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## CASE STUDY

### New Compound Indication — Strategic Assessment of Clinical Study Feasibility

**Project Description:** Phase IIa study of a compound for treatment of diabetic maculopathy

**Project Objectives:** Proof of concept

**PMI Services:** Strategic consulting

**Narrative:**

An established Asian pharmaceutical development company contracted with PMI to assist with evaluation of the feasibility of performing a proof of concept study in the US for a compound to treat diabetic maculopathy. Similar compounds had been evaluated by other companies for a similar indication in the past; however, none of the evaluations was deemed successful. The company wanted to assess regulatory requirements and retinal specialists' concerns with respect to conducting another study in this area.

The project required PMI to:

- Review previous clinical data,
- Assess the company's proposed protocol,
- Evaluate the company's current regulatory position and provide suggested strategies (and associated rationale) for moving forward,
- Develop a comprehensive, detailed budget for the program assuming the company chose to proceed,
- Set-up and lead on-site meetings between sponsor-representatives and key researchers involved in the National Eye Institute's Diabetic Retinopathy Clinical Research Network including use of an appropriate language translator to facilitate sponsor representative understanding of researchers' feedback regarding project feasibility, and
- Prepare a written report summarizing project findings and recommendations.

PMI performed requested services over a two month period, which provided the company with critical information needed to complete program review in accordance with executive management's schedule.