The Collaborative Community on Ophthalmic Imaging

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Purpose:
The purpose of the presentation is to introduce the formation, mission and initial efforts of the Collaborative Community on Ophthalmic Imaging (CCOI) which was formed in April 2019 and recognized by the FDA in September 2019 as an independent self-governing consortium of stakeholders whose mission is to act as a forum for the purpose of helping speed innovation in healthcare imaging technology. ([https://www.idigitalhealth.com/news/fda-announces-participation-in-collaborative-communities](https://www.idigitalhealth.com/news/fda-announces-participation-in-collaborative-communities))

Methods:
In 2018 the FDA and CDRH designated as one of its key strategic priorities the formation of collaborative communities bringing together stakeholders to achieve common outcomes, solve shared challenges and leverage collective opportunities. Given the profound impacts of newer forms of laser based ophthalmic image acquisition, as well as the first successful efforts to use Artificial Intelligence (AI) and Machine Learning (ML) techniques for autonomous interpretation, a group was brought together from within the retinal and glaucoma communities to develop a charter and mission including an organizing committee and disease specific sub-groups.

Results:
An organizing committee of the CCOI was formed with broad global representation from multiple specialty societies, including but not limited to the AAO, ASCRS, Retina Society, AGS, ESCR, PAAO and APAO, as well as the FDA, industry and patient advocacy organizations. A series of meetings were held in conjunction with their annual meetings as well as by video-conference throughout 2019-2020 and separate disease specific work-groups were formed in the areas of ROP, Age Related Macular Degeneration, Choroidal Melanoma, and Glaucoma. A fifth horizontal workgroup on the larger disease agnostic challenges of software technology development including best practices and platforms was also formed. Their efforts have been focused on identifying gold standards for rigorous clinical and scientific studies that can help to inform regulatory oversight of the increasingly important domain Software as a Medical Device (SaMD) including AI and ML enabled algorithmic image interpretation systems. The results of those efforts to date of those work-groups will be summarized in the presentation.

Conclusions:
The CCOI represents a potential advance in helping to speed the development of new imaging technology including consensus-building around clinical endpoint standard setting for clinical research and regulatory science.