Case Study:

INNOVATIVE SOLUTIONS FOR FASTER STUDY START-UP AND ENROLLMENT IN DIABETIC RETINOPATHY

BACKGROUND

Despite advances in anti-vascular endothelial growth factor (anti-VEGF) therapies, diabetic retinopathy (DR) remains a leading cause of vision loss and continues to present a significant unmet clinical need. Successfully executing DR clinical trials requires overcoming operational complexities that can delay study start-up, limit patient access, and slow enrollment.

In this case study, Medpace addresses common challenges encountered during a Phase II study, including site selection, study activation, investigator training, and patient recruitment.

By implementing a strategic operational approach including optimized site selection, centralized laboratory support, streamlined regulatory processes, and targeted site engagement, Medpace accelerated study execution, improved patient randomization, and completed enrollment a month ahead of schedule.

These tactical approaches led to:

- Increased patient randomization through enhanced site engagement and recruitment support.
- Exhibited enrollment timeline completed one month earlier than projected.
- Improved study start-up efficiency across participating sites.

100+ PATIENTS ENROLLED

20+ CLINICAL SITES ACTIVATED

SERVICES PROVIDED

- Medpace Central Laboratories
- Regulatory Affairs
- Site Feasibility and Selection
- Site Training and Engagement
- Medpace Patient Recruitment and Retention

STUDY CHALLENGES

- **Restrictions on Site List**
  - The original site list provided included retinal surgical centers only; many of which would not see non-proliferative diabetic retinopathy (NPDR) cases as referrals and would only consider once patients reached proliferative diabetic retinopathy (PDR) stage.
- **Delayed Study Start-Up**
  - The limitation of only utilizing local laboratories resulted in delays; many sites did not have on-site laboratory services and required a third-party contracting to meet this requirement.
  - The initial site list had a **mix of central IRB/EC and local IRB/EC**. These startup timelines varied from 12 weeks to 36 weeks depending on the IRB/EC selected.
- **Limited Diabetic Retinopathy Study Training**
  - The level of training varied among site staff (including PIs, Sub-Is, and imaging technicians) for the 13-step Diabetic Retinopathy Severity Scale (DRSS) guidelines.
  - Site staff frequently encountered differences between clinical assessments and DRSS severity criteria, resulting in patients who appeared clinically eligible but did not meet study qualification requirements.
- **Competition for Patient Population**
  - DR is an active area of research with PIs often recruiting for more than one DR study at a time.
  - Site staff limited due to the ratio of personnel to studies.
- **Increased Screening Requirements**
  - Due to the country the study was being conducted in, challenges involved additional site payments for site screenings and rewards for top-enrolling sites. These incentives were not applicable in all regions / countries.

MEDPACE SOLUTIONS

To address study start up and enrollment challenges, Medpace implemented a tailored operational strategy focused on improving site selection, accelerating activation timelines, and supporting recruitment throughout the study.

Optimized Site Identification

- Expanded site selection beyond the initial investigator pool to identify experienced ophthalmology centers with access to appropriate patient populations.
- Leveraged cross-functional expertise from clinical operations, medical monitoring, and therapeutic specialists to evaluate site capabilities and enrollment potential.
- Conducted targeted feasibility assessments to confirm operational readiness and required infrastructure before site activations.

Accelerated Study Start Up

- Introduced centralized laboratory services to simplify study operations and reduce logistical burden on participating sites.
- Optimized regulatory pathways by prioritizing the most efficient ethics review processes where appropriate.
- Leveraged established investigator relationships, standardized study documents, and proven activation workflows to reduce site activation timelines.

Enhanced Site Performance

- Collaborated with imaging experts to develop standardized educational resources that improved consistency in disease severity assessments across study sites.
- Delivered targeted site training and ongoing operational support to reinforce protocol adherence and improve study execution.

Recruitment Optimization

- Partnered with patient recruitment specialists to implement targeted enrollment strategies that increase site engagement and support patient randomization.
- Continuously monitored recruitment performance and adapted enrollment tactics throughout the study to maintain momentum.

MAKING THE COMPLEX SEAMLESS® IN GLOBAL OPHTHALMOLOGY CLINICAL TRIALS

Drive the successful execution of Phase I-IV ophthalmology clinical trials through a partner with strong communication, coupled with early planning and experience collaborating with global regulatory authorities. Sponsors from emerging biotechs to global pharmaceutical companies have trusted Medpace for over 30 years to lead their ophthalmology development across a wide range of indications, including but not limited to Age-Related Macular Degeneration, Inherited Retinal Disease, Cataracts, Glaucoma, Cornea, Diabetic Macular Edema, and Natural History Studies.

FULL-SERVICE CLINICAL DEVELOPMENT

Medpace is a scientifically-driven, global, full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services to the biotechnology, pharmaceutical and medical device industries. Medpace's mission is to accelerate the global development of safe and effective medical therapeutics through its high-science and disciplined operating approach that leverages local regulatory and deep therapeutic expertise across all major areas including oncology, cardiology, metabolic disease, endocrinology, central nervous system and anti-viral and anti-infective.