MEDPACE

OPHTHALMOLOGY CLINICAL DEVELOPMENT

Medpace's expertise in ophthalmology studies and consistent track record of success as a full-service CRO ensures the flexibility to adapt to the unique needs of each ophthalmology trial. With recent and promising advances in ophthalmology gene therapy clinical trials, Medpace's deep experience in advanced therapy research across multiple therapeutic areas, is beneficial for Sponsors.

Our cross-specialty experience is key for managing complex ophthalmology trials. The expertise we provide to other therapeutic areas, where endpoint and sub-studies with ophthalmology may exist, is invaluable. Our expertise and lessons learned provide guidance on the complexities often involved in complex research.

Indication Experience:

- Natural History Studies
- Age-Related Macular Degeneration
- Leber's Congenital Amaurosis
- Retinitis Pigmentosa
- Achromatopsia
- Cataracts
- Glaucoma
- Presbyopia
- Retinal Vein Occlusions
- Diabetic Macular Edema
- Devices

As a therapeutically-focused CRO, Medpace's expertise and multi-disciplinary teams are experienced in many different areas. Our experience with global regulatory authorities, coupled with early planning and collaboration with Sponsors, accelerates the path to approval. Our therapeutically trained teams including clinical trial managers and program coordinators provide knowledgeable training to sites and help mitigate challenges.

MAKING THE COMPLEX

SEAMLESS™

EXPERTS

- **Embedded physician leadership including board certified ophthalmologist**
- **Scientific and medical expertise provided in protocol development**
- **Experienced trial and data managers drive efficiency and quality**
- **Cohesive, experienced study team with expertise in monitoring ophthalmic disease progression across large populations**

EXPERIENCE

- **Conducted global Phase I-IV trials**
- **Advanced therapy experience in macular degeneration and retinitis pigmentosa**
- **Experienced in the regulatory and feasibility considerations for glaucoma, cataract, and presbyopia device trials**
- **Dedicated global regulatory submissions team and global regulatory affairs for comprehensive support**
- **Skilled in drug, medical device, and combination products**

EXECUTION

- **Long-term relationships with successful, experienced sites, networks, and key opinion leaders**
- **Experienced clinical trial managers and program coordinators**
- **Recruitment expertise in patient populations including pediatrics, geriatrics, and rare diseases**
- **CAP accredited central lab services for safety testing, PK/PD, biomarkers, and genomic testing**
- **Clintrak® technology for proactive study management**

IMAGING CORE LAB

The Medpace imaging core lab is led by a group of board-certified ophthalmologists including retinal specialists, and PhD scientists with backgrounds in medical physics, imaging, and quantitative image analysis. This experienced group has an in-depth understanding of the various ophthalmic techniques available including many modalities and measurement criterion for critical imaging endpoints required for evaluations and provide reliable and reproducible interpretations of ocular images.

The imaging core lab has extensive global experience with trial design, data interpretation and analysis, global study management, and regulatory strategy consultation. Further, the imaging group has long-standing relationships and collaboration with central reading centers with various modalities of ophthalmic imaging. The ability to streamline imaging and data management services into the overall clinical trial provides seamless integration and efficiency while lessening the burden on sites and patients.

Imaging Modalities

- Adaptive Optics (AO)
- B-Scan Ultrasonography
- Confocal and Specular Microscopy
- Corneal Topography
- Electrophysiology
- Fluorescein Angiography (FA)
- Full-field Stimulus Testing (FST)
- Indocyanine Green Angiography (ICG)
- Microperimetry
- Monochromatic Imaging
- Optical Coherence Tomography (OCT)
- OCT Angiography
- Perimetry

SPECIALIZED TEAMS

Medpace and its ophthalmology team are experienced in conducting clinical trials spanning in scope and complexity. Our in-house physicians are board-certified medical doctors that are embedded within the project team and are fully-involved throughout the study, providing leadership, consulting with Sponsors, training project teams, and investigative sites to ensure our operational strategy is firmly aligned with the Sponsor's scientific and medical objectives.

This full integration of our medical experts differentiates us and makes collaborating with Medpace a particularly positive experience for Sponsors. Our physicians and professional staff understand the complexities of ophthalmology trials from the perspective of the Sponsor, the clinical investigator, the scientific leader, and the reviewer at the regulatory agencies. We bring these perspectives to each clinical trial that we conduct.

CENTRAL LAB

Medpace's central labs is experienced in clinical research from discovery and proof of concept through large, long-term global trials. Located in the US, Belgium, China, and Singapore, all are wholly-owned and purpose-built with state-of-the-art infrastructure. Each location has the same testing instrumentation, follow global operating procedures, and utilize a single laboratory information system, ensuring perfect harmonization of global data.

- Scientific consulting and concierge service
- Global logistics
- Safety testing and biomarkers
- Genomics and molecular assays
- Global biorepository
- External lab management
- ClinTrak Lab portal

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a global full-service clinical research organization providing Phase I-IV core development services for drug, biologic, and device programs. With medical and regulatory expertise in multiple therapeutic specialties. Medpace has assembled therapeutically focused teams to execute at every level of the company's operations, providing complete and seamless drug and device development services.

WE CAN'T SIMPLIFY CLINICAL DEVELOPMENT – BUT WE CAN EXECUTE IT SEAMLESSLY.

MAKING THE COMPLEX SEAMLESS™