***Implementing point-of-care diabetic retinopathy screening using autonomous artificial intelligence (AI) in a pediatric diabetes center to improve screening rates and early detection of diabetic retinopathy in youth with diabetes***

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Aims:

1. To determine if POC AI for the diabetic eye exam is more effective for screening and diagnosis of diabetic retinopathy compared to ECP, in a randomized control trial recruiting participants at two clinical sites.
2. To assess follow-up rates with ECP in participants in the standard of care arm, in comparison to participants in the AI arm who screen positive and receive a referral to ECP for further evaluation.
3. To evaluate if point-of-care autonomous AI diabetic eye exams integrated into the diabetes clinic mitigates racial/ethnic disparities in access to diabetic eye exams.

Summary of project progress since last progress report 8/25/2021

Redcap database built

Randomization allocation for randomized control trial generated and uploaded into redcap

IRB approval obtained November 18, 2021; IROC Committee approval obtained

Retinal camera software updated November 23, 2021

First patient enrolled in trial November 24, 2021

Upcoming milestones:

Data safety monitoring board (DSMB) meeting for study Dec 7, 2021

Enrollment at second site (Mount Washington) to begin Dec 20, 2021

Ongoing plans and target

For Aim 1, the randomized control study requires 164 participants, which we believe can be recruited at both sites between November 2021 and March 2022.

Aim 2 to assess follow-up rates with ECP will require follow-up for these participants for 6 months and will extend until June – Sept 2022. Aim 3 will include a large cohort study at both research sites and will begin after completion of the randomized control trial.

Problems that have arisen

The startup for this project took longer than expected as noted in the prior progress report, particularly due to the regulatory approvals. Although this is a low-risk study, retinal images are now considered biometric identifiers and thus required many discussions with the IRB, investigators in the Wilmer Eye Institute at Johns Hopkins, and clearance by the Imaging and Recording Oversight Committee.

Meeting objectives by the end of this funding cycle

We will partially meet the goals of Aims 1 & 2 by completion of the funding cycle. We anticipate completion of patient recruitment for Aim 1 by March, 2022, and completion of follow-up (Aim 2) by September 2022. Thus ***we are requesting a no-cost extension through June 2022*** to continue utilizing the funds granted by the DRC as we complete this randomized control trial. Data analysis and the larger cohort study for Aim 3 will continue beyond the funding cycle.

Abstracts/Presentation:

Plan to submit late-breaking abstract on randomized control trial preliminary results to American Diabetes Association 82ND Scientific Sessions to be presented in June 2022.