Contributor Report

The Vision Community Observes Key Discussions at the NEI/FDA Ophthalmic Clinical Trial Design and Endpoints Symposium

On November 28-29, 2006, the NEI and the FDA hosted a collaborative symposium entitled *Ophthalmic Clinical Trial Design and Endpoints* to discuss outcomes variables and clinical trial strategies for evaluating new treatments for age-related macular degeneration (AMD), diabetic retinopathy and other eye diseases. More than 250 attendees from the vision community served as “observers” to the roundtable discussions, which included representatives from NEI, FDA, CMS, CDC, academia and industry. Although the symposium did not decide policy, it provided a forum for discussion of important questions on the topics of: visual acuity parameters as outcomes measures; endpoints for diabetic retinopathy; study design and endpoints for “wet” and “dry” AMD; and post-marketing drug surveillance.

Keynote speaker Stephen Ryan, M.D., (Doheny Eye Institute/University of Southern California) commented on the need for more efficient and cost-effective clinical trials, which is a goal of both NIH Director Dr. Elias Zerhouni and FDA Commissioner Dr. Andrew von Eschenbach. “This is especially important in ophthalmology,” stated Dr. Ryan, “since new technologies (e.g., imaging) are enabling better quantitative measurement of outcomes, which subsequently expedites the translation of clinical trials into improved practice patterns. Dr. Ryan concluded that it is patients who will ultimately benefit from the collaborative federal investment in research, as the more quantitative the treatment outcomes are, the faster they will be adopted into clinical practice.

NAEVR Executive Director James Jorkasky emphasized this latter point. “The recently passed House NIH reauthorization bill that is now under review by the Senate HELP Committee requires NIH to report on its collaborations with other health-related federal entities. I am pleased that NEI can be recognized as a leader with FDA in this regard, as well as in its trans-Institute collaborative research within the NIH.” He added that key Congressional authorizers and appropriators with jurisdiction over the NIH and FDA were apprised of this meeting.

The NEI/FDA Symposium emerged from a series of NAEVR-led meetings of representatives of the vision community with the FDA’s Center for Drug Evaluation and Research (CDER). The community wanted to ensure the timely approval of new products emerging from NEI-sponsored research.