

# Ophthalmology Experience

*More than 20 staff with experience in ophthalmology projects, including*

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## A Wealth of Experience

At RTI Health Solutions, we have collaborated with our clients on more than 35 projects researching ocular diseases, ocular treatment studies, and complications of ocular diseases. Our experience includes:

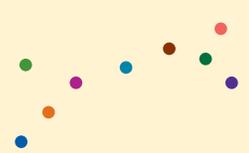
- Benign essential blepharospasm (BEB)
- Cataract surgery
- Conjunctivitis
- Diabetic macular edema
- Diabetic retinopathy
- Dry eye
- Glaucoma
- Macular degeneration
- Nonarteritic anterior ischemic optic neuropathy (NAION)
- Ocular hypertension
- Ocular complications of graft-versus-host disease (GVHD)
- Posterior blepharitis

## Types of Projects

We have implemented studies to help our clients develop strategies in the ophthalmology market and to develop and gain market access for products to treat ocular diseases and complications arising from treatment of ocular diseases. Recent projects have included:

- Epidemiology of disease
- Decision-analytic modeling to examine
  - Cost-effectiveness
  - Budget impact
- Database analyses, using cross-sectional and longitudinal databases
- Economic burden of illness studies
- PRO instrument development, evaluation, and validation
- Psychometric evaluations of PRO instruments
- PRO consulting to support label claims, publication, and regulatory strategies
- Survey research
- Systematic literature reviews
- Preparation of Health Technology Assessment (HTA) submissions
- Global value dossiers
- Value communication strategies
- Pricing and reimbursement strategic assessments
- Pharmacovigilance, including
  - Literature searches
  - Medical review and coding of reported cases
  - Annual Safety Reports (ASRs)
  - Periodic Adverse Drug Experience Reports (PADERs)
  - Periodic Update Safety Reports (PSURs)
- Abstract and manuscript development

*(continued)*



## See How We've Helped Others

### UK Database Study Evaluates Glaucoma Therapies

Using data from the Glasgow Glaucoma database, we implemented a retrospective cohort study to identify initial treatment choices of glaucoma drugs and determine if differences existed with respect to treatment adherence. We analyzed data from 1006 patients with ocular hypertension and glaucoma attending the Glaucoma Clinic in Glasgow, UK. The study showed that there are no significant differences in adherence for current prostaglandin therapies. Study results were published in *British Journal of Ophthalmology*, 2011; 95(7):966-70.

### Cost-Effectiveness of a Treatment

We developed a health economic Markov model to evaluate the cost-effectiveness of pegaptanib in patients suffering from neovascular age-related macular (NV-AMD) degeneration. The study showed that treatment with pegaptanib should be started as early as possible to maximize the clinical and economic benefits in patients with early, moderate, or late stage disease over the age of 65 years. Study results were published in *Value in Health*, 2008;11(4):563-74.

### Clinical Trial Support

We provided pharmacovigilance support for a novel drug in clinical development to treat symptomatic vitreomacular adhesion (SVMA), a disease associated with wet age-related macular degeneration (AMD), diabetic macular edema (DME), retinal vein occlusion, and diabetic retinopathy (DR). We supported the product from Phase II through launch in the US, Canada, Central and Eastern Europe, and Asia Pacific. The project included hosting the central safety database, processing cases, and preparing regulatory documents, including developing responses from health authorities. Our collaborations helped our client achieve its regulatory submission ahead of project timelines.

### Cost-Effectiveness and Cost-Utility Analyses

We developed a cost-effectiveness and cost-utility analysis for pegaptanib, a drug used in the UK for the treatment of age-related macular degeneration. The model was used in submissions to the Scottish Medicines Consortium (SMC) and the National Institute for Health and Clinical Excellence (NICE). The study showed that pegaptanib treatment is cost effective across all groups studied, and marginally more cost-effective in younger patients and those with better pretreatment visual acuity. Study results were published in *Pharmacoeconomics*, 2007;25(10):863-79.

### Pharmacovigilance for a Branded Product

We assumed post-marketing pharmacovigilance operations for a drug to treat eye infections when the client's existing surveillance processes were not compliant due to a lack of resources and a backlog of hundreds of cases. Within one month, we implemented a technology-based system to efficiently manage the client's program. We ensured that the client was in compliance with regulatory requirements as part of our ongoing support for the product.

## Selected Publications and Presentations By Our Staff

**Candrilli SD, Davis KL**, Kan HJ, Lucero MA, Rousculp MD. Prevalence and the associated burden of illness of symptoms of diabetic peripheral neuropathy and diabetic retinopathy. *Journal of Diabetes and Its Complications*, 2007;21(5):306-14.

**Earnshaw SR**, Moride Y, Rochon S. Cost-effectiveness of pegaptanib compared to photodynamic therapy with verteporfin and to standard care in the treatment of subfoveal wet age-related macular degeneration in Canada. *Clinical Therapeutics*, 2007;29(9):2096-106.

Javitt JC, Zlateva GP, **Earnshaw SR**, Pleil AM, **Graham CN**, **Brogan AJ**, Shah SN, Adamis AR. Cost-effectiveness model for neovascular age-related macular degeneration: comparing early and late treatment with pegaptanib sodium based on visual acuity. *Value in Health*, 2008;11(4):563-74.

Patrick AR, Schneeweiss S, Brookhart MA, Glynn RJ, **Rothman KJ**, Avorn J, Sturmer T. The implications of propensity score variable selection strategies in pharmacoepidemiology: an empirical illustration. *Pharmacoepidemiology and Drug Safety*, 2011;20(6):551-59.

Rahman MQ, **Abeyasinghe SS**, Kelly S, **Roskell NS**, **Shannon PR**, Abdiseaed AA, Montgomery DMI. Persistence of glaucoma medical therapy in the Glasgow Glaucoma Database. *British Journal of Ophthalmology*, 2011;95(7):966-70.

**Wolowacz SE**, **Roskell N**, Kelly S, Maciver FM, Brand CS. Cost effectiveness of pegaptanib for the treatment of age-related macular degeneration in the UK. *Pharmacoeconomics*, 2007;25(10):863-79.

**Wolowacz SE**, **Roskell N**, Maciver F, Kelly S. Cost-utility analysis for pegaptanib in age-related macular degeneration in the UK: the impact of demographic and disease characteristics. Poster presented at: ISPOR 9th Annual European Congress, Copenhagen, Denmark, Oct 2006.