

# NEI Ocular Imaging Standards RFI: Executive Summary

Clinicians and researchers using ocular imaging have struggled for years to efficiently share files and access pre-processed components of image files. If ocular imaging files and corresponding data could be more easily diffused it would enable care providers to capture and transmit imaging to collaborating eye health professionals, who could aid in interpreting the images and offer treatment guidance. Additionally, broad adoption of a sharing culture would allow greater access to necessary data for development of artificial intelligence techniques to aid in screening for early sign of potentially blinding eye conditions, such as diabetic retinopathy, for which 25% of Medicare Beneficiaries with diabetes do not receive recommended retinal screenings.

[DICOM®](#), Digital Imaging and Communications in Medicine, is the international standard for all medical images and related information. It defines the formats for images that can be exchanged with the data and quality necessary for clinical use. Currently, meeting these standards is optional and broad DICOM compliance is low for ophthalmic imaging technologies.

In early 2022, the National Eye Institute (NEI) issued a Request for Information (RFI) regarding ocular imaging standards. This RFI requested input regarding eight questions. An executive summary of the responses is provided below.

## **Specific benefits of using the DICOM standard for ocular imaging, both for research and clinical care**

In research, standardization of ocular imaging will have a directly benefit to studies that aim to use big data analyses and artificial intelligence (AI), including machine learning (ML) and deep learning (DL). The proprietary nature of ocular imaging platforms, analytic software and interfaces currently hinders this research and the widespread sharing of data. The lack of imaging standards also impairs the ability to access meta-data fields that may contain meaningful clinical data and technical specifications about the image. Implementing the standard will not only allow for the compilation of larger datasets, but also the combination of smaller, related datasets that may have been collected at different institutions or through different efforts.

In clinical care, the ability to share images with other care providers on the patient's care team reduces unnecessary and duplicative imaging and leads to better coordination of care. The adoption of DICOM standards would allow for a variety of data (for example, imaging measurements from automated segmentation, lab results and clinical data) to be plotted, visualized, and integrated across modalities, which would bring efficiency and reliability at the point of care.

In terms of international engagement, increasing the availability of standardized data will improve the outcome and cost-effectiveness of global eyecare. Among resource-constrained low-to-middle income countries standardization becomes more relevant and financial and personnel resources can be redirected toward early screening to reduce the incidence of vision impairment and blindness.

## **The elements of DICOM that are most important**

The DICOM standards include the following: (1) descriptors of the image itself; (2) definitions of network services for exchange, storage, and access to images; (3) standards for products of image analysis applications; and (4) standards for imaging department workflow management. The elements that are of most immediate importance are those in the first 2 categories: descriptors of the images themselves, and standards for exchange, storage, and access to images. Some of the important data elements within these categories are:

- Patient ID
- Demographic information (date of birth, sex, ethnic group and/or race)

- Time/date of image acquisition
- Equipment name and model
- Imaging modality (i.e. OCT, FAF)
- Anatomic location imaged (i.e. optic nerve, macula)
- Laterality of eye imaged
- Image frame and orientation (as available)
- Image quality (i.e signal strength/intensity)

### **Specific barriers to adoption of ocular imaging standards, and/or approaches to addressing these barriers**

Device manufacturers generally prefer to use their own proprietary format which may be easier for their internal use for software/algorithm development. Unfortunately, many in this field have heavily relied on DICOM-enabled PDF reports or DICOM-enabled generic images. One specific barrier to the adoption of ocular imaging standards comes from backwards compatibility, or lack thereof, among ophthalmic imaging equipment vendors. A further obstacle is that there has not been any activity in the DICOM Ophthalmology Working Group (WG-9) over the past four years. This means that recent imaging innovations are not yet considered in the existing standard proposals.

Lastly, another barrier to working with ocular imaging standards is the difficulty exporting imaging data from imaging machines in a way that retains compliance with an imaging standard such as DICOM.

### **Resources, tools, or technologies that could be further developed to evaluate DICOM conformance**

Respondents noted that the DICOM standard is complex and that resources, tools, and technology to evaluate compliance will require dedicated financial and personnel allocations. Solutions must be vendor agnostic, thoroughly documented, free to use, and based on open-source code. Tools are needed to empower researchers and clinicians to better understand what is meant by “DICOM Compliant” as it relates to ocular imaging and encourage vendors to encode meaningful data elements.

### **Emerging scientific developments, techniques, or other approaches to advance seamless ocular imaging exchange**

Several respondents noted that [DICOMweb](#) is an emerging resource that allows for sending, retrieving, and querying of medical images and related information. This is a newer version of the DICOM protocol that specifies a web-based service for accessing and presenting DICOM objects. Ocular imaging exchanges like DICOMweb present the opportunity to share patient images in a secure and high-speed fashion. A number of other open-source and proprietary tools were also mentioned, some of which utilize DICOMweb.

### **Sustainability of creating, extending, and evolving imaging standards in the future**

As technology is ever evolving, it is critical to ensure that imaging standards reflect that evolution. There have been historical challenges in this space so a commitment among all stakeholders (clinicians, researchers, and manufactures) will be key. To keep up with technological innovation, it would be helpful to have a standing working group for ocular image standardization.

### **Current workflow in capturing and sharing images in electronic health records technology (EHRs) and the use of DICOM or other standards in EHRs**

Current workflows vary by practice. Some clinicians export a PDF of a representative sample of images from each exam and store it in the EHR. Others elect to store images exclusively on the imaging devices and record the interpretation of the image without the raw data in the EHR. Other practices use an image viewing system and repository that provides for multi-modal/multi-device image storage and

review. EHR platforms vary widely from practice-to-practice. Independent private practices often use EHR systems tailored and designed for ophthalmology. Whereas hospital-based/academic practices most often use large platform systems. For the most part, there is a very low level of integration between EHRs and imaging devices.

### **Use of EHRs to capture structured results and reports associated with the images; and the standards used to represent the results**

The close integration of EHRs with ocular imaging and visual field machines is of central importance in improving quality of care and research. In an ideal setup, imaging data elements are directly transferred to a patient's chart, minimizing manual transcription and opportunity for human error. The reality of the most common scenario is that imaging and EHR data often exist as two entirely separate entities. This presents a missed opportunity, especially since the inclusion of even a small number of key variables can unlock tremendous research potential. Key variables stored in the metadata of DICOM compliant files could be interpreted by an EHR and serve as a data source. Currently, EHRs vary by vendor and have different imaging viewing capabilities, integration of standards, and interoperability functionality. Engagement will be important to operationalize capture of structured results.

### **Future directions**

Moving forward, NEI is beginning to implement ideas from this RFI including co-sponsoring an upcoming [NEI-FDA-ONC Joint Workshop on Promoting Adoption of Ocular Imaging Standards](#). This workshop will focus on delineating the state of the science and improving interoperability among ocular imaging modalities and devices to improve biomedical research and patient care. It will consist of a day of discussion that will identify the gaps in knowledge, barriers to progress, and potential strategies for overcoming them in the context of addressing the goal of Promoting the Adoption of Ocular Imaging Standards.

In order to address these barriers that have been identified, we must cultivate support and secure commitment for the arduous journey to full DICOM implementation from all stakeholders, inclusive of the clinical-user community, and most critically from ocular medical imaging device manufacturers. NEI is excited by opportunities in this space and looks forward to working with the community toward this goal.

### **References:**

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