

QUESTIONS FOR PANEL DISCUSSION

1. Do you recommend control population for studies of clear lens extraction (CLE) in the correction of presbyopia? If so, which one of the following controls do you believe to be appropriate?
 - i. Subjects with no previous ocular surgery (active or historical)
 - ii. Historical control of post cataract extraction subjects
 - iii. Historical control of subjects that have undergone clear lens extractions (presbyopia only or all refractive indications)
 - iv. Study subject's own pre-operative data
 - v. Other

2. Should the clinical study inclusion / exclusion criteria limit subject enrollment based on any of the following?
 - i. Refractive error / axial length (high hyperopia, hyperopia, emmetropia, myopia, high myopia)
 - ii. Patient's age
 - iii. Degree of accommodative loss
 - iv. Endothelial cell count
 - v. Any other factors

3. Acceptable adverse event rates for Posterior Chamber IOLs following cataract extraction are listed in the FDA Grid (see attached). Are these percentages applicable for clear lens extraction for the correction of presbyopia? Should any of the following be added?
 - i. Retinal detachment rates
 - ii. Endothelial cell loss
 - iii. Any others

4. In order to adequately detect all the adverse events / complications of concern, what do you feel is the appropriate sample size and the appropriate follow-up period for a CLE study prior to the submission of the PMA? Do you believe a Post-Market study is indicated? If so, what is the appropriate type of study, sample size and length of follow-up for such a study?

5. Table D1, p19 of ANSI draft standard for Multifocal Intraocular Lenses (see attached), outlines the recommended postoperative examination schedule. All multifocal IOLs investigated for clear lens extraction will first have to establish safety and efficacy in cataractous population and will therefore perform most of these tests and substudies in the cataractous population. Which of these substudies do you recommend for inclusion in the clear lens extraction protocol? Do you recommend addition of the endothelial cell substudy? Any others?

6. The only current performance efficacy endpoint for aphakic posterior chamber IOLs (FDA Grid) is post-operative BCVA of 20/40 or better in 92.5% of the subjects. What additional performance efficacy endpoints, if any, need to be set? Do you believe predictability (75% of eyes with MRSE ± 1.00 D, 50% with MRSE ± 0.5 D) and UCVA (85% with 20/40 or better) outcomes outlined in the FDA's Draft Guidance for Refractive Implants are applicable? What are your recommendations regarding UCVA for near?
7. How do you recommend we evaluate patient's quality of life issues?