NEI Features Translational Research in Final 40th Anniversary Event

On June 24-25, the NEI concluded its 40th anniversary celebration with an NIH campus-based meeting entitled Translational Research and Vision. In keynote comments, Dr. Collins recognized the NEI as a leader in translational research—one of NIH’s top five priorities. “The NEI has been central to advances in translational research,” Collins said, adding that “NEI’s vision [for translational research] has allowed us to see farther and better and has enabled the NIH to attain its vision. Most importantly, the best is yet to come.”

In his comments, NEI Director Paul Sieving, M.D., Ph.D. stated that, as rewarding as it was to look back on the 40 years of accomplishments, he was most proud of the future-oriented focus of the Symposia Series that NEI hosted this past year on topics such as genetics/genomics, optical imaging, neuroscience, stem cell therapies, and the latest in glaucoma research. He reminded attendees that the April 2009 inaugural symposium featured blind mountain climber Erik Weihenmayer, who was engaged in testing a new device that uses the tongue to get visual signals to the brain, the development of which had been supported by the NEI.

NEI and FDA Hold Second Joint Symposium on Glaucoma Endpoints

On September 24, the NEI and FDA jointly held a Glaucoma Clinical Trial Design and Endpoints Symposium which engaged the glaucoma research community and the drug and device approval divisions within the FDA—specifically the Center for Drug Evaluation and Research (CDER) and the Center for Devices and Radiological Health (CDRH). Subtitled Measures of Structural Change and Visual Function, this meeting followed up on an initial March 2008 symposium by reviewing the latest research to examine whether measures of structural change can correlate to visual function and therefore serve as endpoints in clinical studies to support the approval of new drug and device diagnostics and therapies for glaucoma. Additional endpoints could potentially make glaucoma trials more logistically feasible by reducing study length, cost, and number of participants enrolled, thereby getting new therapies to patients sooner.

At the March 2008 meeting, FDA representatives stated that new clinically relevant endpoints could be considered in the regulatory review process if they are properly validated. At the follow-up meeting, noted glaucoma researchers, many funded by the NEI, reported data from studies of several imaging techniques to determine structural changes to the optic nerve head or retinal nerve fiber layer that may be correlated to visual function changes in glaucoma progression. For each imaging technique, speakers addressed the optimal criteria for measuring the rate of tissue loss and defining structural events, the statistically significant extent of structural change considering known variability of the imaging technique, and how structure predicts clinically relevant functional outcomes.

The Symposium, managed by ARVO, is the fourth in a series of collaborative meetings 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, and the September 2009 Patient Reported Outcomes meeting. The symposia grew out of NAEVR-initiated meetings between the NEI and FDA and exemplify NEI’s leadership in facilitating the translation of its basic research—an NIH priority.