

Discussion of a Post-Marketing Approval Study for 30-day Continuous Wear Contact Lenses

In the early 1980s, the FDA approved some contact lenses for up to 30 days of continuous wear. Increasing reports of problems with corneal ulcers prompted investigation of extended wear safety that culminated in the studies of Schein et al¹ and Poggio et al². Results from these studies prompted the FDA to recommend that continuous wear be limited to a maximum of 7 days.

Presently there are new lens materials with higher oxygen transmission that promise greater safety and longer periods of continuous wear. The FDA has concerns about longer periods of wear and potentially increased safety risks. Corneal ulcers are the main concern, although the incidence is too low to reliably determine the risk in a reasonable PMA study. The FDA believes that the best way to address this concern is to require a “Post-Marketing Approval Study” of the risk posed by 30 day “continuous wear.”

We intend to discuss study design, feasibility, appropriate level of acceptable risk and statistical power, timing of the study, and definition of endpoints. The FDA seeks a study design that will be least burdensome and will provide a reasonable assurance of safety. There is a natural trade-off between level of acceptable risk and study feasibility (size and cost).

¹ Schein O, et al. The relative risk of ulcerative keratitis among users of daily-wear and extended-wear soft contact lenses. *New Eng J Med* 1989;321:773-778

² Poggio EC, et al. The incidence of ulcerative keratitis among users of daily-wear and extended-wear soft contact lenses. *New Eng J Med* 1989;321:779-783