OVERVIEW

Extensive Ophthalmology Experience and Capabilities

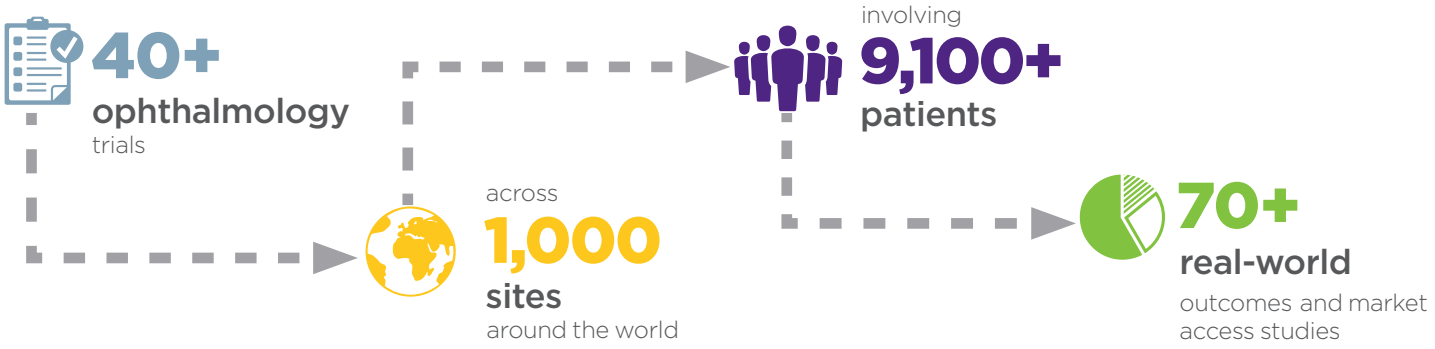
PPD has a **deep understanding** of the range of challenges across the **ophthalmic product development** spectrum and has dedicated professionals to execute successful ophthalmology studies.

Dedicated Ophthalmic Expertise

Our dedicated global ophthalmology team is comprised of approximately 300 clinical professionals, including a global ophthalmology project management team of more than 15 staff members and ophthalmology trained clinical research associates (CRAs) and clinical managers across all regions. In addition, we have key functional lead experts with ophthalmic research experience spanning patient reported outcome development, clinical trials, observational research and registries and market access. The team also includes ophthalmologists, optometrists, certified ophthalmic medical technologists with U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) experience, and staff with experience. Additionally, we have staff with experience from pharmaceutical and biotech companies specializing in ophthalmic drug and device development and expertise in opthalmic epidemiology.

PPD's ophthalmology team is supported by three board-certified ophthalmologists with more than 40 years of combined clinical drug and medical device development experience, which includes office-level experience within the FDA. Our ophthalmologists provide safety oversight, team training and expert consulting advice to clients on protocol and regulatory strategy development.

In the past five years PPD has conducted:



Broad Therapeutic Experience

Our comprehensive ophthalmology services include drug and biologic 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
- Conjunctivitis
- Corneal wound healing
- Diabetic macular edema/diabetic retinopathy
- Dry eye
- Geographic atrophy
- Glaucoma/ocular hypertension
- Leber's congenital amaurosis
- Lens opacification
- Retinal vein occlusion
- Retinopathy of prematurity
- Retinitis pigmentosa
- Usher syndrome
- Uveitis

Extensive Ophthalmology Experience and Capabilities

Our team has experience working on ophthalmic rare disease and pediatric trials, including neonates.

Strategic Guidance

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

- **Relationships with an international network** of experienced investigators with historical information regarding quality of data, enrollment capabilities and key equipment and staff that help us assess and propose the most appropriate sites for a trial
- **Access to clinical trial intelligence databases** that allow 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, biostatistic, quality and regulatory expertise** to appropriately collect and analyze data for ophthalmologic data endpoints
- **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

We also have global experience with more than four certification centers for visual acuity assessments, with NEI VFQ administration, and other quality of life and comfort questionnaires.

> Our experienced professionals also bring a deep understanding of therapeutic-specific vendors and their requirements to successfully meet timelines.

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

Angiography

Endothelial Cell Counts

Fundus Autofluorescence Imaging

OCT (corneal angles, retinal thickness, NFL, ganglion cell layer)

Corneal Haze

Iris Color Photos

Visual Field

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