

Draft Recommendations



Important Notes

- These are ***draft*** based on discussions to date
- Aiming for reaction and refinement
- May meeting focused on recommendations



Draft Recommendations

A plan to identify and address gaps in knowledge and research regarding safe and effective therapies for pregnant women and lactating women, including the development of such therapies



Research is needed to address gaps in knowledge on safe and effective therapies for pregnant and lactating women, including the development of such therapies

- Goal: Women and providers will have an evidence base on which to guide informed decisions on the use of therapeutic products during pregnancy and lactation in order to improve health outcomes for mother, child and family
- Account for different methods needed for pregnancy and lactation
- Account for different methods needed for therapeutic products in use vs in development vs supplements
- Include a prioritization process
- Incorporate metrics to monitor progress



Enhance training for scientists to obtain expertise in obstetric and lactation pharmacology

- Prioritize and support the development of investigators with obstetrical, lactation, and pharmacology expertise for industry, academics, and the federal workspace
- Enhance training of members of IRBs, ethics committees on pregnancy and lactation research



Draft Recommendations

Ethical issues surrounding the inclusion of pregnant women and lactating women in clinical research



Modify Subpart B to facilitate research in pregnant women

- Given the recognized autonomy of a pregnant woman, given the evolution of family structure, given that for a child only one parental signature is required for research to benefit the child (align with pediatric consenting), *46.204(e) in subpart B should be changed to maternal consent alone*
- Add in the option of “Minor increase over minimal risk” from subpart D to 36.046
- Rework the components of subpart B, although useful to assess the risk ratio they are vague and burdensome for the investigator



Create a regulatory framework for evaluating medication use in pregnant and lactating women.

- I don't actually know what this means but it was said a lot



Create the presumption of inclusion of pregnant and lactating women in clinical research.

- Removing pregnant women as an example of a vulnerable population in the common rule *shifts to a presumption of inclusion.*
- Investigators must justify exclusion in their study design



Recommend data collection in pregnant and lactating women for new molecular entities if relevant to the pregnant and lactating communities

- Liability issues and incentives will need to be addressed to achieve this recommendation
- For all new product development, pregnant and lactating women should not be post-market evaluation



Draft Recommendations

Effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women



Develop effective communication strategies with health care providers and the public on information relevant to pregnant women and lactating women

- Highlight the importance of research on therapies in pregnancy and lactation including impact of not taking the medication during pregnancy and lactation as well as the impact of not breastfeeding on mother and child
- Develop evidence based tools for public to understand risk, evidence, and lack of evidence
- Use new methods to disseminate information – crowd sourcing, digital / internet, partner with companies



Draft Recommendations

Identification of Federal activities, including:

- (a) The state of research on pregnancy and lactation;
- (b) Recommendations for the coordination of, and collaboration on research related to pregnant women and lactating women;
- (c) Dissemination of research findings and information relevant to pregnant women and lactating women to providers and the public; and
- (d) Existing Federal efforts and programs to improve the scientific understanding of the health impacts on pregnant women, lactating women, and related birth and pediatric outcomes, including with respect to pharmacokinetics, pharmacodynamics, and toxicities



Create incentives and limit liability to encourage industry to conduct research in pregnant and lactating women

- Develop incentives to engage industry and agencies and to facilitate collaboration, development of public private partnerships.
- Develop incentives for drug development for both on and off patent therapeutics and P&L exclusivity incentives for drug sponsors.
- Limit the legal liability and ethical challenges for physician scientists, researchers, and industry for P&L research



Leverage established and support new networks to perform research in pregnant and lactating women

- Provide support and incentives to established and develop new multicenter infrastructures that capitalize on standard of care procedures (opportunistic studies), innovative designs, with rigorous methodology.
- Develop a platform for collaboration with industry



Enhance research opportunities for pregnancy and lactation studies

- Facilitate longer award periods given needed duration for follow-up
- Ensure trials are designed to appropriately capture the time dependency of physiologic changes in pregnancy and lactation
- Prioritize the development of new tools and methods to assay medications in breastmilk targeted to utilize small volumes and are sensitive to detect minute quantities
- Recommend use of new methods to do research – e.g. crowd sourcing, digital / internet
- Leverage large studies – All of Us, PregSource, etc – to collect data for pregnancy and lactation therapeutic product studies



Change construct of how to retain women who become pregnant in studies

- Require studies to include plans for incident pregnancies to capture outcomes and add to available data



Facilitate access to and sharing of available data to provide information for pregnant and lactating women.

- Examples of available data include VA clinical database, DoD clinical database, federally funded studies, milk banks.



Optimize registries for pregnancy and lactation

- Disease focused registries
- Required vs voluntary registries
- Facilitate access to data and transparency of information in registries
- Can electronic medical records facilitate input into registries
- Develop requirements and provide support for disease focused registries with mandates that facilitate input of pertinent data with easy, transparent access to obtain information in real time



Draft Recommendations

Recommendations to improve the development of safe and effective therapies for pregnant women and lactating women.



The Secretary should consider exercising the authority provided in law to extend the PRGLAC Task Force when its charter expires in March 2019.



If there are recommendations that require HHS authority or action, the Secretary should consider forming an Advisory Committee to oversee updating regulations and guidance, as applicable, regarding the inclusion of pregnant women and lactating women in clinical research