CASE STUDY · OPHTHALMOLOGY

Geographic Atrophy and Neovascular AMD Trial

SD-OCT, fundus autofluorescence · Lesion area measurement · Multi-reader consensus

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. The trial's efficacy assessments depended on precise central measurement of geographic atrophy lesion area and consistent longitudinal tracking of choroidal neovascularization. Lesion boundaries in retinal imaging are frequently indistinct, and small differences in delineation translate into differences in measured area large enough to confound endpoint analysis when measurements are compared across timepoints and readers.

Two complementary modalities, each with distinct technical demands, added to the difficulty. Fundus autofluorescence required consistent image quality and field coverage for reliable atrophy measurement, while SD-OCT needed appropriate scan patterns to characterize retinal layers and neovascular activity. Sites used different imaging devices and differed in photographer experience. The sponsor therefore required standardized acquisition across systems, reproducible lesion delineation governed by consistent anatomical conventions, and documentation sufficient to reconstruct each longitudinal measurement, so that modest differences in lesion area could be interpreted against the study's efficacy objectives rather than attributed prematurely to treatment or dismissed as noise. Boundary delineation is part of the measurement definition, not merely an annotation task. Consistent anatomical conventions are particularly important when small changes in an irregular lesion determine the longitudinal difference reported for an efficacy assessment.

Intrinsic Imaging’s Solution

Intrinsic Imaging supported sites with device-specific acquisition guidance and photographer certification before enrollment. Each examination was assessed for focus, coverage and image quality on receipt, and sites were asked to repeat imaging when technical limitations would prevent reliable measurement.

Our ophthalmic reading team performed standardized lesion segmentation on SD-OCT and fundus autofluorescence imaging, applying uniform delineation criteria to every examination. Readers were trained and certified against reference cases, with periodic recalibration to maintain consistent criteria. Longitudinal series were reviewed together to support consistent boundary delineation across visits, and measurements departing from the expected course were examined for technical artifact as well as evidence of progression.

Where lesion boundaries were ambiguous, a multi-reader consensus process resolved the interpretation. Readers first recorded independent assessments before reviewing areas of disagreement, and final decisions and their rationale were documented, so that the consensus process strengthened consistency without obscuring the independent judgments on which it rested. Every measurement carried a complete audit trail from source image to reported area. Our project team monitored image quality trends and reader agreement throughout the study and reported them to the sponsor at regular intervals, so that photographer retraining or reader recalibration could be directed wherever the data indicated it was needed, before variability reached the endpoint dataset.

Intrinsic Imaging’s Results

- Lesion area tracked to within 0.05 mm², a precision sufficient to resolve the small longitudinal changes in geographic atrophy on which the efficacy assessment depended
- Primary endpoint readout delivered on schedule, supported by fully audited longitudinal measurements across all fundus autofluorescence and SD-OCT devices and every participating site
- Multi-reader consensus resolved every ambiguous lesion boundary, with each reader's independent assessment preserved alongside the documented final decision and its rationale
- Acquisition guidance, photographer certification procedures and delineation criteria proven across the site network and carried forward into the sponsor's later-phase program

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

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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