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





## 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

Time Domain OCT



Spectral Domain OCT



**Swept Source OCT** 



Combined Retinal Angio + OCT



**OCTA** 



Virtual Surgical Displays

Ultra-Widefield **Fundus Imaging** 



**ROP** Imaging

Adaptive Optics (AO) Imaging



Intraoperative OCT





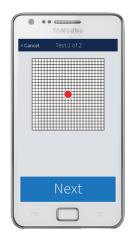




SOURCES: www.alcon.com, www.claritymsi.com, www.optos.com, www.heidelbergengineering.com

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



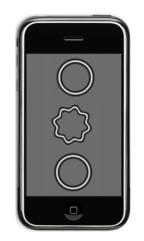




D-EYE



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

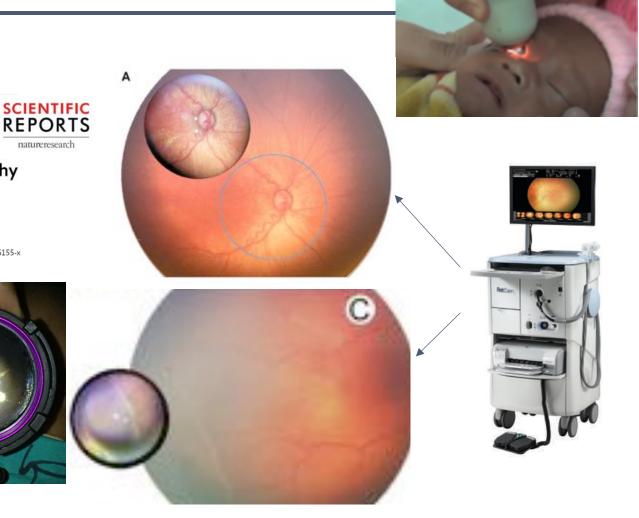
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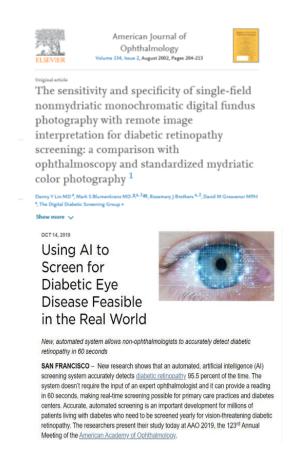
SCIENTIFIC REPORTS | (2019) 9:19711 | https://doi.org/10.1038/s41598-019-56155-x



Paxos being used in Africa for pediatric examinations



# Advances in Machine Leaning Have Resulted in the Development of Al 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.

#### What Is a Collaborative Community?

A collaborative community is a continuing forum in which private- and public-sector members, which can include the FDA, work together on medical device challenges to achieve common objectives and outcomes. They are convened by interested stakeholders and may exist indefinitely, produce deliverables as needed, and tackle challenges with broad impacts. Collaborative communities may develop for a number of reasons, including when.

- · Challenges are ill-defined or there is no consensus on the definition of the challenges
- · Challenges and outcomes are complex
- · Partners are interrelated
- · Incremental or unilateral efforts to address the challenge have been ineffective
- · Partners seek to optimize efforts, including preventing duplication of efforts
- Better outcomes could be achieved with integrating different perspectives, experiences, resources, and expertise.

For more information: Fostering Collaborative Communities to Improve Patient Healthcare (FDA Voices, December 4, 2018)

#### Members of a Collaborative Community

Collaborative communities typically include diverse, relevant organizations and individuals impacted by a specific topic. For example, patients and care-partners, academics, health care professionals, payers, federal and state agencies, international regulatory bodies, and industry may be engaged as part of a collaborative community.





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





#### Accelerating Innovation in Ophthalmic Digital Health

New Frontiers for Medical Devices

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Evaluating New Ophthalmic Digital Devices for Safety and Effectiveness in the Context of Rapid Technological Development

Michael E. Royke, MC, MSA; Caroli Spronger, MC, Wichael Trees, MC, Walteharl E. Systeman, MC

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Special solid places devices have benefited from the study design and data collection." These studies are intended to pain initial inside into direct solds under the control technologies. Noted Vision's Home CCT pattern



## Collaborative Community on Ophthalmic Imaging Members Mission Statement and Recent Events

#### **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.

3 TO SEP 4

#### 2020 COLLABORATIVE COMMUNITY ON OPHTHALMIC IMAGING CONFERENCE

Thu, Sep 3, 2020, 7:00 AM - Fri, Sep 4, 2020, 3:00 PM

#### SAVE THE DATE SEPTEMBER 3-4, 202 The Future of Artificial Intelligence-Enabled Ophthalmic Image Interpretation: Accelerating Innovation and Implementation Pathways A MEETING OF THE COLLABORATIVE COMMUNITY ON OPHTHALMIC IMAGING (CCOI)

REGISTER FOR FREE

This first meeting of the Collaborative Community on Oohthalmic Imaging is gathering experts from around the world and across academia, government institutions, patient groups, and the private sector to discuss the state-of-the-art in artificial intelligence algorithms for ophthalmic imaging and to set out to clarify challenges, best practices, and strategies for implementing these algorithms in four key clinical areas: Macular Degeneration, Retinopathy of Prematurity, Ocular Oncology, and Glaucoma. Held virtually over two days, the conference will feature presentations and panel discussions with key opinion leaders in the space. Working group sessions have been organized and are being led by:













## Current Members of CCOL

CURRENT MEMBER ORGANIZATIONS INCLUDE





Click the image above to visit



American Glaucoma Society

Click the image above to visit



American Society of Cataract and Refractive Surgeons

Click the image above to visit



American Society of Retina Specialists

Click the image above to visit



Asia-Pacific Academy of Ophthalmology

Click the image above to visit



Byers Eye Institute at Stanford

Click the image above to visit



**EURetina** 

Click the image above to visit



European Society of Cataract and Refractive Surgery

Click the image above to visit



U.S. Food and Drug Administration

Click the image above to visit

Foundation



Foundation for Fighting Blindness

Click the image above to visit



Glaucoma Research Foundation

Click the image above to visit



The Lighthouse Guild

Click the image above to visit





Ophthalmology



## Critical Issues in Al 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 Al 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 Al
  - Do Patients Need to Give Informed Consent
  - Do They Receive the Results Directly or Do Their Physicians Convey it to Them

