



The CRO Guidebook

10 Partner Must-Haves for Your Next Ophthalmology Clinical Trial

Ophthalmic research means specialty research — it's imperative to get the right patients to the right study and treatment. That's why CROs, your Contract Research Organization, should not be standing in the way of success but pave the way for it.

Does the right CRO exist?

Biopharmas today are not feeling prioritized by their CROs. The results?

Delays in trial execution, inadequate cost controls, and a feeling that CROs lack the appropriate commitment to the programs they are supporting. Do you feel underserved in study design, project management and supply logistics, or that your partner lacks statistical experience and collaboration skills?

This document details a list of criteria you should consider when navigating through the CRO landscape to find a long-lasting, trusted advisor. Examine this guide and share it with your team to understand what matters most and how your next trial can run seamlessly with the right partner by your side.



Data Quality

Ensuring high-quality, effective data management is crucial in ophthalmology clinical trials, as it directly affects the integrity of research outcomes, including detailed reporting, precise patient monitoring, and accurate interpretation of imaging and biomarker data. Data management in ophthalmology trials involves handling complex datasets from advanced imaging modalities like OCT and FAF (Optical Coherence Tomography and Fundus Autofluorescence) and managing visual acuity assessments and other critical endpoints.

When selecting a CRO, it is important to evaluate how they define and capture key ophthalmic data points, such as retinal thickness measurements and changes in disease biomarkers, while maintaining rigorous standards for consistent monitoring. Additionally, inquire about the experience and expertise of the data management team, particularly in handling ophthalmology-specific data, and the specialized tools they employ to ensure accuracy and efficiency, like image analysis software and automated data capture systems tailored for ophthalmic research.



Proven Expertise

It has been estimated that only about 10% of ophthalmology drug candidates successfully make it from clinical trials to FDA approval¹, making the stakes for effective trial execution extremely high.

Review the log of real case studies, testimonials, referrals, and networking contacts in your niche ophthalmic disease area to build trust as you rely on a team of experts. Consequently, partnering with the right Contract Research Organization (CRO) is crucial.

"Emmes has conducted 250+ clinical trials in ophthalmology (including trials for the National Eye Institute and biopharma companies) and published over 100 journal publications, contributing significantly to advancing research in the space."

¹sources : <https://bmjopen.bmj.com/content/5/6/e007987>
<https://www.altris.ai/article/ai-for-ophthalmic-drug-development/>

Therapeutic Aligned Teams

A CRO's knowledge of the ophthalmic disease impacts the entire clinical trial strategy. Project managers, clinical research associates, and data managers with expert knowledge understand the agility needed as ocular diseases and conditions evolve over time, considering factors such as disease progression, patient response variability, and the impact of comorbidities like diabetes or hypertension. During clinical trials with multiple endpoints, strong data science experience guides analysis for protocol writing, study design, randomization, and reporting.

"We express our gratitude for Emmes' 'support, experience, accountability, and dedication' to our Ophthalmic program. In speaking of the project lead at Emmes, the client said, 'His work ethic and empathy has not gone unrecognized and is one of the major deciding factors in our continuing to expand services with Emmes.'"

Collaborative Partner

Your CRO is your partner. As you speak to potential CROs, ask yourself: Am I getting the appropriate attention in these preliminary conversations? Will I be working with the same dedicated team throughout the entirety of the trial and drug development program? How exactly will they become thought partners and provide established relationships, access to best-in-breed tools, and a scaled development engine for my trial?

Emmes' experience is your experience and our tools are your tools, which is why Emmes has a remarkable 98% client retention rate and an 8.8 out of 10 Net Promoter Score.

Technological Capabilities

Clinical trials evolve and generate large amounts of data. To ensure efficient study management, streamlined data collection, and analysis and reporting, cohesive technology is needed to manage complex processes. Examine the technology used by the CRO at hand for easy system integration, access to real-time data, and a single source of truth.

Emmes harnesses sister company Veridix AI's Advantage clinical platform which was developed by clinicians for clinicians as a one-stop-shop technology suite complete with apps for EDC, RTSM/IRT, ePRO, eCOA, specimen tracking, TeleVisit, automated reporting, and more.

Patient Focus

CROs develop relationships with resources in healthcare for site recommendations to recruit specific patient types. That's why clinical trial sponsors like yourself turn to CROs with a focus on quick access to trial sites with high enrollment potential. In your research, determine if the CRO has contact with investigators specializing in your study's disease as well as access to site and hospital networks with strong recruitment.

Over the past 40 years, Emmes has developed connections to the Ophthalmology community, totaling 26,000+ subjects enrolled and over 250 clinical trials in Ophthalmology.

Geographic Coverage

Territorial service coverage is vital in large-scale clinical trials involving unique scientific, logistical, and operational aspects of various countries. Speak to your potential CRO about their experience in international standards of care. Ask questions like, "Do you have access to trial sites in several countries? Are you up to date with the latest standards and regulations in every country targeted?"

Through involvement in large scale, multi-site projects, Emmes has formed invaluable global relationships with healthcare organizations and professionals, supporting trials across North America, Europe and Australia with additional site relationships in Asia.

Specialized Tools

When evaluating a CRO partner for your ophthalmology trial, prioritize those with specialized tools that leverage the latest technologies to streamline critical processes like visual acuity assessments, trial design, and data management. Look for a partner offering a unified, native cloud-based eClinical platform that integrates advanced data analytics, biostatistics, and AI-assisted trial designs. This approach ensures scalability, reduces operational complexities, and enhances real-time data access across teams, improving decision-making and trial outcomes.



Budget

Transparency is key to a trustworthy biotech/CRO relationship. It is highly recommended to pay keen attention to the main cost drivers in a clinical budget, including tasks, individuals working on each task, hours required, and how it is calculated. Discussing this breakdown at the outset can avoid unexpected fees and reduce the number of budget cycles.

Emmes provides transparency beyond data to its pricing model so you can see where every cost is coming from in detailed and task-based estimates (units, tasks, and hours for each aspect of the project).

Robust Cloud-Based Platform

Does the CRO use outdated or insufficient technology? Given the time sensitivity of clinical trials, receiving data updates from a project manager once a week is not ideal. Sponsors should seek a CRO partner that prioritizes transparency and facilitates access to relevant trial data while maintaining blinding. When feasible in a randomized, masked study, the CRO should provide appropriate aggregate data or summary metrics that support the sponsor's oversight without compromising the integrity of the trial. This could include self-service reporting, data visualizations, and patient profiles to make the best decisions on the go.

By utilizing Veridix AI's Advantage clinical data platform which is responsive and easy-to-use, Emmes is able to ensure site and patient compliance, real-time data "access" and centralized data integration.



Download this checklist and keep it in hand during your quest for the right CRO. Interested in learning more about how Emmes ticks the boxes for a CRO partnership built to last? Contact our experts at info@emmes.com or visit our website to learn more.

The CRO checklist

Quality

- Proven data quality
- Compliance with the FDA and other regulatory agencies
- An established Quality Management System
- An electronic clinical data platform that is user-friendly and accessible

Proof of expertise

- Case studies
- Project team's credentials in the therapeutic area
- Publications in leading journals
- Testimonials

Therapeutic alignment

- Experts with scientific knowledge in Ophthalmology
- Therapeutic expertise
- Study design expertise

Collaborative partner

- Low staff turnover
- Responsiveness
- Easy to work with
- Timely project communications

Technology capabilities

- Unique software that eliminates duplicate data entries and provides real-time data access
- Robust biostatistical capabilities
- Cloud-based clinical data platform



Geographic coverage

- Local market/regulatory knowledge
- 1400+ employees running operations in 90+ countries
- Access to international trial sites and patient populations



Patient Focus

- Experience in patient/volunteer recruitment (Phase 1)
- Speed of site start-up
- Experience in patient recruitment (Phase 2/3)



Specialized tools

- Latest techniques to deliver visual acuity at scale
- Assisted trial designs
- Unified native cloud based eClinical platform



Budget

- Transparency
- Detailed quote – by unit, tasks, and number of hours

Want to know how Emmes ticks the boxes of your criteria list?
Discover why 98% of those who choose us stick with us.

Contact our Ophthalmology Experts

For additional information on our ophthalmology expertise please contact our team of experts at info@emmes.com or visit www.emmes.com