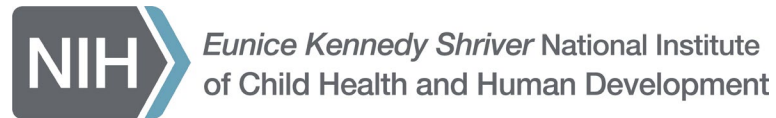


Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC)

Diana W. Bianchi, M.D., Chair

June 24, 2020



Recap of PRGLAC Activities Since February 2020

- Task Force members and *ad hoc* working group members received drafts of implementation plan
- First draft
 - Sent in batches, by working group recommendation assignments
 - Two-week timetable to review
 - Drafted using:
 - Notes and discussions from working group meetings
 - Worksheets compiled by each working group
 - Points made at the February meeting
- Second draft
 - Incorporated many of the comments
 - Sent to Task Force and *ad hoc* working group members for review and today's discussion



Proposed Roadmap to the Final Implementation Plan

- Today, June 24: Discuss key points/questions that need consensus
- July 15: Final draft to be sent to Task Force members, incorporating comments from today
- July 24: Request for concurrence for final Implementation Plan
- July 31: Submit to HHS Secretary Azar, through Dr. Francis Collins, NIH Director



Goal for Today: Discuss Key Questions/Comments

- Recommendation 7: Incentives and liability
- Recommendation 9: Scope to focus only on conditions specific to pregnancy and lactation
- Recommendation 10:
 - Inclusion of PRGLAC Assessment and a PRGLAC study plan
 - Different PK/PD during different phases of pregnancy and lactation
 - Evidence for inclusion, drug safety in preclinical phase
- Recommendation 12: Other sources to cite
- Additional issues



Reminder

- The recommendations submitted in the September 2018 report to the HHS Secretary and Congress **were voted on and agreed to by the Task Force.**
- Although we received comments, we did not change the wording of the recommendations.



Discussion of Remaining Issues (20 minutes each)

- **Recommendation 7:** Are there incentives that would encourage industry to include pregnant women and lactating women in clinical trials despite liability concerns? Can the Task Force move ahead with these implementation steps even if the larger liability issues are unresolved?
- **Recommendation 9:** Some commenters suggested that the steps for this recommendation focus only on conditions specific to pregnancy and lactation, which would narrow the scope considerably. Do you agree? Are chronic conditions that pregnant women and lactating women have adequately covered in the other recommendations' steps?



Discussion of Remaining Issues (continued)

- **Recommendation 10:**

- Comments were received discouraging the steps of a PRGLAC Assessment and a PRGLAC study plan, as recommended by the working group. Does the Task Force agree? (The alternative proposed is that sponsors should include pregnant women only if there is enough evidence to support inclusion.)
- What are the implications for industry? Are there other solutions to pursue?
- Also, some commenters made the case for different PK/PD during different phases of pregnancy and lactation. Are drugs metabolized differently throughout these periods? Are different drug formulations required?
- What other preclinical evidence is needed to provide information that would permit inclusion?
- How else can we prove safety of a drug in the preclinical phase?



Discussion of Remaining Issues (continued)

- **Recommendation 12:** Are there other data sources we could cite?
- **Overarching:** Was the use of examples too much, not enough?



Additional Issues (Time Permitting)

- **Overarching:** Use of examples throughout the document
- Diversity of study populations
- Partnerships
- Use of registries





Thank you

**Send additional comments to:
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