NEI and FDA Collaborate on Clinical Trial Issues for Glaucoma Drug and Device Diagnostics and Therapies

On March 13-14, NEI and FDA held a Glaucoma Clinical Drug Trial Design and Endpoints Symposium with FDA’s Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH), engaging investigators and clinicians to discuss how research studies can apply to clinical trials used to support new product approvals.

“This was a landmark meeting, and the glaucoma community made considerable progress. We learned from NEI how to improve clinical trial design, and heard a great deal of flexibility from the FDA regarding new outcomes endpoints used to support approvals of products,” said Robert N. Weinreb, M.D. (Hamilton Glaucoma Center/University of California-San Diego), who served as Program Co-Chair with Paul Kaufman, M.D. (University of Wisconsin-Madison).

“Program Co-Chairs Robert N. Weinreb, M.D. (left) and Paul Kaufman, M.D. (right) with NEI Director Paul Sieving, M.D., Ph.D.”

“The development of an exciting new generation of treatments for glaucoma will require close collaboration between researchers and the FDA if we are to be able to demonstrate that the treatments are safe and effective in the shortest time possible,” said NEI Clinical Director Rick Ferris, M.D. He was joined by symposium co-sponsors Wiley Chambers, M.D. (CDER/Acting Director, Division of Anti-Infective and Ophthalmic Products) and Malvina Eydelman, M.D. (CDRH/Director, Division of Ophthalmic and ENT Devices) in predicting a new generation of glaucoma drugs and devices, including combinations of products that deliver drug therapies directly into the eye.

As researchers noted, glaucoma is a complex disease in which detectable structural and functional changes may not progress linearly or in concert, that is, early disease may be detected and characterized primarily by observable structural change, middle-stage by both, and end-stage primarily by measurable functional change. As a result, the regulatory process should be flexible to reflect this disparity between detectable structural and functional changes, especially when considering, for example, a new class of neuro-protective drugs that could mitigate damage to the optic nerve before it is manifested in visual function change. Much of the meeting’s discussion focused on how these new structural endpoints—which would be a direct endpoint, rather than a surrogate endpoint such as intraocular pressure—are incorporated into clinical trials and, as appropriate, correlated to visual function and concomitant quality of life indicators to ensure clinical significance and ultimate benefit to patients.

“The Glaucoma Endpoints meeting, developed by NAEVR and ARVO, is the second collaborative meeting between the NEI and FDA, following up on the November 2006 Ophthalmic Clinical Trial Design and Endpoints Symposium, which focused on new treatments for AMD and diabetic retinopathy.

Rohit Varma, M.D. (Doheny Eye Institute/University of Southern California) presented findings from the NEI-funded Los Angeles Latino Eye Study (LALES)