

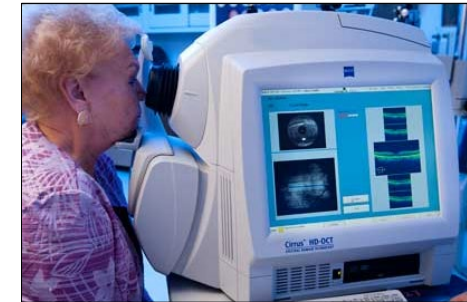
# Partnerships and the Role of Government Agencies as Facilitators

Amber Reed, Assistant Director  
NEI Office of Data Science and Health Informatics

June 4, 2025

# Need: Ocular Imaging Standards

- Imaging: basis for AI/data science
- **Challenges in exchanging or retrieving imaging data** from devices (proprietary formats)
  - Clinical: need to maintain multiple image management systems
  - Research: informatics PhD student unable to obtain data (OCT, VF)
  - 20 years effort (DICOM standards): virtually no impact on field
  - 5/2022: **ONC (now ASTP)-FDA-NEI Imaging Standards Workshop** to identify barriers & approaches to standards for interoperability
- **11/2022: AAO-ARVO statement** (“the time is now”)
  - “The use of standard formats for digital imaging is in the best interests of the ophthalmic community & the patients they serve...”



**Joint American Academy of Ophthalmology and Association for Research in Vision and Ophthalmology Policy Statement: The Time for Digital Imaging Standards Implementation Is Now**  
Aaron Y. Lee, MD, MSCI - Seattle, Washington  
Srinivas Sadda, MD - Los Angeles, California  
Flora Lum, MD - San Francisco, California

# FDA-ASTP-NEI Position Statement



## ■ FDA levers

- Formally recognized DICOM as a standard for ocular imaging, vendors can add standard compliance in labeling, subject to auditing

## ■ ASTP levers

- ISA (catalog of standards & implementation specifications, including DICOM), USCDI (consider data elements that facilitate exchange of medical images), consider adoption criteria requiring EHRs to provide access to medical images & drive conformance to DICOM standard



## ■ NEI levers

- Future NOFOs: studies including imaging will be strongly encouraged to include details about standards conformance
- Open-access GitHub repository to share coding scripts built on DICOM

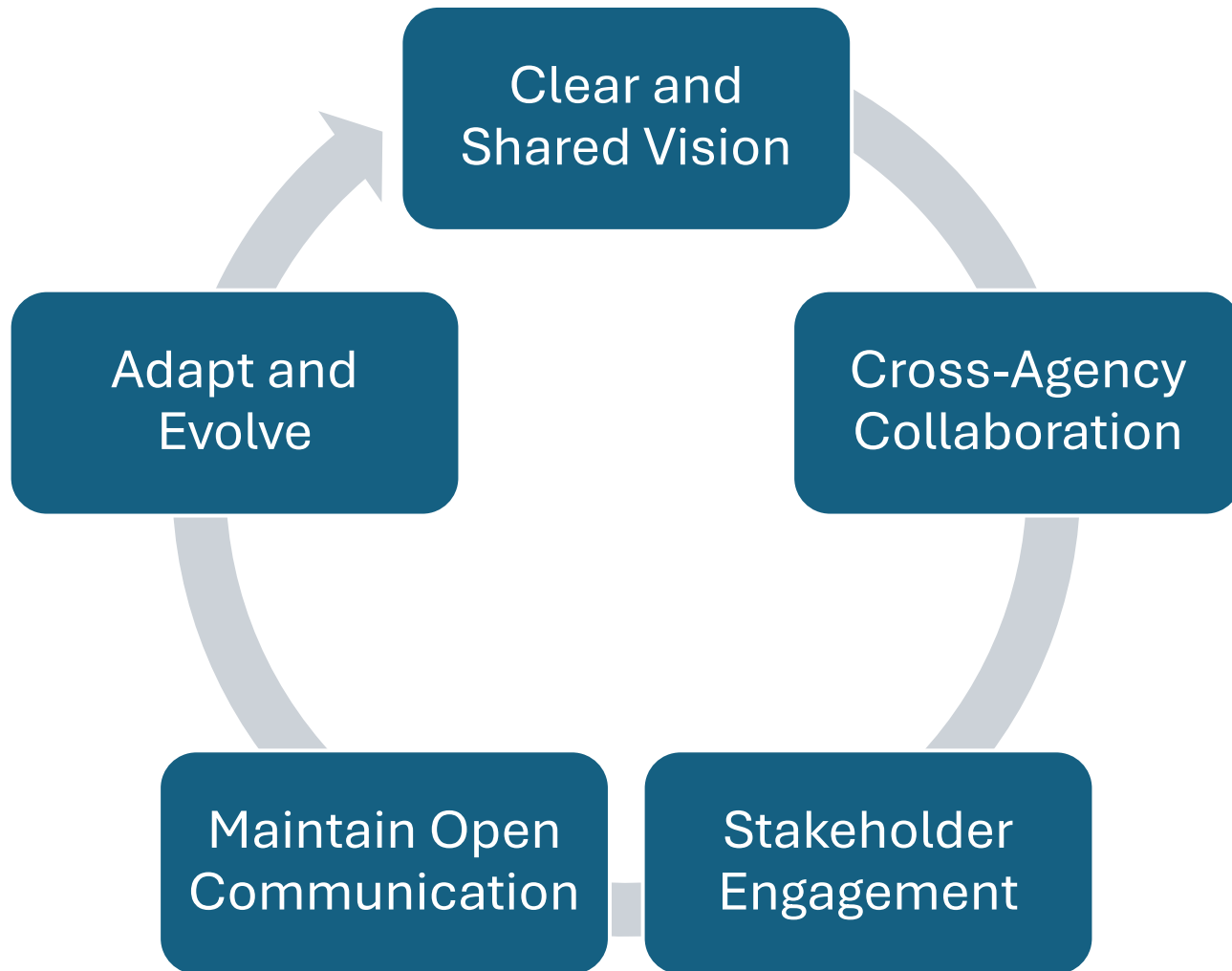


**Accelerating Care: A Roadmap to Interoperable Ophthalmic Imaging Standards in the United States**

Kerry E Goetz <sup>1</sup>, Amberlynn A Reed <sup>2</sup>, Michael F Chiang <sup>2</sup>, Thomas Keane <sup>3</sup>, Micky Tripathi <sup>3</sup>, Elvin Ng <sup>4</sup>, Tieuvi Nguyen <sup>4</sup>, Malvina Eydelman <sup>4</sup>



# Why This Partnership Was Successful



- Defined the problem and desired outcomes from the outset
- Focused on promoting **standardized ocular imaging**
- Leveraged each agency's unique strengths
- Combined **scientific, regulatory, and technical perspectives**
- Built buy-in from the start
- Involved **vendors and researchers** early in the process
- Provided **regular updates** and maintained **transparent decision-making**
- Helped keep all partners aligned throughout the project
- Stayed flexible and adjusted strategies as new challenges or insights emerged