FDA / AGS Workshop
Validity, Reliability, and Usability of Glaucoma Imaging Devices

Malvina B. Eydelman, MD
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
ODE / CDRH / FDA
Impact of Glaucoma on Public Health

- Open-angle glaucoma affects an estimated 2.2 million people in the United States, and that number is likely to increase to 3.4 million in 2020 as the population ages.*

- 130,000 in US are blind from glaucoma**

---


Use of Imaging Devices in Glaucoma Patients

- “From 2001 to 2009, [other ocular imaging] increased dramatically whereas VF testing declined considerably.” *

OCT Utilization

[Graph showing the utilization of OCT, Fundus Photography, and Fluorescein angiography over years, with an increasing trend for OCT.]

E Swanson & D Huang, Retinal Physician May 1, 2011
FDA’s Motivation for the Workshop

- Glaucoma imaging devices are the focus of significant premarket activity.

- These devices are increasingly used in clinical practice for clinical decision making and management.

- Imaging device parameters are increasingly being used as part of the enrollment criteria in glaucoma therapeutic studies.
Dependence on Technology

“I don’t feel like rubbing your back. Set your phone to ‘vibrate,’ place it on your back and I’ll call you.”
“When clinicians observe red lettering in data printouts or see red numbers out of the normal range, the presumption is that those results are abnormal.” *

“…we have become enamored with sophisticated analysis algorithms and colorful printouts before we have studies that show what the results of the tests mean.”**

“Although there is objective image … subjective quality assessment is still necessary to ensure that the image acquired is adequate for evaluation and that the analysis algorithm has functioned properly.”***


Workshop Objectives

• To highlight issues that the user should be aware of when interpreting the information from glaucoma diagnostic devices

• To provide industry insight into current FDA thinking

• To receive input from academia (clinicians and statisticians), industry, and other stakeholders on how to improve “regulatory science” in this product area:
  » Fine tune endpoints and strategies for assessing the relative safety and effectiveness of this new diagnostic information in the management of glaucoma
The Challenge to Users of Glaucoma Imaging Devices

“…if future studies confirm our specific findings regarding the recent shift in eye care providers’ methods for following OAG and suspected glaucoma, greater attention will need to be paid to more fully understand and overcome some of the known limitations associated with current [other ocular imaging] devices.”