



**NAEVR**  
National Alliance For  
Eye And Vision Research

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To Whom It May Concern:

On behalf of the community of support for eye and vision research, the National Alliance for Eye and Vision Research (NAEVR) is pleased to submit these brief comments regarding the efforts of the National Institutes of Health (NIH)-FDA Joint Leadership Council to collaborate more effectively to advance the translation of biomedical research.

Throughout its 40 year history, the NIH's National Eye Institute (NEI) has had an active and productive working relationship with FDA's ophthalmic drug and device reviewing divisions within the Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH), respectively, regarding diagnostics and therapies for vision impairment and eye disease.

As just one recent example, the NEI and FDA have held a series of *Endpoints Symposia* since 2006 which engage investigators and clinicians in addressing how NEI-funded research studies can apply to clinical trials used to support new product approvals. These public meetings, documented through published papers, have included a September 2009 session on *Patient Reported Outcomes*, a March 2008 session on *Glaucoma Clinical Drug Trial Design* and a November 2006 *Ophthalmic Clinical Trail Design* that addressed age-related macular degeneration (AMD) and diabetic retinopathy. A September 2010 *Glaucoma Endpoints* follow-up session is planned, since the previous meeting identified new endpoints that could be incorporated into clinical trials.

These public meetings, managed by the Association for Research in Vision and Ophthalmology (ARVO) and documented through published papers, have engaged representatives from "sister" Department of Health and Human Services (DHHS) agencies, such as the Center for Medicare and Medicaid Services (CMS) and the Center for Disease Control and Prevention (CDC).

With Congress designating 2010-2020 as *The Decade of Vision*, we are pleased that NEI and FDA are already leading efforts to facilitate the translation of research into products that benefit patients, reducing healthcare costs, maintaining productivity, and improving quality of life.

Sincerely,

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