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CASE STUDIES FROM PROMEDICA INTERNATIONAL

Class III Ophthalmic Device: Pivotal Study. Aggressive Timeline.

Study Description: Pivotal study of an ophthalmic laser for photorefractive keratectomy (PRK) treatment of myopia

Study Objectives: FDA registration via Premarket Approval (PMA)

PMI Services: Clinical site management and monitoring, data management

Description:

A start-up company contracted with PMI to provide clinical site management and monitoring and data management services in support of their US-based pivotal study of their Class III ophthalmic laser.

The first generation version of this technology had been cleared by FDA for U.S. marketing by a competitive company 12 months prior to initiation of this sponsor's study. Other competitors had also initiated research and development activities in this area. As the study design required analyses of one and two year follow-up on 500 patients, this project needed to move expeditiously in order for the sponsor to successfully impact the market.

The sponsor had selected and qualified six study sites in advance and, immediately upon signature of the project contract, PMI's project team was assembled and trained by the sponsor.

The team worked collaboratively with the sponsor and study sites to accelerate study initiation and patient enrollment. Additionally, PMI's monitors conducted regular on-site monitoring visits to review and collect data for just under 1,000 subject eyes enrolled. Data captured was entered and verified at PMI and queries were rapidly processed with study site personnel.

As study patients were generally healthy and typically recognized immediate improvement in vision subsequent to treatment, there was concern that they may be apt to ignore required study follow-up visits. A system was implemented to track and proactively confirm each patient's scheduling promptly at the time their follow-up visit "window" opened. Additionally, a detailed procedure specifying a regimen of escalating activity was developed for use with patients who were noncompliant with follow-up requirements.

The required primary cohort subjects were enrolled in less than eight months. Subject accountability at the 6 and 12 month exams was 95%+. The sponsor submitted their application for premarket approval (PMA) based on 12 month data collected and, 18 months after PMI initiated work, the sponsor received FDA Ophthalmic Panel's recommendation for approval. As the result, clearance to market came approximately one year earlier than projected.