

Phase 4 Commitments

Question 27. What designs should be considered for Phase 4 studies of hormonal contraceptives and what are the strengths and limitations of each type of design? What are the most important cost/benefit considerations and limitations of each design (e.g., a more rigorous design but a delay in obtaining outcome data)?

Question 28a. Phase 4 commitments have generally been confined to obtaining information primarily or entirely related to safety issues. Can such studies be designed to obtain a better estimate of true “actual use” product effectiveness?

Question 28b. If so, how best can this information be obtained?

Question 29. In addition to thrombotic and thromboembolic risk, are there other safety issues that should be addressed within long-term or large Phase 4 studies?