

The participation of pregnant women in clinical research: Implications for practice within the U.S. pharmaceutical industry

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Abstract: Background: The treatment of medical conditions complicating pregnancy is challenged by a serious lack of information about the safety and effectiveness of the medications used by pregnant women. To improve our knowledge of what constitutes the most effective therapy, we conduct systematic research. Research for pregnant women, however, is challenging. The U.S. pharmaceutical industry is the leading conductor of clinical research, yet there is a dearth of published information from industry regarding pregnant women and drug studies. The extent of their exclusion has not been quantified, nor has its rationale been articulated. Industry input will be solicited when FDA releases its new guidance document on pregnant women in clinical research. Methods: To quantify the proportion of pharmaceutical company-sponsored studies that exclude pregnant women, we reviewed exclusion criteria from Phase IV trials posted on ClinicalTrials.gov from October 2011 - January 2012. To articulate the rationale for exclusion, we conducted key informant interviews (KIs) with representatives from industry and related organizations.

Results: Of 368 studies in which pregnant women could appropriately participate (drugs in FDA pregnancy categories A, B, or C and conditions that could occur during pregnancy), 94% excluded pregnant women. KIs found that exclusion is primarily based on beneficence - the desire to avoid causing harm. Other issues include perceived risk of litigation, scientific validity, risk to drug approval and company reputation, and increased study complexity. Lack of advocacy, lack of regulatory requirement, and historic precedent are other barriers. However, KIs also revealed that industry stakeholders agree with other advocates that pregnant women and their fetuses are at a higher risk of adverse medical consequences if they are not included in clinical trials than if they are included - and that opportunities exist within industry for more inclusive practices.

Conclusion: We verified the perception that pregnant women are largely excluded from clinical studies and found that industry has both practical rationales for exclusion and recommendations to improve inclusion. This study adds industry's perspective to the dialogue on the barriers to, and opportunities for, a rational inclusion of pregnant women in clinical research to ultimately improve evidence-based treatment decisions for pregnant women.

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