



Workshop Questions

Questions; Session 1 & 2 – April 27, 2016

1. Reflecting on our current experiences for the collection and application of lactation data, what are the most pressing challenges to collect the data needed to balance the benefits of breastfeeding with the possible risks of drug exposure?
2. What are potential strategies to overcome roadblocks related to obtaining information from lactation studies

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3. Should lactation data from animal studies be used to inform FDA labeling for lactation? If so, under what circumstances? If not, why not?

4. Understanding that there is an implementation schedule for the re-formatting of labeling, there are a large number of drugs that will have labeling revisions. Are there certain classes of drugs that should be prioritized because of their possible use for a breastfeeding woman?

Questions; Session 3– April 27, 2016

1. What information resources are the most useful, and why?
2. How do we best ensure consistency amongst these information resources?
3. Is outreach lacking to any particular professional or patient group that would further increase awareness about safe drug use during lactation? If so, what is the best way to communicate with that/those group(s)

Questions; Session 4– April 28, 2016

1. When data are available, what is the level of evidence required to support FDA labeling statements for lactation (e.g., formal lactation studies, case reports, predictive clinical pharmacology data)?
2. What research areas (data gaps) are priorities and how can these data be collected? How can collaboration and resources be leveraged to conduct clinical lactation studies? Are there additional mechanisms to support funding for lactation studies?
3. Are there other data collection approaches beyond what has been discussed here that should be discussed? Are there other issues that need to be addressed that have not been discussed?