

Federal Register Notice 86 FR 46278, <https://www.federalregister.gov/documents/2021/08/18/2021-17737/request-for-information-rfi-on-an-implementation-plan-for-a-national-artificial-intelligence>, October 1, 2021.

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# Request for Information (RFI) on an Implementation Plan for a National Artificial Intelligence Research Resource: Responses

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October 1, 2021

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**Re: RFI Response: National AI Research Resource**

Dear Dr. Lander and Dr. Panchanathan,

On behalf of Digital Diagnostics, a national healthcare innovator dedicated to health equity and access headquartered in Coralville, Iowa, we are pleased to offer our feedback on the “Request for Information: National AI Research Resource (NAIRR).” We believe that patient access to rigorously validate, U.S. Food and Drug Administration (FDA) authorized healthcare AI is an important tool to address social determinants of health and health equity. The autonomous AI service provided by our technology, IDx-DR (described by CPT code 92229), has transformed access to care for Medicare beneficiaries with diabetes and improved the ability of practitioners to prevent diabetes-related vision loss at the point-of-care. We offer below additional detail on our technology and our specific experience in the area of AI ethics and bias.

### **Digital Diagnostics’ Autonomous AI Technology**

Digital Diagnostics, formerly IDx Technologies, is a pioneering autonomous AI diagnostics company on a mission to transform healthcare accessibility, quality, and affordability. Its flagship product IDx-DR (the service described by CPT 92229) is an autonomous AI system that was granted De Novo authorization by the U.S. Food & Drug Administration (FDA) to diagnose diabetic retinopathy and diabetic macular edema after rigorous FDA validation for safety and equity. The FDA determined that IDx-DR met the standards for “breakthrough device” designation in accordance with section 3051 of the 21<sup>st</sup> Century Cures Act. The technology has proven that intelligent diagnostic platforms can be used safely, efficiently, and equitably to improve patient outcomes.

Founded and led by Michael Abramoff, MD, PhD, a practicing physician and fellowship-trained retina specialist, Digital Diagnostics uses a patented biomarker-based approach to build autonomous AI, and a

rigorous, ethical framework for designing, developing, and deploying its AI.<sup>1,2,3</sup> Driven to remove the health inequities in diabetes-caused vision loss and blindness by early detection and timely treatment, the IDx-DR system was designed to make the diabetic eye exam more accessible, especially for underserved populations, including racial and ethnic minorities and rural populations. The AI driven system performs the process of the diabetic eye exam at the point-of-care following similar cognitive processes as a highly trained eye care provider.

The IDx-DR technology diagnoses diabetic retinopathy and diabetic macular edema during a patient's routine diabetes management visit, closing a significant care gap. Thirty million people in the U.S. have diabetes, and diabetic retinopathy affects nearly 30 percent of diabetic patients.<sup>4</sup> The disease is the most frequent cause of blindness among people ages 20-74 years old.<sup>5</sup> In spite of the severity of diabetic retinopathy, nearly half of Medicare beneficiaries who have diabetes do not have an annual eye exam,<sup>6</sup> and only 15 percent of people with diabetes have regular eye exams, as per the Standard of Diabetes Care from the American Diabetes Association (ADA).<sup>7</sup> Diabetic retinopathy accounts for nearly \$500 million in total direct medical costs annually,<sup>8</sup> much of which is due to late stage, undiagnosed disease.

Diabetic retinopathy and its concomitant visual loss and blindness is a major source of health disparities. Greater access to the diabetes eye exam is an important health equity issue, as significant health disparities exist in diabetes care and access to the diabetic eye exam. According to the U.S. Centers for Disease Control (CDC), the percentage of U.S. white adults with diagnosed diabetes (7.4 percent) is less than that of Black (12.1 percent) and Hispanic (12.7 percent) adults, and roughly half of American Indian /Alaska Native (15.1

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<sup>1</sup> Abramoff, M. D., D. Tobey, and D. S. Char. "Lessons Learned About Autonomous Ai: Finding a Safe, Efficacious, and Ethical Path through the Development Process." *Am J Ophthalmol* 214, no. 1 (2020): 134-42. <https://dx.doi.org/10.1016/j.ajo.2020.02.022>.

<sup>2</sup> Char, Danton S., Michael D. Abramoff, and Chris Feudtner. "Identifying Ethical Considerations for Machine Learning Healthcare Applications." *The American Journal of Bioethics* 20, no. 11 (2020/11/01 2020): 7-17. <https://dx.doi.org/10.1080/15265161.2020.1819469>.

<sup>3</sup> Abramoff, M.D., B. Cunningham, B. Patel, M.B. Eydelman, T. Leng, T. Sakamoto, R. M. Wolf, A.K. Manrai, J.M. Ko, and M.F. Chiang. "Foundational Considerations for Artificial Intelligence," *Ophthalmology* [in press] (2021). [https://www.aajournal.org/article/S0161-6420\(21\)00643-6/fulltext](https://www.aajournal.org/article/S0161-6420(21)00643-6/fulltext).

<sup>4</sup> Lundeen EA, Wittenborn J, Benoit SR, Saaddine J. Disparities in Receipt of Eye Exams Among Medicare Part B Fee-for-Service Beneficiaries with Diabetes — United States, 2017. *MMWR Morb Mortal Wkly Rep* 2019;68:1020–1023. DOI: [http://dx.doi.org/10.15585/mmwr.mm6845a3external icon](http://dx.doi.org/10.15585/mmwr.mm6845a3external%20icon).

<sup>5</sup> U.S. Centers for Disease Control & Prevention, "Vision Loss and Age" (accessed August 19, 2021), available at <https://www.cdc.gov/visionhealth/risk/age.htm>.

<sup>6</sup> Lundeen EA, Wittenborn J, Benoit SR, Saaddine J. Disparities in Receipt of Eye Exams Among Medicare Part B Fee-for-Service Beneficiaries with Diabetes — United States, 2017. *MMWR Morb Mortal Wkly Rep* 2019;68:1020–1023. DOI: [http://dx.doi.org/10.15585/mmwr.mm6845a3external icon](http://dx.doi.org/10.15585/mmwr.mm6845a3external%20icon).

<sup>7</sup> Benoit, S. et al. "Eye Care Utilization Among Insured People with Diabetes in the U.S., 2010-2014," *Diabetes Care* (March 2019) available at <https://pubmed.ncbi.nlm.nih.gov/30679304/>.

<sup>8</sup> Rein et al. "The Economic Burden of Major Adult Visual Disorders in the United States," *JAMA Ophthalmology* (2006) available at <https://jamanetwork.com/journals/jamaophthalmology/fullarticle/418866>.

percent) adults.<sup>9</sup> Although Medicare covers annual eye exams for all diabetic patients, approximately 55 percent of white Medicare patients with diabetes received an annual eye exam in 2017, while the prevalence of having an eye exam was lower for Black (48.9 percent) and Hispanic (48.2 percent) patients.<sup>10</sup>

The IDx-DR service provides a complete point-of-care service, including image acquisition, AI driven quality feedback, analysis and individualized, per patient results. As CMS noted in the preamble to the CY 2021 PFS final rule, “the AMA CPT Editorial Panel also created CPT 92229 (*imaging of retina for detection of monitoring of disease; with point-of-care automated analysis with diagnostic report; unilateral or bilateral*) for point-of-care automated analysis that uses innovative artificial intelligence technology to perform the interpretation of the eye exam, without requiring that an ophthalmologist interpret the results. CPT code 92229 can be used at an outpatient clinical setting and the artificial intelligence technology interprets the test instead of a remotely located ophthalmologist.”<sup>11</sup>

### **Health Equity**

The OSTP and NSF pose the question, “How can the NAIRR and its components reinforce principles of ethical and responsible research and development of AI, such as those concerning issues of racial and gender equity, fairness, bias, civil rights, transparency, and accountability?” Our experience in AI ethics and bias may inform NAIRR’s efforts in this regard.

IDx-DR (described by CPT 92229) was designed specifically to create equitable access for diabetes patients in underserved and rural areas. The service has already been used to test thousands of patients across the U.S and has identified previously undiagnosed cases of disease that would have otherwise gone undetected and likely resulted in irreversible vision loss. For example, at the University Medical Center (UMC) in New Orleans, a predominantly Black patient population, there had been a backlog of over 800 patients with diabetes who had not received an eye exam. Wait times for a visit to an eye care provider in that area exceeded 4 months, leading many patients to give up seeking eye care. After adoption of the autonomous AI service in the diabetes clinic at the point of care, backlogs were entirely eliminated, and over 25% of the patients were identified with potentially blinding diabetic retinopathy that otherwise would have been entirely missed.<sup>12,13</sup>

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<sup>9</sup> U.S. Centers for Disease Control, “Addressing Health Disparities in Diabetes,” *2017 Diabetes Score Card* (2017) available at <https://www.cdc.gov/diabetes/disparities.html>.

<sup>10</sup> Lundeen EA, Wittenborn J, Benoit SR, Saaddine J. Disparities in Receipt of Eye Exams Among Medicare Part B Fee-for-Service Beneficiaries with Diabetes — United States, 2017. *MMWR Morb Mortal Wkly Rep* 2019;68:1020–1023. DOI: [http://dx.doi.org/10.15585/mmwr.mm6845a3external icon](http://dx.doi.org/10.15585/mmwr.mm6845a3external%20icon).

<sup>11</sup> CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies, available at <https://public-inspection.federalregister.gov/2020-26815.pdf> (“2021 MPFS”), page 489.

<sup>12</sup> Harris, Richard, “FDA AI Challenge: How to Assess Safety and Effectiveness,” *National Public Radio* (April 19, 2019.) Available at <https://www.npr.org/sections/health-shots/2019/04/14/711775543/how-can-we-be-sure-artificial-intelligence-is-safe-for-medical-use>.

<sup>13</sup> Company data. Digital Diagnostics. August 26, 2021.

In another clinical setting in Georgia, incorporating IDx-DR (CPT 92229) directly into the comprehensive diabetes management workflow increased compliance with the quality measure for evaluation of diabetic retinopathy from 16 to over 50 percent. Relatedly, the clinic almost tripled the number of previously undiagnosed vision related disease occurrences and was able to arrange immediate follow up with eye care specialists. And in Alabama, after implementation during the PHE at a Federally Qualified Health Center (FQHC) serving diverse and underserved beneficiaries with multiple chronic conditions, over 25% of the patients had potentially blinding diabetic retinopathy. Without the IDx-DR service, many of these patients would have gone on to develop costly vision threatening complications from diabetes. Finally, a cost effectiveness analysis from the patient perspective on IDx-DR installed at Johns Hopkins showed that autonomous AI for the diabetic eye exam reduces patients co-pay, compared to in-person eye care provider visit, thereby improving access for socioeconomically disadvantaged populations.<sup>14</sup>

In addition to the positive impact that increased access can have to advance health equity, we have also focused on how to design our clinical algorithms to eliminate bias and support equitable care, including the development of a rigorous ethical framework.<sup>15,16,17</sup> Accordingly, when conceptualizing IDx-DR, we were concerned with the risk of racial, ethnic and other inappropriate bias during its entire lifecycle, namely, impact on patient benefit, algorithm design, algorithm training, AI validation, and populations in which it is implemented. Thus we chose the exact severity of diabetic retinopathy and macular edema diagnostic cutoffs, designed the AI to mitigate diagnostic and follow-up bias, and analyzed the distribution during the machine learning training phase.<sup>18</sup> When designing the first ever preregistered pivotal trial for autonomous AI together with FDA, we created a novel endpoint for equity.<sup>19</sup> This endpoint tested whether or not there was any race or ethnicity effect on the accuracy of the AI – the trial showed there was none. Finally, we chose to emphasize implementation in those populations where health disparities for diabetic retinopathy need to be addressed.<sup>20</sup>

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<sup>14</sup> Wolf RM, Channa R, Abramoff MD, Lehmann HP. Cost-effectiveness of Autonomous Point-of-Care Diabetic Retinopathy Screening for Pediatric Patients With Diabetes. *JAMA Ophthalmol*. Oct 1 2020;138(10):1063-1069. doi:10.1001/jamaophthalmol.2020.3190

<sup>15</sup> Abramoff, M.D., B. Cunningham, B. Patel, M.B. Eydelman, T. Leng, T. Sakamoto, R. M. Wolf, A.K. Manrai, J.M. Ko, and M.F. Chiang. "Foundational Considerations for Artificial Intelligence," *Ophthalmology* [in press] (2021). [https://www.aaojournal.org/article/S0161-6420\(21\)00643-6/fulltext](https://www.aaojournal.org/article/S0161-6420(21)00643-6/fulltext).

<sup>16</sup> Char, Danton S., Michael D. Abramoff, and Chris Feudtner. "Identifying Ethical Considerations for Machine Learning Healthcare Applications." *The American Journal of Bioethics* 20, no. 11 (2020/11/01 2020): 7-17. <https://dx.doi.org/10.1080/15265161.2020.1819469>.

<sup>17</sup> Abramoff, M. D., D. Tobey, and D. S. Char. "Lessons Learned About Autonomous Ai: Finding a Safe, Efficacious, and Ethical Path through the Development Process." *Am J Ophthalmol* 214, no. 1 (2020): 134-42. <https://dx.doi.org/10.1016/j.ajo.2020.02.022>.

<sup>18</sup> Ibid.

<sup>19</sup> Abramoff, M. D., D. Tobey, and D. S. Char. "Lessons Learned About Autonomous Ai: Finding a Safe, Efficacious, and Ethical Path through the Development Process." *Am J Ophthalmol* 214, no. 1 (2020): 134-42. <https://dx.doi.org/10.1016/j.ajo.2020.02.022>.

<sup>20</sup> Abramoff, M.D., B. Cunningham, B. Patel, M.B. Eydelman, T. Leng, T. Sakamoto, R. M. Wolf, A.K. Manrai, J.M. Ko, and M.F. Chiang. "Foundational Considerations for Artificial Intelligence," *Ophthalmology* [in press] (2021). [https://www.aaojournal.org/article/S0161-6420\(21\)00643-6/fulltext](https://www.aaojournal.org/article/S0161-6420(21)00643-6/fulltext).

**Conclusion**

Thank you for your efforts to provide feedback on the NAIRR. If you have any questions on our comments, please contact Juli Goldstein, MHS, Vice President, Government Affairs & Market Access at [REDACTED]

Sincerely,

Michael Abramoff, MD, PhD  
Founder and Executive Chairman  
Digital Diagnostics, Inc.