A Year in the Life of a Trailblazing AI Healthcare Company
How IDx Grabbed the Nation's Attention with a Breakthrough Autonomous AI System that Detects a Leading Cause of Blindness

(Coralville, Iowa) December 12, 2018 – AI diagnostics company IDx spent the first 8 years of its existence operating in stealth mode. But on April 11, 2018, that instantly changed when the company hit the national spotlight after receiving FDA clearance for IDx-DR, an autonomous AI system that detects diabetic retinopathy, the leading cause of blindness in the U.S.

This marked the first time the FDA has ever cleared an autonomous AI diagnostic system that does not require a physician to interpret the images or results, enabling specialty level diagnostics in primary care. However, this historic clearance is only one of many milestones achieved by IDx in 2018. The company also secured a significant round of venture funding and launched IDx-DR in patient care.

At a time when the world is eager to see AI make a real-world impact amidst the hype, it is refreshing to see the technology being used to improve patients' lives. For people with diabetes living in rural areas, like Kevin Sales, being able to be tested for diabetic retinopathy in a single office visit could be what prevents him from going blind.

"We worked hard for many years to prove autonomous AI is safe and bring IDx-DR to patients, so it is incredibly gratifying to see it being used in clinical care," said Dr. Michael Abramoff, the founder and CEO of IDx. "What we accomplished this year lays a strong foundation that will allow us to reach even more patients in 2019 and continue our mission to improve the quality, accessibility, and affordability of healthcare."

IDx 2018 highlights:

- IDx-DR is granted a "Breakthrough Device" designation from the FDA — a classification that offers expedited review of technologies that "provide for more effective treatment or diagnosis of a life-threatening or irreversibly debilitating disease or condition" (February 2018)

- IDx founder and CEO Dr. Michael Abramoff awarded U.S. Patent No. 9,924,867 for systems that automatically measure cardiovascular health from the retina (March 2018)

- IDx-DR earned FDA clearance, becoming the first autonomous AI system to be cleared to make an assessment without requiring a physician to interpret the images or results (April 2018)

- IDx-DR launched at the Diabetes and Endocrinology Center at University of Iowa Health Care (June 2018)

- Pivotal trial study for IDx-DR FDA clearance published in Nature Digital Medicine (August 2018)

- IDx closed series A funding from strategic investors, including 8VC and Optum Ventures, the venture arm of UnitedHealth Group (September 2018)

- IDx signed an exclusive AI partnership agreement with Topcon, the world's leading ophthalmic device manufacturers (October 2018)

- Dr. Abramoff testified for the Federal Trade Commission on AI in healthcare (November 2018)

- Dr. Abramoff awarded U.S. Patent No. 10,140,699 which covers AI systems, both medical and non-medical, that use sample training data to detect objects in images (November 2018)

- IDx more than doubled its staff, growing from 23 employees to 51 in 2018 (December 2018)

About IDx
IDx is a leading AI diagnostics company on a mission to transform the quality, accessibility, and affordability of healthcare. Founded in 2010 by a team of world-renowned clinician scientists, the company is focused on developing clinically-aligned autonomous AI that detect disease in medical images. By enabling diagnostic assessment in primary care settings, IDx aims to increase patient access to high-quality, affordable disease detection.

The company's first product, IDx-DR, is an FDA-cleared AI-based diagnostic system designed for use at the front lines of care to detect diabetic retinopathy. IDx-DR is intended for use by health care providers to automatically detect more than mild diabetic retinopathy in adults (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, an easy to use and highly accurate robotic fundus camera.

IDx is developing additional AI-based diagnostic systems for the detection of macular degeneration, glaucoma, Alzheimer's disease, cardiovascular disease, and stroke risk.

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