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The CRO Guidebook

11 Partner Must-Haves for Your Next Clinical Trial

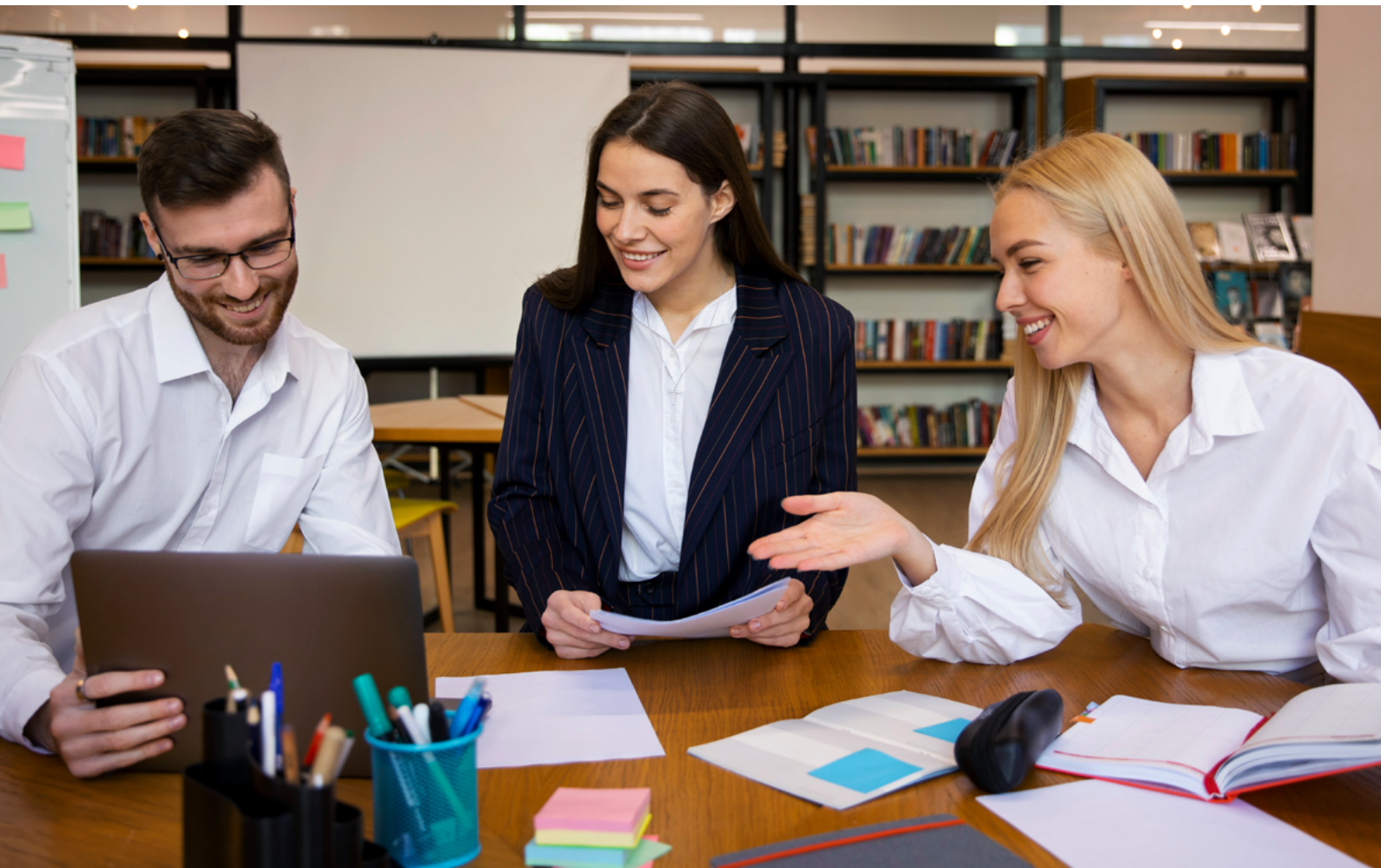
Checklist

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.



1. Data Quality

Ensuring high-quality, effective data management is a critical piece to every clinical trial as it impacts all aspects of the research process — reporting, patient enrollment and safety, specimen tracking, etc. When evaluating your next CRO, investigate how they define critical data points and maintain organization-wide standards for consistent monitoring. Get to know the experience of those involved with defining, collecting, and analyzing data, and what tools they use.

Alongside their established quality management system handling protocol development, eCRF design, eConsent development, statistical programming, and more, Emmes loops in a dedicated team of programmers, regulatory experts, and biostatisticians for data quality at every level.

2. Proof of Success

Only 1 in 4 drugs for infectious diseases are approved, so vetting a CRO for unique credentials specific to your molecule and drug development program is key. Review the log of real case studies, testimonials, referrals, and networking contacts in your niche infectious disease area to build trust as you rely on a team of experts.

Emmes conducted 650 clinical studies in infectious diseases (including trials for The National Institutes of Health and biopharma companies) and published 250 journal publications – half of these in high-impact journals.

3. Expertise

A CRO's knowledge of the infectious disease impacts the entire clinical trial strategy. Project managers, clinical research associates, and data managers with expert knowledge understand the agility needed as bacteria and viruses change throughout their lifespan, along with seasonality and location variations. And 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 Opthalmic program. In speaking of the project lead at Emmes, he 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.

4. Synergetic Collaboration

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.

5. Team Retention

High employee turnover = high team turnover. Continuous personnel changes can disrupt your trial and negatively affect service quality, along with the relationships between the CRO, the sponsor's team, and the clinical site staff. On the other hand, long-term CRO staff continuity improves and consolidates clinical trial management processes. It is wise to investigate how long experts on your potential team have been at the specific CRO.

Most Ophthalmology team members have been with Emmes for years, i.e., Traci Clemons, Ph.D. Chief Research Officer, who has worked at Emmes for over 24 years.

6. 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' Advantage clinical data platform was developed by clinicians for clinicians as a one-stop technology suite complete with apps for EDC, RTSM/IRT, ePRO, eCOA, specimen tracking, TeleVisit, automated reporting, and more.

7. Patient Recruitment

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.

8. 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 epidemics and rare tropical diseases, Emmes has formed invaluable relationships with healthcare organizations and professionals to support thousands of studies in over 90 countries across North and South America, Europe, Asia, and Africa.

9. End-to-End Services

Outsourcing to multiple third parties for one trial requires additional (and avoidable) vendor management efforts to ensure high-quality, timely services. Outsourcing to different CRO's for each study creates inconsistent strategies, reports, data, and communications. Look for a CRO with end-to-end solutions, including regulatory strategy, for an efficient, agile, and dependable partnership.

As a full-service CRO, the Emmes' consistent, proven project management process can help you from the earliest stages of planning to reporting, regulatory submissions, and publications.

10. 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).

11. 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. Your data belongs to you, so consider a CRO that won't hold it hostage and provides transparent access to all information collected, self-service reporting, data visualizations, and patient profiles to make the best decisions on the go.

> **The Emmes Advantage clinical data platform is a responsive, easy-to-use system ensuring 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 an expert or visit your personalized content hub for additional resources today.

The CRO checklist

Quality

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

Proof of success

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

Expertise

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

Synergetic collaboration

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

Team Retention

- ☑ Consistent experience team

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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
- Access to international trial sites and patient populations
- 2,150 Phase I, II, III, and IV clinical trials in 75+ countries

Patient recruitment

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

End-to-end services

- Full service
- Dedicated PM to follow the project

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 an Ophthalmology Expert