# Extensive Ophthalmology Experience and Capabilities

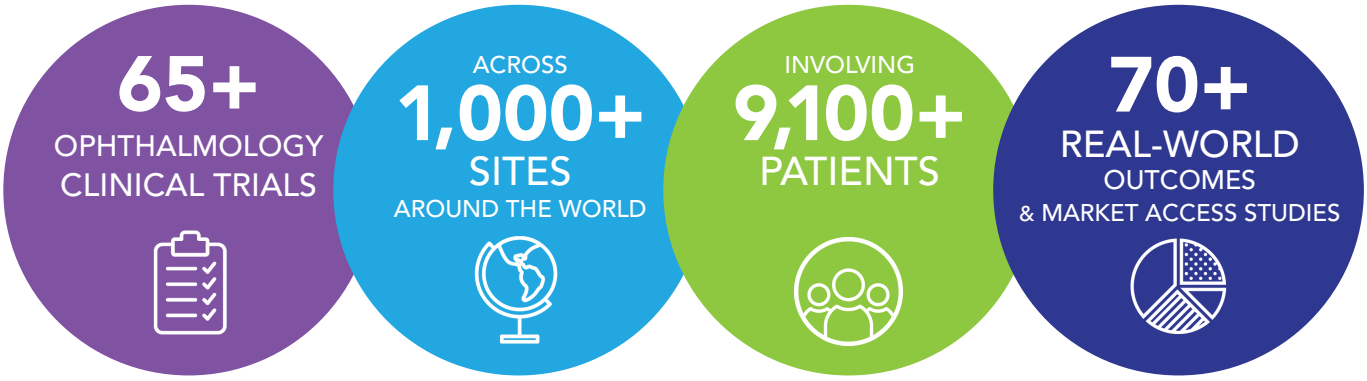
## Dedicated Ophthalmic Expertise

PPD's ophthalmology team is supported by board-certified ophthalmologists, optometrists, epidemiologists, and certified ophthalmic medical technologists. Additionally, our professionals have direct leadership experience in pharmaceutical and biotech companies specializing in ophthalmic drug and device development, and members with experience within the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). Our medical and scientific leaders bring more than 75 years of combined ophthalmic drug and medical device development experience. Additionally, our leadership team provides safety oversight, team training, and expert consulting advice to clients on clinical development strategy, protocol development, regulatory strategy, and market access. We have key functional lead experts with deep ophthalmic research expertise and experience spanning patient-reported outcome development, epidemiology, clinical trials, observational research and registries, natural history studies, and market access.

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

Our dedicated global ophthalmology team is comprised of approximately 300 clinical professionals and includes an ophthalmology operations team, ophthalmology trained clinical research associates (CRAs), and clinical managers across all geographic regions.

### In the past five years PPD has conducted:




## Broad Therapeutic Experience

Our comprehensive ophthalmology services include drug, biologic, and device 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 (AMD)
  - *Dry AMD*
  - *Geographic atrophy*
  - *Neovascular*
- Cataract/lens opacification
- Conjunctivitis
- Corneal wound healing
- Diabetic retinopathy/macular edema
- Dry eye disease
- Glaucoma/ocular hypertension
- Leber's congenital amaurosis
- Rare ophthalmic indications
- Retinal vein occlusion
- Retinopathy of prematurity
- Retinitis pigmentosa
- Usher syndrome
- Uveitis

## A Proven Strategic Partner

**Full-service provider**: Full suite of end-to-end global research and development capabilities allowing us to be an impactful extension of your team from early development through commercialization

**Therapeutic area expertise**: In-house network of ophthalmologists, optometrists, epidemiologists, scientists, safety experts, and global research operations professionals with experience across a wide range of ophthalmic indications

**Operational excellence**: Deep in-house experience, established relationships with therapeutic area-specific vendors and reading centers, and custom-tailored processes for rapid study start-up and the highest level of program management across the drug development lifecycle

**Study design and protocol development**: Expertise in study design, protocol development, endpoint selection, PRO development and validation, and statistical analysis plans. Identification of factors that impact enrollment rates, patient retention, and program success

**KOL relationships**: Extensive network of national and global opinion leaders by ophthalmic sub-specialty to manage data and safety monitoring boards, steering committees, scientific, and medical advisory boards

**Real-world and post-approval studies**: 30+ years of experience in generating and communicating evidence of effectiveness, safety, product value, patient access, health-related QoL, treatment satisfaction, adherence, resource use, epidemiology, and burden of illness

**Tailored site and patient services**: Site activation, enrollment, and retention strategies by ophthalmic indication, and access to clinical trial intelligence databases that allow us to ensure proper country and site selection along with enrollment metric baselining

**Data collection and analysis**: Data management, biostatistics, quality control, and regulatory expertise to appropriately collect and analyze data for ophthalmic trials and observational research studies. Advanced analytics, modeling and simulation, machine learning, and natural language processing

**Asset differentiation and commercial optimization**: Evidence plan and payer/provider research to define value story, inform pivotal studies, and streamline spend. Market access landscape analysis, pricing strategy/tactical plan, dossiers, database studies, PROs, and economic modeling

## PPD's Comprehensive Services

### Early Development

- Chemistry, Manufacturing & CMC Consulting
- Manufacturing & Controls
- Nonclinical Development & Chemistry
- Pharmacology & Toxicology
- Phase I Clinic (Healthy Volunteers)
- Phase I Patient Network
- Translational Medicine

### Clinical Development

- Early Lifecycle Evidence Planning
- Feasibility Studies
- Patient Recruitment
- Clinical Trial Start-up & Monitoring
- Data Management & IVR
- Biostatistics
- Global Pharmacovigilance
- Medical Writing & Communications
- Pharmacokinetics & Pharmacodynamics (PK/PD)
- Quality & Compliance
- Regulatory Affairs

### Peri- and Post-Approval

- Phase IIIb/IV Clinical Trials
- Pragmatic Trials
- Post-Approval Safety (e.g., REMS, RMP, PASS)
- Global Pharmacovigilance
- Epidemiology & HEOR Studies
- Registries & Observational Studies
- Compassionate Use Programs
- Extended Access Programs
- Healthcare Communications
- Modeling & Simulation
- Market Access

### Laboratories

Bioanalytical • Biomarkers • Central Lab • Genomics • GMP Lab • Vaccine Sciences

### Consulting

Strategic Evidence Planning • Trial Design (Adaptive, Platform, Pragmatic, Virtual) • Biosimilars • Medical Devices • Pediatrics Product Development • Rare Diseases • Precision and Transformative Medicine • Market Access

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