Pivotal Study Demonstrates Efficacy of AI in enabling Home OCT Monitoring

Manassas, VA (February 3, 2024) Digital healthcare provider, Notal Vision, announced that the results of a pivotal study evaluating the performance of an artificial intelligence (AI) algorithm for the estimation of key biomarkers in neovascular AMD (nAMD) using a home-based optical coherence tomography (OCT) system, were recently published in *Ophthalmology Science*.[1] The publication details the study that led to the first-ever US Food and Drug Administration (FDA) clearance of an AI algorithm applied to OCT images.

The role of AI-based analysis is critical for in-home monitoring, as the large number of images produced by patients with up to daily frequency does not lend itself to manual review and grading. The reliability of AI algorithms is critical for giving physicians confidence to utilize such data in their clinical decision making.

The cross-sectional study involved 336 nAMD patients from six US retina clinics. Study subjects presented with a diverse set of co-existing pathologic features, which make segmenting specific biomarkers associated with nAMD particularly challenging for AI algorithms. Patients took four images each on two home OCT devices in clinic without any technician assistance. Patients were also imaged on an in-office OCT device for comparison.

The AI algorithm looked for hypo-reflective spaces (HRS) in the images, including sub- and intraretinal spaces, and quantified total retinal hypo-reflective space (TRO) volumes. The home and in-office OCT images were then graded by experts for detecting HRS in the intra- and subretinal compartments. The study looked at two key outcomes: a) repeatability of the algorithm estimating TRO volumes on home OCT images, b) the agreement between the AI and expert graders in segmenting HRS.

The algorithm performed well in both outcomes, showing strong repeatability and agreement with expert graders. Specifically, the repeatability of TRO estimates from successive home OCT images and the algorithm was higher than repeatability of estimates using an in-office imaging device and expert grading. The agreement of HRS segmentation between AI and graders was no different than the agreement between graders themselves.

"This is one of the most significant studies related to artificial intelligence and retinal disease management as it led to clearance of the first-ever AI for OCT," said Eric Schneider, MD of Tennessee Retina and senior author of the study. "It should give retina specialists a great deal of confidence in adopting this patient monitoring program."

"We are excited to see the publication of the pivotal study results that led to the first FDA clearance of an AI algorithm for processing OCT images", said Kester Nahen, PhD, CEO of Notal Vision. "The positive results enable SCANLY Home OCT, the first marketing authorized

home imaging device in eyecare, to provide physicians with actionable insights in disease activity and treatment response between patients' office visits."

The published study sets a benchmark for the complexity and level of rigor required to achieve regulatory clearance for quantitative, AI-based analysis of OCT images. Study results will be presented at the Bascom Palmer Eye Institute Angiogenesis meeting by Anat Loewenstein, MD professor and director of the Department of Ophthalmology at Tel Aviv Medical Center in Tel Aviv, Israel

Reference:
1. Schneider EW et al. Pivotal Trial Toward Effectiveness of Self-administered OCT in Neovascular Age-related Macular Degeneration. Report 2—Artificial Intelligence Analytics. *Ophthalmology Science.* Volume 5, Issue 2, April 2025. doi: 10.1016/j.xops.2024.100662.

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About Notal Vision

Notal Vision is a patient-centric ophthalmic remote monitoring services provider extending retinal disease monitoring from the clinic to the home, providing physicians with remote monitoring services to support their patient care between office visits. With a proven approach to home-based, self-operated diagnostics, AI-enabled data analysis, and patient engagement, our goal is to help doctors preserve patients' vision. www.notalvision.com

The Notal Vision Monitoring Center (NVMC) is a remote, Medicare credentialed ophthalmic monitoring center and the epicenter of patient engagement. Led by practicing ophthalmologists and supported by certified ophthalmic professionals, the Monitoring Center offers a nationwide age-related macular degeneration (AMD) home monitoring service for patients.

The ForeseeHome® AMD Monitoring Program is a comprehensive program, which includes an FDA-cleared device that monitors visual changes in intermediate dry AMD patients at risk of vision loss from undiagnosed wet AMD.

With the addition of the SCANLY Home OCT system to the Notal Vision family of monitoring products, wet AMD patients are able to perform technician-free OCT scanning at home with rapid and self-guided fixation – critical components, especially for elderly patients frequently with pre-existing vision loss. The Notal Vision Monitoring Center provides patient data to the physician via the online SCANLY Portal. Physicians are provided 24/7 access to all their patients' B-scan images from each SCANLY Home OCT scan with the location of the hypo-reflective spaces annotated on each B-scan. The Notal OCT Analyzer (NOA), a proprietary

machine learning algorithm, performs automated analysis of the Home OCT scans and generates a report to the physician when a physician specified change is detected. Following physician receipt of a change notification, a patient may be brought to the office for further evaluation if warranted.