used in practice. Sites may lack the necessary equipment, leading to the need for additional equipment and specialized trained staff.

Finally, other common challenges for sites that must be addressed to conduct successful clinical trials include staffing limitations, inadequate resources, and the complexity of certain procedures, such as those in retinal gene therapy studies. These factors can reduce site capabilities and require careful management to ensure they do not impact the overall study.



What are key considerations when selecting sites for ophthalmology studies? How does partnering with high performing sites help accelerate clinical development in ophthalmology?

When selecting sites for ophthalmology studies, there are several key factors that must be considered to ensure success. These include a site's strong interest in the study, access to the appropriate patient population, availability of study required equipment, the ability to collaborate with vendors, and having well-trained site staff, including a dedicated Clinical Research Coordinator (CRC).

Sites that are familiar with the nuances of a protocol are more likely to execute the study efficiently, while helping accelerate enrollment. CROs and Sponsors can benefit from a site's patient database from previous studies in similar indications. Sites often have access to loyal patients that meet the inclusion criteria, allowing them to begin enrolling patients into the study immediately. Loyal patients are also comfortable with the site staff and more likely to remain engaged throughout the study. This pre-existing patient database expedites enrollment and improves retention, making the process more streamlined.

It is important to select a site based on the specific study. Choosing a site with relevant experience in the specific indication and a proven track record of success in executing similar trials is crucial. A site's experience will not only create efficiencies, but it will also enhance data quality, helping facilitate quicker data cleaning and analysis. While timely enrollment is important, maintaining data quality is paramount, and balancing these two factors is the key to success. Medpace has established relationships with a network of experienced sites and KOLs that are enthusiastic and are well-equipped to conduct ophthalmology studies seamlessly.

What are strategies Medpace uses to reduce site and patient burden?

Reducing site and patient burden is essential for increasing patient retention, enhancing data quality, and ultimately reducing trial costs while accelerating the path to approval. One effective strategy to minimize burden is to collaborate with the Sponsor to review the protocol and ensure assessments and study outcomes are carefully selected. This limits extraneous testing requiring unnecessary visits or prolonged stays, which reduces both patient/companion and site burden, making the patient more likely to enroll and remain engaged in the study.

Another approach to reduce site burden is partnering with experienced and efficient vendors. For instance, using a central reader that supports quick certification of sites, is responsive and timely in providing updates, and efficiently reviews data can reduce challenges for site. Timely communication from the vendors will limit site burden associated with follow up and will also allow the patients to meet study enrollment and visit timelines. Medpace has extensive knowledge of qualified vendors and central readers, making enrollment and patient oversight easier for sites.

Additionally, Medpace plays a vital role in supporting marketing and recruitment initiatives. Providing sites with high-quality, IRB approved patient materials and advertisements—such as brochures and social media ads—can help reduce recruitment timelines. These patient materials aid in engaging potential participants more efficiently and effectively.



Providing patient and companion travel support, including compensation for time and travel, is essential to ensure a patient can get to a site for a visit without financial strain. Making participants' experience as smooth as possible has proven to be critical for successful enrollment and retention. These visits offer patients high-quality care, often more frequently than they would in typical standard of care, and ideally at no cost to them. Medpace has extensive experience in the coordination of travel and accommodation of study participants in ophthalmology studies, which depending on the nature of the disease, could be coordination of travel for entire families. Medpace is able to support this internally or with a managed vendor.

Site burden can also be reduced by providing sites with the necessary equipment required for the study that they may not have onsite access to. Medpace's logistics department can assist with procuring equipment and ensure availability at sites in a timely manner.

Ultimately, reducing site and patient burden creates a better trial experience, leading to better patient recruitment and retention, better outcomes, and a more seamless trial.

Tell me a little bit about Medpace's site relationships and experience in ophthalmology clinical development.

Sponsors from emerging biotechs to global pharmaceutical companies have trusted Medpace for over 30 years to lead their clinical development. The Medpace ophthalmology team has a deep understanding of the complexity of managing clinical trials in a broad range of indications—including in rare diseases—and extensive experience in gene therapy research. As of April 2025, Medpace has experience conducting 80 ophthalmology studies at over 885 sites across 25 countries. Our experience and site database continues to grow as new studies are started up, supported by a global network of site connections across common and rare diseases. By leveraging ongoing feasibility work and drawing on our extensive experience and established site relationships from previous studies, we maintain a robust site database.

Our global, cross-functional teams are made up of ophthalmology-specialized clinical trial managers and project coordinators, in addition to in-house, board-certified ophthalmologists and gene therapy specialists. Our ophthalmology team has strong relationships with top performing sites and utilizes strong communication skills to ensure open, transparent lines of communication with Sponsors, sites, and vendors to drive forward project deliverables to meet timelines.

Medpace was a finalist for the 2024 SCRS Eagle Award, an award that honors one Sponsor and one CRO that exemplify a site-focused approach to clinical trial management and have demonstrated outstanding leadership, professionalism, integrity, passion, and dedication to advancing clinical research through strong site partnerships.

What advantages does Medpace offer Sponsors as a CRO partner?

A CRO partner should be an extension of the Sponsor's team and culture, with similar standards, values, and goals. Medpace offers strong communication strategies and teamwork, which foster a good working relationship with the Sponsor. Having access to people with experience that can share their knowledge and expertise, makes a trial run smoother. Further, Medpace is experienced in providing quality training and is able to support sites with study needs.

Not only is strong communication with a Sponsor important, but so is the timely communication with sites. Medpace sends out routine site emails with ongoing study updates and share best practices. Additionally, Medpace holds PI CRC teleconferences so that the information is provided proactively. This communication style ensures that all sites globally are provided with consistent study information and updates, which will maintain global continuity.

Maintaining efficient oversight and quality in the study with use of a full-service model is also important when considering a CRO. A full-service model includes contracting and management of vendors. Smaller pharmaceutical and biotech companies will benefit the most from having the oversight of one CRO.



As a global, full-service CRO, Medpace's dedicated teams serve as an extension of your team. We engage quickly and provide strategic thinking, ensuring start-up times are met, superior quality, and the most efficient delivery of every phase of your clinical trial. Our project teams are actively involved throughout the lifecycle of the project, and we build close relationships and provide a personal touch. Medpace's mission is to accelerate the development of safe and effective medical therapeutics. To accomplish this, we enable Sponsors to leverage the experience and expertise our study team brings to ophthalmology clinical research.

"Working with Medpace on ophthalmology studies has been a great experience. Their team brings deep expertise, strong operational support, and a collaborative approach that truly fosters trust and efficiency. The collaboration has been smooth and professional, with clear communication and a genuine understanding of site needs. Medpace stands out as a CRO that understands the unique demands of ophthalmic research and delivers with excellence."

- Gerhard Garhöfer, MD,
Associate Professor, Medical University of Vienna and Renowned Principal Investigator in the Field of Ophthalmology

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