

Clinical Lactation Studies:  
Questions for Advisory Committee

1. Would data from clinical lactation studies be useful to practitioners and pregnant and breastfeeding patients when making risk/benefit decisions regarding medicine use during breastfeeding?
2. Are there any situations where it is appropriate to enroll healthy volunteers in clinical lactation studies (Please consider: single versus multiple dose studies, ongoing breastfeeding versus weaning, and continued nursing during drug administration versus pumping and discarding milk)?
  - If no, explain why.
  - If yes, describe the acceptable situations.
3. FDA is seeking guidance from the Advisory Committee regarding timing of study enrollment for mother/infant pairs.
  - Is it important for breastfeeding to be well established before enrolling mother/infant pairs in clinical lactation studies?
  - Is there a minimum number of weeks postpartum before which mother/infant pairs should not be enrolled? Please consider both infant feeding issues and maternal physiology and pharmacokinetics issues.
4. Should clinical lactation studies only enroll mother/infant pairs who are exclusively breastfeeding? If yes, explain why. If no, describe study scenarios where enrollment of mother/infant pairs who are not exclusively breastfeeding would be useful.
5. Given that estimated infant daily dose can be calculated from drug concentrations in breast milk, are there situations where a maternal milk/plasma ratio would offer additional clinically useful information?
6. Based on drug characteristics or existing clinical concerns, are there situations when a mother/infant pair study with infant plasma sampling should be recommended? Are there situations when a mother-infant pair study should be conducted without a prior milk-only or milk/plasma study? Please describe.
7. When in the drug regulatory process should clinical lactation studies be requested and done?