PHARPOINT RESEARCH

FACTBOOK

4 Keys to Successfully Supporting Ophthalmology Clinical Trials

JAN23-FINAL1

About PharPoint Research

PharPoint Research is an award-winning, client-focused CRO that has supported over 1,000 clinical trials. Our dedicated teams have extensive ophthalmology experience, and are equipped to proactively face the unique challenges that are common within ophthalmology trials.

OPHTHALMOLOGY INDICATIONS PHARPOINT & OUR STAFF HAVE EXPERIENCE WITHIN INCLUDE:

- Age-Related Macular Degeneration (AMD)
- Conjunctivitis
- Dry Eye Disease (DED)
- Thyroid-Related eye Disease
- Uveitis

1) Putting Yourself into the Patient's Shoes

As you plan your ophthalmology study, it's important to place yourself into your patients shoes and consider their journey and potential challenges.

Where will patients affected by the indication you're studying likely go for treatment? Will they be seeing an ophthalmologist, or will it be more likely that their opthalmologic condition will be handled by their primary care providers (PCP)?

In a 2019 article in the Osteopathic Family Physician, it was noted that 2-3% of primary care office visits are eye-related complaints. Conditions commonly seen by PCPs include conjunctivitis, strabismus, uveitis, entropion, ectropion, pterygium, stye, and chalazion. (Kaur et al., 2019)

If your ophthalmology study includes pediatric populations, the consent process must be especially clear, with procedures in place for any possible situations that may arise. What happens if the patient's parents separate or divorce during the study? What happens if guardianship changes?

2) The Importance of an Excellent Medical Monitor

Medical monitors are always important assets to a study team, as they have an intimate knowledge of study protocol and robust clinical and academic experience as physicians. A specialized medical monitor with experience within ophthalmology is especially important for these clinical trials.

3) Qualifying Site Staff

It's important to look closely at the qualification of treatment administrators and staff members.

For example, if retina injections are required for your ophthalmology study, a qualification process may need to be created to distinguish between qualified staff (whether they are retina specialists or non-retina specialists) and unqualified staff who may not perform injections on the study.

Similarly, if your study includes imaging, it's critical to qualify each sites technicians to confirm that images are comparable.

4) Limitations During Site Selection

Unlike many clinical trials in non-ophthalmology indications, equipment for ophthalmology is typically not supplied due to cost limitations. This adds an additional layer of assessment as sites are evaluated. During the feasibility process, exam rooms must be qualified to see what equipment is available at each site. Sponsors may opt to work with large vendors to encompass the standard equipment used across all sites.

References

Kaur, S., Larsen, H., & Nattis, A. (2019). Primary Care Approach to Eye Conditions. Osteopathic Family Physician, 11(2), 28–34. Retrieved May 6, 2022, from 2019.

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PharPoint Research is an award-winning and client-focused contract research organization (CRO) that offers clinical operations, data management, biostatistics, and strategic clinical trial consulting services to clients of all sizes. Founded in 2007, PharPoint's team has participated in over 1,000 clinical trials with a high business repeat rate.

Our services include:

- Clinical Operations
- Medical Monitoring
- Project Management
- Data Management
- Biostatistics
- Statistical Programming
- Medical Writing
- Study Rescue
- Strategic Consulting