Pivotal Data Validates Diagnostic Equivalence of SCANLY Home OCT and In-Office OCT in Wet AMD Management

Manassas, VA (July 9, 2025) — Notal Vision, a digital healthcare provider advancing remote patient monitoring in ophthalmology, announced the publication of pivotal study data in *Ophthalmology Science* validating the clinical performance and patient usability of the SCANLY Home OCT in the management of neovascular age-related macular degeneration (AMD).[1] The results contributed to the FDA's first-ever clearance of an AI-powered home OCT device for use in ophthalmology.

Until now, the ability of wet AMD patients to self-image on a compact, home-based OCT device had only been demonstrated in smaller longitudinal at-home[2,3] and cross-sectional in-office studies.[4] This pivotal longitudinal study expanded on those findings and demonstrated strong agreement between SCANLY-acquired images and standard in-office OCT in identifying hypo-reflective spaces (HRS), an important biomarker in wet AMD that typically indicates fluid. Conducted across seven U.S. retina practices representing a mix of urban and rural populations, the longitudinal trial enrolled 180 patients from a broader 500-subject study program, including those with concurrent ocular conditions to reflect real-world pathology.

Participants received SCANLY devices via courier from the Notal Vision Monitoring Center. They did not receive any training on how to use the device but had the option to call the Monitoring Center for support if needed. Patients were instructed to self-image daily over a five-week period. To assess image agreement, patients also underwent 2–3 in-office visits for comparative OCT scans. All images were independently graded by masked graders for the presence of HRS.

SCANLY met its prespecified endpoint of ≥80% agreement, achieving a positive percent agreement (PPA) of 86.6% and a negative percent agreement (NPA) of 86.1%. Discrepancies were primarily attributed to grader errors or trace amounts of HRS.

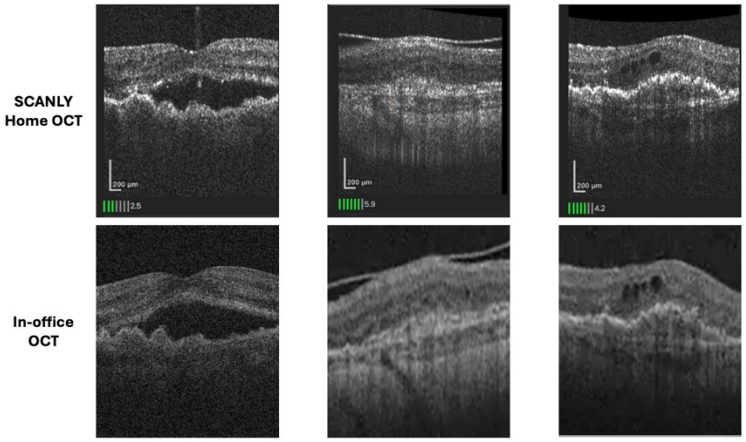

Figure: Side-by-side comparison of SCANLY and in-office OCT demonstrating high concordance in detecting hypo-reflective spaces in wet AMD patients.

The study also confirmed high patient usability: 96.1% of eligible participants successfully initiated at-home imaging, averaging 5.9 scans per eye per week. Phone support was minimally required, with patients averaging just 0.21 support calls per month.

"Home-based OCT monitoring represents a fundamental shift in personalized retina care," said Jeffrey S. Heier, MD, Director of the Retina Service at Ophthalmic Consultants of Boston. "The

SCANLY pivotal data and subsequent FDA clearance represents a significant advance in remote diagnostics for chronic retinal disease."

"We're proud to share these robust findings," added Kester Nahen, PhD, CEO of Notal Vision. "They validate that patients with wet AMD can reliably self-image at home, supporting treating retina specialists in their clinical decision-making between office visits."

The SCANLY Home OCT Monitoring Program, provided by the Notal Vision Monitoring Center, enables prescribing retina specialists to leverage AI-enabled alerts and real-time imaging data to individualize care while maintaining clinical oversight.

References:

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About Notal Vision

Notal Vision is a patient-centric ophthalmic remote monitoring services provider extending care from the clinic to the home. We empower physicians with innovative home-based technologies and remote monitoring services that support patient management between office visits. Our solutions combine self-operated digital diagnostic devices, AI-enabled data analysis, and a physician-led monitoring center—all with the goal of helping preserve patients' vision. Learn more at www.notalvision.com

The Medicare-accredited and ophthalmologist-led Notal Vision Monitoring Center is dedicated to remote monitoring and patient engagement. Staffed by certified ophthalmic professionals, the center provides nationwide service for age-related macular degeneration (AMD) monitoring.

Notal Vision offers two distinct remote monitoring solutions:

- **ForeseeHome AMD Monitoring Program:** Designed for patients with intermediate dry AMD, this FDA-cleared and Medicare covered program uses an at-home, AI-powered visual function test to detect changes that may indicate conversion from dry to wet AMD. The Monitoring Center alerts physicians to potential disease progression—often

before the patient notices symptoms—enabling earlier intervention and improved outcomes.

- SCANLY Home OCT Monitoring Service: Indicated for patients diagnosed with wet AMD, the first-in-class, FDA-cleared SCANLY allows technician-free OCT imaging from home. Patients perform regular self-scans using an intuitive device with AI-assisted image analysis. The physician receives 24/7 access to annotated OCT B-scans and automated alerts when clinically relevant changes are detected, enabling timely office visits.

Together, these programs support physicians across the full spectrum of AMD care—from early detection to ongoing disease management.