CASE STUDY · OPHTHALMOLOGY

Diabetic Macular Edema Trial OCT Endpoints

70 sites · SD-OCT, fluorescein angiography · Central subfield thickness

Challenge

Intrinsic Imaging supported this study’s imaging activities, addressing the scientific and operational considerations that inform the work of an imaging CRO and imaging core lab. Central subfield thickness measured by OCT anchored this diabetic macular edema trial's primary endpoint, yet automated retinal layer segmentation introduces platform-dependent boundary errors that compromise measurement reliability. With 70 sites using multiple OCT platforms, uncorrected segmentation errors threatened the comparability of the thickness measurements on which the efficacy analysis depended.

Diabetic macular edema distorts retinal anatomy and challenges automated segmentation, particularly when intraretinal cystic spaces or other fluid-related changes alter layer boundaries, and poor image quality further limits boundary identification. Fluorescein angiography also required consistent acquisition and grading to characterize leakage reliably. The sponsor required consistent review of automated segmentation, predefined correction conventions and standardized angiographic grading across platforms, with corrections, qualified results and exclusions each carrying a documented rationale linked to the examination. Explicit handling of segmentation failure was central to cross-platform comparability and to the sponsor's ability to evaluate the final dataset with a transparent account of its technical limitations. Correction conventions determine which retinal boundaries contribute to the reported thickness. Consistency across platforms therefore requires explicit anatomical definitions rather than assuming that outputs from different segmentation algorithms measure identical structures.

Intrinsic Imaging’s Solution

Intrinsic Imaging provided sites with device-specific acquisition guidance and certified photographers before enrollment. Each examination was reviewed for scan quality, centration and completeness, and sites received feedback when repeat imaging was needed, so that avoidable technical limitations were corrected at acquisition rather than compensated for at grading.

Our certified ophthalmic graders reviewed the automated segmentation of every OCT examination, manually correcting boundary errors wherever they were identified so that thickness measurements reflected true retinal anatomy rather than algorithmic artifact. Fluorescein angiography underwent centralized review of leakage characteristics under standardized grading criteria. Graders were trained and certified on segmentation correction and angiographic grading conventions, and quality review and grader agreement were monitored throughout the study so that corrections and leakage assessments were applied consistently across devices and timepoints.

Examinations with substantial segmentation failure or limited image quality were reviewed under defined criteria to determine whether reliable measurements could be obtained. Where measurements were corrected, qualified or excluded, the rationale was documented consistently, providing a transparent record for data review. Segmentation software remains a valuable tool, but its errors can be systematic and device-specific, particularly in eyes with significant pathology; expert review allowed those errors to be identified and corrected uniformly, protecting the primary endpoint across a heterogeneous device network and giving the sponsor a grading framework applicable to subsequent retinal disease trials.

Intrinsic Imaging’s Results

- Grader agreement above 0.92 for corrected central subfield thickness, sustained across multiple OCT platforms and all 70 participating sites throughout the study
- Retinal thickness measurements corrected across all OCT devices, with automated segmentation errors resolved manually by certified graders so that reported values reflected true retinal anatomy
- Primary endpoint data delivered on schedule, supported by a consistent, documented grading process for both SD-OCT thickness and fluorescein angiographic leakage
- Documented rationale for every correction, qualification and exclusion, giving the sponsor a transparent account of the technical limitations underlying the final dataset

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Read the full study online: https://intrinsicimaging.com/case-studies/ophthalmology-dme

About Intrinsic Imaging, LLC

Intrinsic Imaging is an ISO certified medical imaging CRO and imaging core lab providing comprehensive services in support of Phase I-IV clinical trials and Class I, II, III medical device trials. Intrinsic Imaging is also a world leader in conducting Artificial Intelligence studies. With its team of more than 650 board-certified and fellowship-trained physicians, Intrinsic Imaging’s team has sub-specialization in all therapeutic areas, including Cardiovascular, Central Nervous System,Gastroenterology, Musculoskeletal, Oncology and Ophthalmology. Certified by the British Standards Institution (BSI), Intrinsic Imaging is the only company in the world to hold five ISO certifications specifically for providing imaging core lab services on clinical trials. For more information, please visit www.IntrinsicImaging.com.

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