IDx | Case Study

IDx-DR Trial Site Identifies Patient at Risk of Vision Loss

Introduction

In April 2018, the U.S. Food and Drug Administration made a historic decision: It authorized the marketing of IDx-DR, an AI system that enables the automated detection of diabetic retinopathy in primary care.

This is the first time the FDA has granted clearance for an autonomous AI diagnostic system that does not require a physician to interpret results.

IDx-DR detects more than mild diabetic retinopathy (DR), a complication of diabetes that causes blindness in up to 24,000 Americans annually. Early detection and treatment of DR can prevent or delay visual loss or blindness in 90 percent of people with diabetes, according to the U.S. Centers for Disease Control (CDC).

The FDA's decision to clear IDx-DR was based, in significant part, on data from a pivotal clinical trial evaluating the safety and efficacy of the system. The trial involved 900 subjects with diabetes at 10 sites across the United States.

Wilmington Health, a multispecialty medical center in Wilmington, N.C., was the largest participating trial site, enrolling approximately 150 people with diabetes.

According to John C. Parker, MD, FACE, ECNU, an endocrinologist who led the study at Wilmington Health, healthcare professionals can have strong confidence in the system's ability to detect DR because of the trial's robust research framework.

"Not all trials are as thorough as this one, in that the IDx-DR system's accuracy was checked against the leading reference standard for assessing diabetic retinopathy," said Parker.

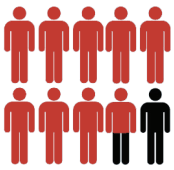
John C. Parker, MD, FACE, ECNU

One Patient's Story

To understand the potential impact of IDx-DR on reducing blindness, it's helpful to examine the case of one patient who participated in the trial at Wilmington. **According to Parker, it is unlikely the patient, a female 49-year-old with diabetes, would have been identified as someone with DR had she not been enrolled in the trial.**

After being tested with IDx-DR, the patient was referred to an ophthalmologist who started her on a treatment regimen. In other words, after participation in the study, "her risk of blindness was substantially lowered and a genuine acknowledgement of her condition was accepted," Parker said.

As with many individuals with diabetes, the threat of losing her vision was a catalyst for the patient to start managing her blood glucose levels and taking better care of her overall health.



Over 85% of individuals with diabetes will develop DIABETIC RETINOPATHY within 20 years

"The patient felt like it was a wake-up call – an awareness moment that will help her to take charge of her diabetes," Parker said. "Sometimes you don't see the real manifestations of diabetes, but when you have something that is concrete and objective, it gets the patient's attention. There are crossroads that people enter, and this was one of them."

It's important to note the actual diagnosis of the patient in the clinical trial was made by the reading center. However, the robust study design enabled a level of care that was comprehensive enough for the patient to be identified and treated.

IDx-DR is intended for use to automatically detect more than mild diabetic retinopathy (mtmDR) in adults ages 22 years of age or older diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. IDx-DR is indicated for use with the Topcon NW400.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

Minimal Training, Fast Results

As an endocrinology practice embedded within a primary care group, Parker's clinic was a perfect setting for the study, largely due to the fact that IDx-DR is intended for use in primary care – the most frequently visited care setting for the vast majority of people with diabetes.

Training Time:

4 Hours

Image Throughput:

96%

After undergoing a standard four-hour training program, staff had mastered the ability to capture high-quality images with the assistance of the IDx-DR AI system. Ultimately, operators were able to generate a diagnostic result for over 95 percent of subjects. One medical assistant who performed many of the image captures **"was impressed by the ease-of-use and the quality and clarity of the images," Parker said.**

The system was designed to fit seamlessly into existing clinical workflows, resulting in minimal necessary training and a simple implementation.

"I'm encouraged by IDx-DR's capacity to help close care gaps in our diabetic patient population," Parker said. "Its greatest strengths include ease-of-use and its ability to be deployed in the care setting where most patients already are."

What's Next

IDx-DR's greatest benefit may lie in its potential to improve accessibility to DR testing – or in other words, make DR testing more readily available for people with diabetes who aren't adhering to recommendations for annual eye exams, according to Parker. **There is certainly a sizable patient population for whom increased accessibility would be beneficial; just half of the estimated 30 million adults in the U.S. with diabetes received a retinal exam by an eye doctor in the past year, according to the CDC.**

30 Million

Adults in U.S. with Diabetes

~50%

DR Exam Compliance Rate

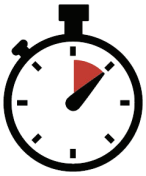
Through its use of autonomous AI to detect DR in the frontlines of care, rather than employing a specialized clinician, IDx-DR holds significant potential to close the care gap for people with diabetes foregoing annual eye exams.

While the system is not intended as a replacement for the annual eye exam, it offers important access to eyecare for the approximately 30 million U.S. adults classified as being at high-risk for vision loss from diabetic retinopathy who have not visited an eye doctor in the past 12 months. Patients who test positive for DR are referred to an eye specialist for further review.

For healthcare professionals, a test by IDx-DR can serve as a valuable reinforcement tool to persuade behavior change for those at risk of diabetic retinopathy. Conversely, negative results can provide some reassurance that patients who are managing the disease well are on the right track, according to Parker.

At Wilmington Health, Parker looks forward to further scaling the practice's use of IDx-DR to make DR detection available to a wider, often-underserved patient population. **"I am excited about the possibility of moving forward with IDx-DR in the real-world clinical setting," Parker said.**

With IDx-DR, visits can include an EASY, ACCURATE test for diabetic disease



Patients will be notified DURING THEIR OFFICE VISIT if a potentially treatbale level of diabetic retinopathy is detected

Eye care professionals receiving IDx-DR referrals will have the opportunity to PREVENT VISION LOSS IN TREATABLE PATIENTS

About IDx

IDx is a leading AI diagnostics company on a mission to transform the quality, accessibility, and affordability of healthcare world-wide. Founded in 2010 by a team of world-renowned clinician scientists, IDx is focused on developing clinically-aligned autonomous algorithms that detect disease in medical images. **For more information, visit www.eyediagnosis.net.**

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