

Inclusion of Pregnant and Lactating Persons in Clinical Trials – A Workshop

Breakout Group Worksheet (Virtual)

Breakout group discussions will be held **3:10 – 5:00 pm (ET) on Thursday, June 16**. The breakout groups will offer workshop participants the opportunity to identify barriers to the inclusion of pregnant and lactating persons in clinical trials and to the generation of adequate evidence for the use of drugs in this population. Breakout groups will then prioritize these barriers and collectively brainstorm solutions that would provide opportunities to overcome these barriers.

Zoom participants will have the ability to self-select which breakout group they would like to join. To ensure you are able to select the breakout group of your choice, **please [update](#) your Zoom application prior to the workshop**.

Instructions:

- Click on the ‘Breakout Rooms’ icon in the Zoom controls. A pop-up window will appear with four room options, each corresponding to the numbered groups below. Once you have identified the group you would like to join based on your affiliation and/or interest, find the corresponding room number in the list on the pop-up window and click ‘Join.’
 - Group 1: Opportunities to address liability concerns on the part of clinical investigators
 - Group 2: Opportunities to address liability concerns on the part of trial sponsors
 - Group 3: Opportunities to improve evidence generation for persons during pregnancy
 - Group 4: Opportunities to improve evidence generation for persons during lactation
- Breakout groups will have approximately 45 minutes to answer the discussion questions below. A designated facilitator in each breakout group will help guide this discussion and report out key points.

Discussion Questions:

1. Based on your assigned group topic, what are the barriers or concerns that prevent the inclusion of pregnant and lactating persons in clinical trials (Groups 1 & 2) OR the barriers or concerns that prevent the adequate generation of evidence to inform clinical care of pregnant and lactating persons (Groups 3 & 4)? Prioritize the top 2-3 barriers that are the most easily addressed and have the greatest impact. (Suggested Duration: 10 minutes)
2. How can the barriers prioritized in question 1 be effectively addressed? For example, are there educational/outreach approaches for engaging particular audiences, research design/methodologies that could be implemented, and/or incentives or regulatory/policy changes to spur a change in behavior on the part of particular stakeholders? (Suggested Duration: 35 minutes)