

Diabetic Macular Edema Trial OCT Endpoints

70 sites

SD-OCT, fluorescein angiography

Central subfield thickness

Challenge

Central subfield thickness measured by OCT anchored this diabetic macular edema trial's primary endpoint, yet automated segmentation—the software process that identifies retinal layer boundaries—fails often enough, and differently enough across devices, to compromise measurement reliability. With 70 sites using multiple OCT platforms, uncorrected segmentation errors threatened the comparability of thickness measurements on which the efficacy analysis depended.

Our Solution

Intrinsic Imaging's 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. This dual process delivered thickness and angiographic data of uniform quality across all device platforms and sites.

Results

- Retinal thickness measurements corrected across OCT devices
- Grader agreement above 0.92
- Primary endpoint data delivered on schedule

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

About Intrinsic Imaging, LLC

Intrinsic Imaging is a full-service medical 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 750 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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