

Amber Ophthalmics Benefits from an Integrated Image Reading Center to Develop new Treatment Options for PCED

Lexitas Pharma Services' unique in-house Reading Center provides Amber with improved visibility, significantly faster communication, and greater control.

Better Visibility

Access images immediately without having to wait on an external Reading Center.

Greater Control

Ensure image quality is appropriate from study beginning to end, with ability to rapidly educate sites if issues arise.

Rapid Communication

Communicate with sites immediately if corrective action is required instead of waiting months for initial image review.

About Amber Ophthalmics

Amber Ophthalmics (San Diego, CA, USA) is a clinical stage biopharmaceutical company focused on developing novel therapeutics for rare anterior segment ophthalmic diseases. The company aims to address conditions affecting the ocular surface, and in particular, is focused on providing an innovative treatment option for persistent corneal epithelial defects (PCED).

Over 100,000 patients: the burden of PCED

PCED is an ocular surface sequelae stemming from a variety of underlying conditions, which include, but are not limited to inflammatory disease, autoimmune disease, neurotrophic keratitis, diabetes mellitus, viral eye disease, and chemical and/or thermal injury.

PCED affects over 100,000 people annually in the United States alone, creating a significant burden for patients. It is characterized by a disruption in the corneal epithelium, the outermost layer of the cornea, which acts as a protective barrier for the underlying structures of the eye. A PCED can result in severe pain, decreased visual acuity, and even a permanent loss of vision. Unfortunately, there are currently no FDA-approved drugs indicated specifically for the treatment of PCED. This creates a significant gap in effective treatment options for patients.

A new treatment option: the Nexagon AMB-01-006 clinical trial

Amber is currently partnering with Lexitas Pharma Services in a Phase II/III trial to evaluate the safety and efficacy of NEXAGON® (lufepirsen ophthalmic gel), a first-in-class, patent protected, naturally occurring, unmodified antisense oligonucleotide that restores ocular surface homeostasis by downregulating pathogenically elevated connexin 43 protein transcription for the treatment of PCED.

"We envision Nexagon changing the PCED treatment paradigm and once development is complete, offering effective relief to those suffering from PCED," says Dr. Shawn Scranton, President and Chief Scientific Officer at Amber.



This is the defining moment in a study, it's the primary endpoint. So, for small and midsized companies, it's a significant advantage to have this level of integration and communication from the beginning."



An in-house Reading Center provides greater transparency and control for Amber

Most ophthalmic studies utilize third-party Reading Centers. While these are a good option for some sponsors, Amber wanted faster insights and better communication to help sites deliver high-quality images right from the beginning.

"External reading centers have their place for some types of studies," says Scranton, "but having one integrated directly into the process allows us to rapidly see what is happening. Having the CRC team integrated into the CRO, with appropriate separation, of course, allows for faster communication and, as a result, better quality of data, leading to better decision making."

Amber is now able to guide sites with precise education right from the beginning. "As integration occurs during the site initiation visit (SIV), at the clinical trial coordinator level, the results are awesome. Once trained, we are seeing the site provide high quality photographs from the first subject study photo."

Due to the rapid communication chain that is created by having the Reading Center directly integrated into the CRO, issues in the image quality are noted right away instead of months later. Amber and Lexitas can then proactively work with the clinical team to educate the site.

A jointly operated CRO and Reading Center helps smaller companies have the same level of services as the largest sponsors, while also offering the ability to easily develop novel endpoints.

"This is the defining moment in a study, it's the primary endpoint. So, for small and midsized companies, it's a significant advantage to have this level of integration and communication from the beginning."

Lexitas medical and clinical experts helped make sure that the setup was appropriate, and they were involved in the early meetings. With an outside Reading Center, this would have been significantly more difficult for us to achieve, if at all."