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Eyenuk's AI eye screening system for Diabetic Retinopathy demonstrates exceptional performance

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The EyeArt AI Eye Screening System makes in-clinic, real-time DR screening possible for any physician, enabling quick and accurate identification of patients with referable DR during diabetic patient's regular physician visit.

Eyenuk, a global artificial intelligence (AI) medical technology and services company and the leader in real-world applications for AI Eye Screening has announced results from its landmark prospective, multi-center, pivotal clinical trial to validate the EyeArt AI Eye Screening System for autonomous detection of diabetic retinopathy (DR), a blinding disease estimated to affect 191 million people globally by the year 2030. The results were presented at the ARVO Imaging in the Eye Conference by Jennifer Lim, MD, Marion H. Schenk Esq. Chair and Professor of Ophthalmology and Director of Retina Service at the University of Illinois at Chicago.

The EyeArt AI Eye Screening System makes in-clinic, real-time DR screening possible for any physician, enabling quick and accurate identification of patients with referable DR during diabetic patient's regular physician visit. Once the patient's fundus images have been captured and submitted to the EyeArt System, the DR screening results are available to view and export to a PDF report in less than 60 seconds. The EyeArt system can free eye care specialists to focus on sight-saving treatment rather than screening for DR.

Key aspects of this prospective, multi-center, pivotal clinical trial (NCT03112005) include:

- 942 subjects enrolled at 15 centers that included primary care, endocrinology, ophthalmology, and retina specialty clinics.
- EyeArt AI system's assessment of 2-field undilated images was compared to comprehensive clinical reference standard comprising adjudicated grading of 4 wide-field dilated stereo images on the ETDRS severity scale[2]. The grading was performed by the Wisconsin Fundus Photograph Reading Center.
- Multiple fundus camera models were included and evaluated with the EyeArt AI eye screening system.
- Board-certified ophthalmologists (in a subset of sites) independently performed dilated ophthalmoscopy, the most-prevalent method for DR screening today.

Study results show that all pre-determined primary endpoints were met with $p<0.0001$. "This study is significant as it shows this AI system is quite accurate in determining the presence of referable diabetic retinopathy by a very rigorous method which compared the AI results to that of photos read by expert graders of diabetic retinopathy," said Dr. Jennifer Lim, an Investigator in the EyeArt pivotal trial. "In this prospective multi-center study, we showed feasibility and applicability of this system for screening for referable diabetic retinopathy. This holds great promise in accomplishing screening of the millions of diabetic patients for referable diabetic retinopathy in order to identify those at risk of visual loss and refer them for prompt treatment by ophthalmologists!" Dr. Lim continued, "The high sensitivity and specificity achieved by the EyeArt system shows that it can enable point-of-care DR screening and that it is a safe way to identify patients with DR who require ophthalmology referrals."

"Completion of this EyeArt prospective pivotal trial is an exciting step for Eyenuk, and this study once again validates the EyeArt System's exceptional diagnostic sensitivity and specificity without needing dilation," said Kaushal Solanki, PhD, Founder and CEO of Eyenuk. "Today I am proud to say that artificial intelligence is living up to its promise and can deliver substantial and meaningful impact to patients' lives globally. Regular and quality eye screening can soon be accessible and affordable to hundreds of millions of people living with diabetes, leading to vision preservation for many of them."

About the EyeArt AI Eye Screening System

The EyeArt AI Eye Screening System is the most extensively validated AI technology for autonomous detection of DR, tested in the real-world on more than half million patient visits globally with over two million images collected in real-world clinical environments. The EyeArt System was developed with funding from the US National Institutes of Health (NIH) and is validated by the UK National Health Service (NHS). The EyeArt System has CE marking in the EU and a Health Canada license. In the US, the EyeArt System is limited by federal law to investigational use.

About Diabetic Retinopathy (DR)

DR is a complication of diabetes caused by damage to the blood vessels of the light-sensitive tissue at the back of the eye (retina). It is a silently progressing disease that at first may cause no symptoms or only mild vision problems. Eventually, it can cause blindness. The condition can develop in anyone who has type 1 or type 2 diabetes. It is estimated that one-third of all patients with diabetes will develop DR, making it the leading cause of vision loss in working-age adults.

While DR screening is recommended for all diabetic patients, less than half get screened annually, even in the developed world. Since diabetic patients outnumber ophthalmologists by 1,600 to 1 in the U.S., there are just not enough eye care specialists to meet the DR screening needs of the growing diabetic population. Even for those receiving their annual screening, ophthalmology appointment wait times for DR screening can be weeks or even months.

Eyenuk is a global artificial intelligence (AI) medical technology and services company and the leader in real-world AI Eye Screening for autonomous disease detection and AI Predictive Biomarkers for risk assessment and disease surveillance. Eyenuk is on a mission to screen every eye in the world to ensure timely diagnosis of life- and vision-threatening diseases, including diabetic retinopathy, glaucoma, age-related macular degeneration, stroke risk, cardiovascular risk and Alzheimer's disease.