**Clinical Trial Design Issues**

Question 1. Should entry criteria be more reflective of actual clinical prescribing regarding BMI, smoking, and family history of thrombosis or thromboembolism?

Question 2. The Division has seen different efficacy results in foreign studies compared to U.S. studies (often better efficacy results in Europe). Should a certain minimum percentage of the subjects in Phase 3 studies be studied at U.S. sites?

Question 3. Are there cultural or physical attributes in foreign populations that would render contraceptive study data from such populations less applicable to the U.S. population?

Question 4. Should a certain percentage of the study population represent "fresh starts" as opposed to "switchers?"

Question 5. Is there a role for active controlled trials; if so, under what circumstances?

Question 6. Should electronic diaries be recommended for pivotal contraceptive clinical trials?

Question 7. The Division has typically used premature termination rates as an assessment of patient satisfaction in clinical trials. Would information obtained from validated Patient-Reported Outcome (PRO) instruments be more useful in contraceptive trials?

Question 8. Could a validated PRO instrument be used to obtain a secondary labeling claim of superiority (e.g., better cycle control)?