

CASE STUDY

Complex Ophthalmic Imaging Solutions

MERIT's Imaging Expertise and Proprietary Software Performed a Crucial Role in Global Phase III Wet AMD Study

SITUATION

A large global biotechnology company sponsored a phase III trial at multiple global sites to evaluate the efficacy and safety of a new Vascular Endothelial Growth Factor (VEGF) antagonist administered via intravitreal injection in subjects with neovascular age-related macular degeneration (Wet AMD).

This study required approximately 500 subjects to complete up to 26 monthly visits over two years.

CHALLENGES

The following challenges arose in this large Phase III trial:

- **QUICK TURNAROUND TIME:** Rapid turnaround time was required to determine eligibility with 150 sites worldwide and approximately 500 patients. Quick turnaround time was also required for all image processing and grading throughout the study
- **MULTIPLE EQUIPMENT MANUFACTURERS:** The imaging data from many manufacturers needed to be harmonized and certified
- **COMPLEX COORDINATION OF SERVICES:** Management of multiple Reading Centers and synchronization with CRO partners on an ongoing basis
- **MULTIPLE IMAGING MODALITIES:** The protocol required many different imaging modalities including spectral domain optical coherence tomography (SD-OCT), fundus photography (FP), and fluorescein angiography (FA)

SOLUTION

MERIT’s exceptional reading center services for ophthalmic imaging can be easily configured to meet sponsor and study requirements. Our EXCELSIOR™ platform was employed by our team of experienced experts to help the sponsor flawlessly manage all facets of the study.



TIME-SENSITIVE QUALITY CHECKS & DICOM STANDARDIZATION: With numerous sites and diverse imaging equipment, the success of this trial was dependent on time-sensitive quality checks and DICOM conversion for the partner Reading Center to grade quickly per the trial protocol. The timely quality checks and DICOM standardization was empowered by EXCELSIOR™, our secure cloud-based software application, which was specifically built for supporting image data collection and management



DIRECT, EFFICIENT, & TRANSPARENT PROCESSES: Our team of experts provided efficient management of services with Reading Center and CRO partners. We received messages directly from our data acquisition platform which empowered smoother tracking of images. Immediate QC enabled quick confirmation that images were acquired correctly. Prompt feedback to the sites proactively prevented further images from being acquired incorrectly



REAL-TIME PERFORMANCE UPDATES: MERIT offered real-time snapshots of trial performance, allowing stakeholders at multiple locations to work concordantly with diverse images. Our advanced reporting functions and access to expert analysis helped study teams track, organize, visualize, and understand this study data



ROBUST TRAINING & CERTIFICATION: MERIT ensured all sites were qualified, trained, and able to acquire and submit patient timepoints correctly. We have a proven in-depth process for training and certifying sites, assuring that the data was correctly acquired and reviewed



QUALITY ASSURANCE & COMPLIANCE: Adherence to regulatory controls and quality policies and procedures reduced the risk of manual error and increased the transparency and reliability of trial data

EXCELSIOR screenshot illustrating OCT split view in grading:



RESULTS & HIGHLIGHTS

- **RAPID TURNAROUND TIME:** Efficient, quick turnaround times for image processing and grading, including 48-hour turnaround for eligibility. On average, the results of the eligibility visits were determined within 6 hours
- **COMPLEX COORDINATION OF SERVICES, EQUIPMENT, AND IMAGING MODALITIES:** MERIT successfully managed multiple Reading Centers, harmonized imaging data from many manufacturers, and evaluated various imaging modalities
- **VOLUME OF DATA SERIES:** There were 82,448 total data series processed and reviewed for this study. MERIT ensured thorough and punctual quality control, enabling the partner Reading Center to quickly grade per the trial protocol



150
SITES
WORLDWIDE



500
PATIENTS



85,448
TOTAL NUMBER
OF DATA SERIES



640,219
TOTAL NUMBER
OF IMAGES

It's important to have a team of domain experts for complex imaging studies to assure high-quality, consistent data review and interpretation. With MERIT, your critical primary endpoint is safe in our hands.

MERIT

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.

START A CONVERSATION

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