

Key Words: **Ophthalmology, Retina, Vitreomacular Adhesion / Traction (VMA/VMT), Program Management, Ocular Imaging, Patient Recruitment**

A close-up photograph of a man's face, wearing black-rimmed glasses, is overlaid on a grid of white circles. The circles are arranged in a pattern that partially obscures his features, with some circles being solid white and others containing parts of his face.

## Clinical Program Partnering Leads to Regulatory Approval for Retina Drug

### THE KEY QUESTION:

How could a small biotech take its lead compound all the way to regulatory approval with limited resources?

### The Specific Situation

- A small biotech company partnered with Chiltern to perform full services across over 15 projects for their entire clinical program in retinal indications starting at Phase II.
- Over 2,000 subjects were enrolled at 280 sites across North America and Europe.
- Numerous requests for subgroup analyses, new analytical approaches and missing data handling conventions required rapid response times..
- There were subject recruitment and retention challenges on several protocols due to study design issues, competing trials and long clinic visits with lengthy follow-up periods.

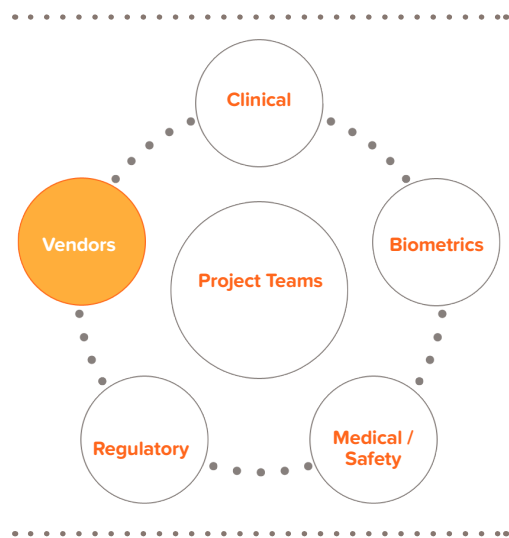
Designed Around You

## A Customized Solution

- Chiltern maintained dedicated project teams for several years allowing application of lessons learned and continuous improvement for consecutive studies.
- Replacement sites were quickly implemented in active regions where regulatory scrutiny delayed initiation. Chiltern and the Sponsor worked hand-in-hand to respond to regulatory questions and implement protocol design changes while maintaining close contact with sites even prior to activations.
- Ophthalmic vendors for visual acuity certification and central image reading were treated as part of the core teams. (see insert)
- Chiltern conducted subject recruitment and retention workshops to share successful patient support strategies including use of “patient comfort kits” during long visit days.
- The Chiltern Lead Statistician participated directly in several mock advisory committee meetings in order to identify additional analyses that were useful for the actual advisory committee meeting. Chiltern responded to requests quickly and provided the required outputs to urgent inquiries.

*Vendors undergo multidisciplinary qualification before being fully integrated as part of Chiltern teams. Vendors participate in team meetings and reporting, site newsletters and communications, training events, study planning and data coordination. This is particularly critical for ophthalmology studies in which specialists are required to perform essential tasks, including:*

- *Image reading centers*
- *Visual acuity training / certification*
- *Microperimetry*
- *Electroretinography (ERG)*
- *Investigational product management*
- *Clinical and safety laboratories*
- *Cardiac safety*
- *Electronica Patient Reported Outcomes (ePRO) and diaries*
- *Specialty equipment and software providers*



## The Positive Outcomes

- The Sponsor achieved marketing authorization throughout US and Europe, and Chiltern continues to support post-approval initiatives, inspection readiness and long-term studies in this partnership.
- The close relationship established with sites has continued to be a strong, positive factor in keeping investigators and subjects motivated. Chiltern continues to work with many of the sites on subsequent trials for other indications and Sponsors.



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