

THE COLLABORATIVE COMMUNITY ON OPHTHALMIC IMAGING

FORMATION MISSION AND INITIAL EFFORTS

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Schuman, Carol Shields

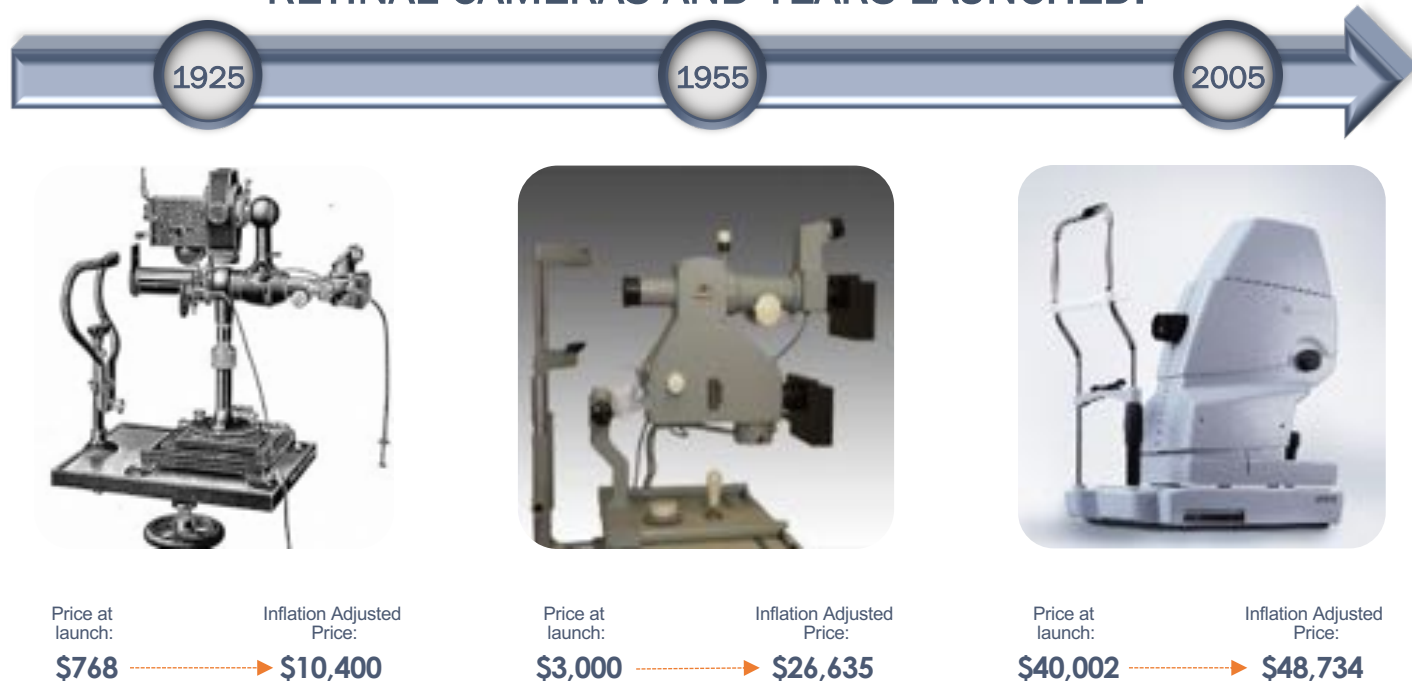


Disclosures for the Presenter Mark Blumenkranz

- BVI
- Combango 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:



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

Time Domain OCT



Spectral Domain OCT



Swept Source OCT



Combined Retinal Angio + OCT



OCTA



Ultra-Widefield Fundus Imaging



ROP Imaging



Adaptive Optics (AO) Imaging



Intraoperative OCT



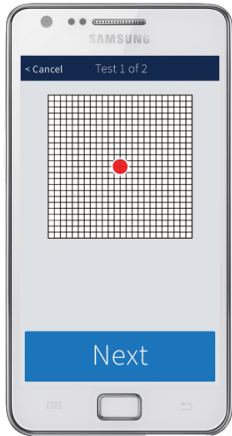
Virtual Surgical Displays



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

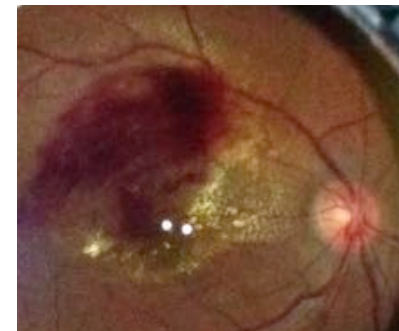
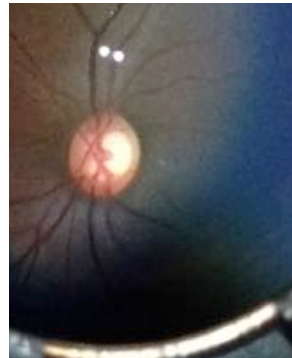
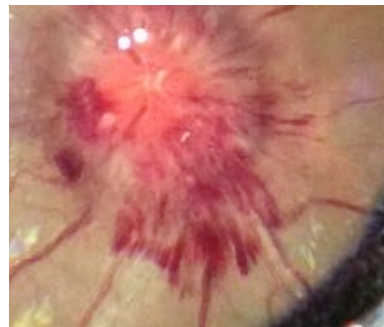
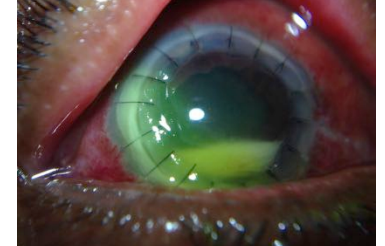
VITAL ART AND SCIENCE

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

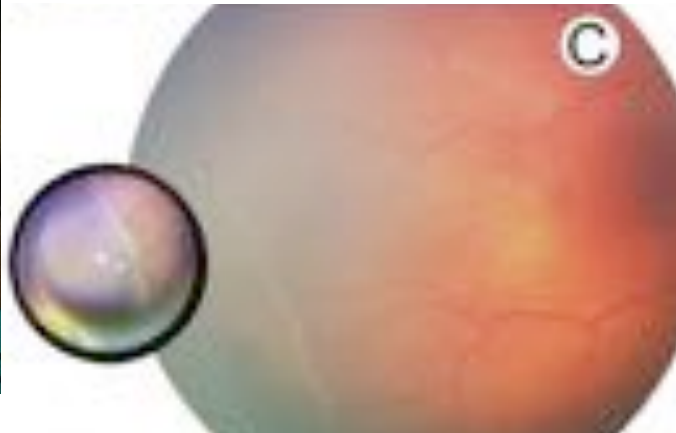
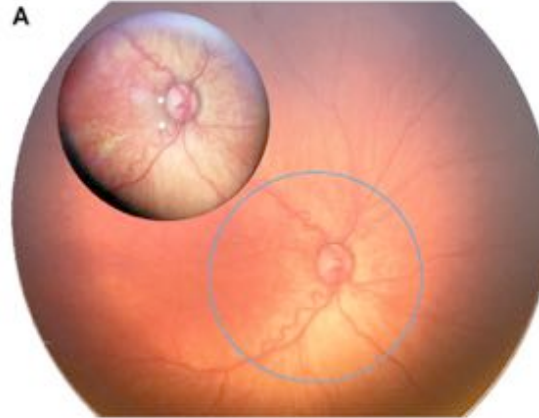
OPEN

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

**SCIENTIFIC
REPORTS**
nature research


Maximilian W. M. Wintergerst¹, Michael Petrak¹, Jeany Q. Li¹, Petra P. Larsen¹, Moritz Berger², Frank G. Holz¹, Robert P. Finger¹ & Tim U. Krohne^{1*}

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 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

 American Journal of
Ophthalmology
Volume 134, Issue 2, August 2002, Pages 204-213

Original article


The sensitivity and specificity of single-field nonmydriatic monochromatic digital fundus photography with remote image interpretation for diabetic retinopathy screening: a comparison with ophthalmoscopy and standardized mydriatic color photography ¹

Danny Y Lin MD ¹, Mark S Blumenkrantz MD ^{1,2,3,4}, Rosemary J Brothers ^{4,5}, David M Grosvener MPH ⁴, The Digital Diabetic Screening Group ⁺

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OCT 14, 2019

Using AI to Screen for Diabetic Eye Disease Feasible in the Real World



New, automated system allows non-ophthalmologists to accurately detect diabetic retinopathy in 60 seconds

SAN FRANCISCO – New research shows that an automated, artificial intelligence (AI) screening system accurately detects diabetic retinopathy 95.5 percent of the time. The system doesn't require the input of an expert ophthalmologist and it can provide a reading in 60 seconds, making real-time screening possible for primary care practices and diabetes centers. Accurate, automated screening is an important development for millions of patients living with diabetes who need to be screened yearly for vision-threatening diabetic retinopathy. The researchers present their study today at AAO 2019, the 123rd Annual Meeting of the American Academy of Ophthalmology.

 **Automated and Computer-Assisted Detection, Classification, and Diagnosis of Diabetic Retinopathy**

Michael D. Abramoff ^{1,2}, Theodore Ling, Daniel S.W. Ting, Kyo Won Moon, Christopher J. Brady, and Michael F. Chiang

Published Online: 16 Apr 2020 | <https://doi.org/10.1089/ajtm.2020.0008>

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Abstract

Background: The introduction of artificial intelligence (AI) in medicine has raised significant ethical, economic, and scientific controversies.

Introduction: Because an explicit goal of AI is to perform processes previously reserved for human clinicians and other health care personnel, there is justified concern about the impact on patient safety, efficacy, equity, and quality.

Discussion: Systems for computer-assisted and fully automated detection, triage, and diagnosis of diabetic retinopathy (DR) from retinal images show great variation in design, level of autonomy, and intended use. Moreover, the degree to which these systems have been evaluated and validated is heterogeneous. We use the term DR AI system as a general term for any system that interprets retinal images with at least some degree of autonomy from a human grader. We put forth three conceptual descriptors to form a means to categorize systems for computer-assisted and fully automated detection, triage, and diagnosis of DR. The components of the categorization system include level of device autonomy, intended use, level of evidence for

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Automated and computer-assisted detection, classification, and diagnosis of diabetic retinopathy
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Keywords
[retinopathy](#) [ophthalmology](#) [diagnosis](#) [classification](#)

 **U.S. FOOD & DRUG**
ADMINISTRATION

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FDA NEWS RELEASE

FDA permits marketing of artificial intelligence-based device to detect certain diabetes-related eye problems

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The U.S. Food and Drug Administration today permitted marketing of the first medical device to use artificial intelligence to detect greater than a mild level of the eye disease diabetic retinopathy in adults who have diabetes.

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.



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  AMERICAN ACADEMY OF
OPHTHALMOLOGY
  The Retina Society
  AAPOS
AMERICAN ASSOCIATION
OF
POSITIVE OPTICS
  AMERICAN
GLAUCOMA
SOCIETY
  AMERICAN
OPTOMETRIC
ASSOCIATION
  ASCRS

 AMERICAN SOCIETY OF
LENS & CONTACT LENS SOCIETY
  Cornea Society
  ASRS
AMERICAN SOCIETY OF
RETINA SPECIALISTS
  Stanford
EYE INSTITUTE
MEDICINE
  AMERICAN SOCIETY
OF
OPHTHALMOLOGY

Several applications have been identified from the breakthrough designation, including 1 recently approved indication. Notable items have (C) entries

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.

SEP
3
TO SEP 4

2020 COLLABORATIVE COMMUNITY ON OPHTHALMIC IMAGING CONFERENCE

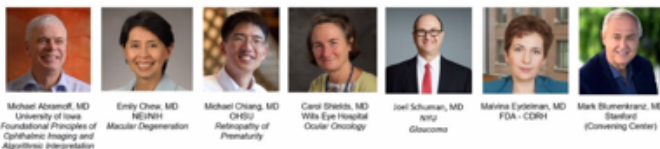
Thu, Sep 3, 2020, 7:00 AM – Fri, Sep 4, 2020, 3:00 PM



REGISTER FOR FREE

ABOUT THE MEETING

This first meeting of the Collaborative Community on Ophthalmic 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 CCOI

CURRENT MEMBER ORGANIZATIONS INCLUDE:



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