Ophthalmology

An experienced ophthalmology partner

Bringing ophthalmology drugs to the marketplace comes with a unique set of challenges. The PPD™ clinical research business of Thermo Fisher Scientific has extensive global experience in planning, implementing, accelerating and delivering ophthalmology clinical trials across a broad range of drug classes to help you overcome these challenges and advance your therapeutic development.

Dedicated ophthalmic expertise

Our dedicated global ophthalmology team is comprised of approximately 500 clinical professionals, including a global ophthalmology project management team of more than 15 staff members, clinical research associates (CRAs) trained in ophthalmology, clinical science liasons (CSLs), clinical managers across all regions and key functional lead experts with ophthalmic trial experience.

The team also includes ophthalmologists, optometrists, certified ophthalmic medical technologists with U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) experience. Additionally, we have staff with biopharma and biotech company experience specializing in ophthalmic drug and device development, as well as ophthalmic epidemiology expertise.

Our ophthalmology team is supported by three board-certified ophthalmologists located in North America, EMEA and APAC with more than 40 years of combined clinical drug and medical device development experience.

Our ophthalmologists provide comprehensive clinical development and regulatory strategy, safety oversight, team training and expert consulting services.

In the past five years we have conducted:

- **60+** ophthalmology trials
- Involving **12,000+** patients
- Across **2,800** sites around the world
- **70+** real-world outcomes and market access studies

Broad therapeutic experience across indications

Our comprehensive ophthalmology services include drug development expertise and consulting, as well as all functional areas of expertise to run a clinical trial and/or program. We have experience across a broad range of indications, both anterior and posterior, including:

- Acute optic neuritis
- Age-related macular degeneration
- Cataracts
- Conjunctivitis
- Corneal wound healing
- Diabetic macular edema/ diabetic retinopathy
- Dry eye
- Fuch's Dystrophy
- Geographic atrophy
- Glaucoma/ocular hypertension
- Leber's congenital amaurosis
- Myopia
- Retinal vein occlusion
- Retinopathy of prematurity
- Retinitis pigmentosa
- Thyroid Eye Disease
- Usher syndrome
- Uveitis

We have also managed multiple cell and gene therapy studies and have extensive experience working on ophthalmic rare disease, neonatal and pediatric studies

Strategic guidance

Our experienced team provides strategic guidance for development, protocol and operational activities across all stages of drug development through:

- Full clinical development and regulatory strategy support
- Strategic development consulting expertise in core disciplines (CMC, toxicology, pharmacology)
- Relationships with an international network of experienced investigators with historical information regarding quality of data, enrollment capabilities and key equipment and staff to assess and propose the most appropriate sites for a trial
- Access to clinical trial intelligence databases that enable us to combine our historical expertise in individual indications with industry enrollment trends, competing trial environment review and other factors to ensure proper country and site selection along with enrollment metric baselining
- Site activation, enrollment and retention strategies by ophthalmic indication
- Knowledge of key protocol components that impact enrollment rates, development and program success
- Data management, biostatistics, quality and regulatory expertise to appropriately collect and analyze data for ophthalmologic data endpoints
- Strong relationships with key opinion leaders by ophthalmic specialty with access to identify national coordinators to manage data and safety monitoring boards and any necessary steering committees
- More than 30 years of experience in generating and communicating evidence of product value, effectiveness and safety to optimize patient access
- Access to our proprietary Vestrum retinal database registry comprised of more than 370 retinal physicians and their approximately 2.5 million patients. This database can be leveraged for both feasibility and protocol design, for identifying and pre-screening high-quality trial candidates, and to reduce site burden
- Global experience with more than four certification centers for visual acuity assessments, with NEI VFQ administration and other quality of life and comfort questionnaires

We bring a deep understanding of therapeutic-specific vendors and their requirements to successfully meet or exceed timelines.

We have experience with more than 12 central reading vendors in the following assessments:

- Angiography
- Fundus Autofluorescence Imaging
- Endothelial Cell Counts
- OCT (corneal angles, retinal thickness, NFL, ganglion cell layer)
- Corneal Haze
- Iris Color Photos
- Visual Field

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