

Risk/Benefit Assessment

Question 14

For historically controlled trials, should evaluation of pregnancy rate be based only upon the point estimate, the upper bound of the 95% confidence interval around that point estimate, or both?

Question 15

15a. Is there a pregnancy rate that would be unacceptably high, regardless of the risk/benefit balance of the product?

15b. If so, what would that rate be?

Question 16. Should the Division approve lower-dose products that have apparent decreased efficacy and possible decreased risk of serious adverse events as compared to higher-dose products (e.g., 20 µg estrogen vs. 30-35 µg estrogen contraceptive products)?