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- HJN
7. Please provide your agreement (or justification for not agreeing) that retreatments done to improve refractive outcome are NOT considered as treatment failures, whereas retreatments done to achieve resolution of an adverse event ARE considered as treatment failures.
8. Please clarify why you have omitted or modified the following inclusion criteria (Section 3.2.4.1):
- a. BSCVA should be 20/40 or better in both eyes.
  - b. Contact lens wearers should:
    - i. remove soft or gas permeable contact lenses two weeks prior to baseline measurements
    - ii. remove hard contact lenses three weeks prior to baseline measurements, and have two central keratometry readings and two manifest refractions taken at least one week apart that do not differ by more than 0.50 diopter in either meridian; mires should be regular.
  - c. Spherical or cylindrical portion of manifest refraction should progress 0.50 diopter or less during the year prior to the baseline exam.
  - d. Subjects should be willing and capable of returning for follow-up examinations for the duration of the study.
  - e. Videokeratography should be normal.
9. Please clarify why you have omitted or modified the following exclusion criteria (Section 3.2.4.2):
- a. Taking systemic medications likely to affect wound healing, such as corticosteroids or antimetabolites
  - b. Immunocompromise (e.g., AIDS, autoimmune disease)
  - c. Unstable central keratometry readings with irregular mires
  - d. History of glaucoma or an intraocular pressure > 21 mm of Hg.