Contraceptive Efficacy Assessment

Question 9. Pearl Index versus life table analyses:
9a. What are the relative merits of each approach?

9b. Are there situations where one approach should be favored over the other? If so, what are they?

9c. How should divergent pregnancy rates calculated by the Pearl Index versus life table methods be considered in the approval process and in labeling?

Question 10
How should divergent pregnancy rates, obtained in U.S. and non-U.S. populations, be considered in the approval process and in labeling?

Question 11
11a. Should "on-study pregnancies" be defined to include only those pregnancies that occur while subjects are within the treatment cycle or also include those pregnancies with an estimated date of conception that may have occurred within a certain number of days after the end of the last treatment cycle (e.g., 2, 5, 14 days – where the treatment cycle is defined to include the pill-free interval following active treatment)?

11b. If yes, where should the cut-off be established or should it vary according to how reliably a drug inhibits ovulation?

Question 12. How can the life table analysis of pregnancy rates be adjusted for the use of back-up contraception midway through the exposure period, for example, back-up contraception used only during treatment cycle 6 in a 13-month treatment cycle?

Question 13. How should the analysis of pregnancy rates be adjusted for the use of back-up contraception in extended cycle contraceptive trials? For example, in an 84/7 dosing regimen, should an entire 91 day cycle be considered nonevaluable, or should only a 28 day portion of the cycle be excluded from consideration of at risk cycles?