THE COLLABORATIVE COMMUNITY ON OPHTHALMIC IMAGING

FORMATION MISSION AND INITIAL EFFORTS

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Disclosures for the Presenter Mark Blumenkranz

- BVI
- Combangio Corporation
- Iveric
- Jellisee
- Kedalion Therapeutics
- Lagunita Biosciences
- One Medical
- Optrx
- PEEL Therapeutics
- Verana Health
Ophthalmic Image Capture is Nearly 100 Years Old (1925) But Innovation Was Modest at Best for the First 50 Years Until the Advent of Microprocessors and Lasers in the Late 1970’s

RETINAL CAMERAS AND YEARS LAUNCHED:

1925

Price at launch: $768
Inflation Adjusted Price: $10,400

1955

Price at launch: $3,000
Inflation Adjusted Price: $26,635

2005

Price at launch: $40,002
Inflation Adjusted Price: $48,734

SOURCE: www.zeiss.com
It Finally Exploded Beginning in the Mid 1990’s With Powerful Table-Top Devices Enabled by Advances in Digital Capture and Display, Powerful Microcomputers, Widefield and Adaptive Optics and Laser Scanning Fueling OCT Development

The Invention of Powerful Miniaturized Smart Phones from Apple, Samsung and Google Capable of Capturing Medical Grade Images and Related Out-of-Office Monitoring Created Opportunities for Care Outside the Traditional Office Setting.

DIGISIGHT TECHNOLOGIES

D-EYE

VITAL ART AND SCIENCE

WELCH ALLYN

PEEK
The Use of Portable Devices Has Had a Major Impact in Improving Screening and Advanced Care to Under-Served Populations Around the World
Pediatric and Neonatal Eye Exams in Europe & Africa

Non-contact smartphone-based fundus imaging compared to conventional fundus imaging: a low-cost alternative for retinopathy of prematurity screening and documentation

Maximilian W. M. Wintergerst, Michael Petraki, Jenny O. Li, Petra P. Larsen, Moritz Berger, Frank G. Holz, Robert P. Finger & Tim L. Krohne

Paxos being used in Africa for pediatric examinations
Advances in Machine Learning Have Resulted in the Development of AI Enabled Autonomous Algorithmic Interpretation of Ophthalmic Images that Rival Expert Human Graders and Recently Been Approved for Human Use by the FDA in Ophthalmology.
FDA’s CDRH Identified a Need for Well-Defined Methods to Inform Safety & Effectiveness of Rapidly Evolving Digital Health Technologies

Collaborative Communities: Addressing Health Care Challenges Together

In the medical device ecosystem, collaborative communities bring together stakeholders to achieve common outcomes, solve shared challenges, and leverage collective opportunities. CDRH believes collaborative communities can contribute to improvements in areas affecting patients and health care in the United States. Accordingly, participation in collaborative communities is one of CDRH’s strategic priorities for 2018-2020.

CDRH encourages interested stakeholders to learn more about collaborative communities and review the toolkit, which provides a collection of helpful ideas to foster strong collaborative communities that are well-prepared to take on health care challenges.
Key Constituency Groups Involved in and Impacted by Ophthalmic Imaging Were Already Involved in Cooperative Research and Educational Initiatives to Accelerate Innovation in This Field and Elected to Come Together to Organize a Collaborative Community on Ophthalmic Imaging Imaging (CCOI) with FDA Participation
OUR MISSION

The Collaborative Community on Ophthalmic Imaging has set out to clarify challenges, best practices, strategies and standards while advancing innovation in the ophthalmic imaging space. The stakeholders involved are seeking to develop solutions to refine the diagnosis, management and treatment of patients with eye diseases, along with other medical conditions.
Critical Issues in AI Enabled Algorithmic Image Interpretation That Will Benefit From the Work of the CCOI

• What are the Performance Objectives
  • What are Acceptable Sensitivity and Specificity
  • Are They the Same for Screening, Change Analysis and Prognostication
  • Physician Decision Support or Autonomous Operation
  • Do They Vary Depending on Use Case and Location
  • How Do We Regulate AI Software Capable of Learning and Changing Autonomously Over Time

• What are the Standards for Oversight of Software Developed by Physicians or Healthcare Systems But Not Sold Commercially

• What is the Reimbursement Model

• What is the Liability Exposure

• What are the Ethical Considerations Involved in AI
  • Do Patients Need to Give Informed Consent
  • Do They Receive the Results Directly or Do Their Physicians Convey it to Them