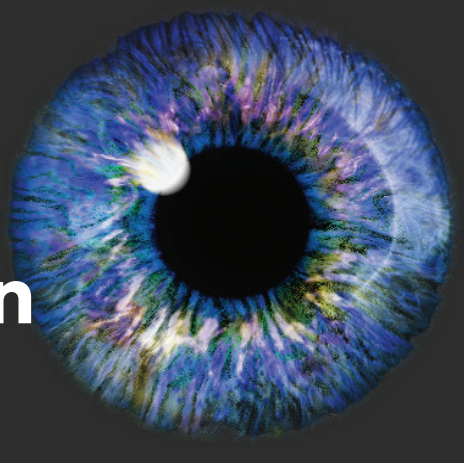
MERIT
Your Clinical Endpoint Expert

Complex Global Imaging Study in Pediatric Population



CASE STUDY

SITUATION

A leading biotechnology company conducted a Phase 3, multicenter clinical study to assess the efficacy and safety of intravitreal injection of an anti-VEGF medication versus laser treatment in pre-term infants with Retinopathy of Prematurity (ROP).

The study was conducted at approximately 60 sites in North America, South America, Asia, and Europe with projected enrollment of 112 patients. The duration of study participation was approximately 52 weeks.

IMPACT

Anti-VEGF treatment via intravitreal injection has the potential to offer improved outcomes in the high-risk, vulnerable premature newborn population with ROP.

CHALLENGES

Conducting a study with specialized imaging in a pediatric population can bring forth many challenges. This study presented the following potential issues:

- **Color Fundus Photography-ROP** (CFP-ROP) using wide-field digital retinal cameras was required at numerous timepoints over the course of an extensive study period.
    - The procedure was made more challenging by working with hand-held cameras with preterm infants.
    - As the ocular optics of preterm infants were not fully developed, acquisition of good images was especially challenging and required extensive training to the site ophthalmic technicians.
- **Fluorescein Angiography-ROP** (FA-ROP) for an FA sub-study was performed at selected sites that had acceptable previous experience.
- **Complex ROP staging** and/or resolution needed to be confirmed by expert readers.
- **A specific grading grid for ROP** needed to be developed and applied.

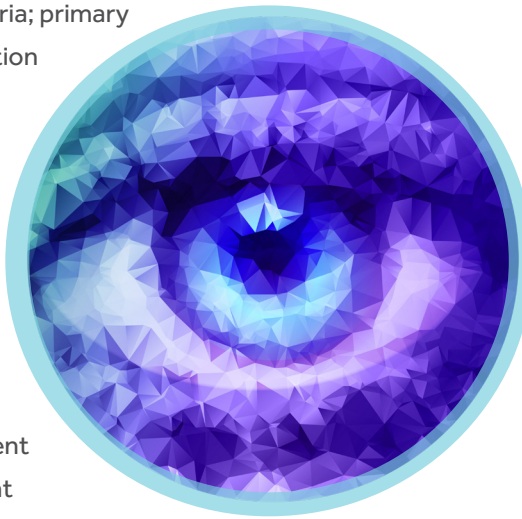
SOLUTION

MERIT's EXCELSIOR™ platform was employed by our expert reader group to help the Sponsor flawlessly manage the retinal imaging for the study.

- **Detailed image procedure manuals** for CFP-ROP and FA-ROP image acquisition and transmission were provided to the sites.
- **Extensive training and monitoring** to the site ophthalmic technicians were provided to ensure the best possible image quality.
- **The expert readers** at MERIT's central reading center confirmed the ROP staging or resolution, as well as performing Double-Reader Reading with Adjudication for all images.
- **EXCELSIOR's customizable workflows** and configurable grading forms supported the required analyses.

RESULTS AND HIGHLIGHTS

- **FDA Approval:** the FDA approved the treatment as the first pharmacologic treatment for preterm Infants with ROP.
- **Training:** Thorough, study-specific training was necessary to support the complex imaging protocol. Training covered inclusion/exclusion criteria; primary and secondary endpoints and objectives; ocular data collection and evaluation requirements per time point; and evaluation procedures as detailed in the Imaging and Grading Charter.
- **High Quality Study Conduct:** Our team of expert readers supported by experienced project managers, data managers, and technologists assured high-quality, consistent data review and interpretation.
- **EXCELSIOR™:** Our cloud-based EXCELSIOR software made it possible to handle numerous time points and different imaging modalities efficiently. The technician and equipment certification, image upload, archiving, viewing, and evaluation were all managed through EXCELSIOR's configurable workflows.



ABOUT MERIT

MERIT has provided image collection, centralized reading, and data management services for clinical trials since 2012. Using our innovative and proven technologies and intuitive, seamless workflows, MERIT's experienced staff bring more than a decade of clinical endpoint expertise to ensure the success and integrity of your independent imaging review studies.

Connect with us to learn more about how our expertise and approach can support bringing your product to market on-time and on-budget. Your success is our priority.

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