Advancing Drug Development for the Prevention of Spontaneous Preterm Birth
January 23 & 24, 2024 • 1:00 – 4:30 PM • Virtual Public Workshop (Zoom)

Workshop Agenda

Day One | Current Landscape, Challenges, and Perspectives on Prevention of Spontaneous Preterm Birth

1:00 PM   Welcome and Introduction
Mark McClellan, Duke-Margolis Center for Health Policy

1:05 PM   Opening Remarks from FDA
Robert Califf, U.S. Food and Drug Administration

1:15 PM   Session 1: Current Understanding of Spontaneous Preterm Birth
This session will highlight the impacts of spontaneous preterm birth and provide an overview of the epidemiology, etiologies, and pathophysiology of spontaneous preterm birth. There will be discussion of the current tools and methods used to predict spontaneous preterm birth and the progress made in recent years.

Moderator: Kaveeta Vasisht, U.S. Food and Drug Administration

Presenters:
- Joyce Martin, Centers for Disease Control and Prevention
- Emre Seli, March of Dimes
- Michal Elovitz, Icahn School of Medicine at Mount Sinai

Presentation and Q&A

2:15 PM   Session 2: Ethical and Regulatory Considerations and Challenges Associated with the Development of Therapeutics for Prevention of Spontaneous Preterm Birth
Experts will provide an overview of regulatory considerations, including the process of evaluating efficacy and safety of investigational products. The experts will discuss the ethical considerations used in clinical trials and the challenges to develop therapies for preterm birth.

Moderator: Christine Nguyen, U.S. Food and Drug Administration

Presenters:
- Christina Chang, U.S. Food and Drug Administration
- Annie Lyerly, University of North Carolina at Chapel Hill
- George Saade, Eastern Virginia Medical School

Presentation and Q&A
3:15 PM  Break

3:30 PM  Session 3: Impact of Preterm Birth on Families and Society
This patient-focused session will discuss the short- and long-term challenges of caring for infants and children born preterm from the voices of parents and experienced clinicians, nurses, caregivers, and social workers.

Moderator: Sarahn M. Wheeler, Duke University School of Medicine

Panelists:
• Deb Discenza, PreemieWorld Foundation, Inc.
• Jennifer Degl, Maternal and Infant Health Advocate, Author
• Ashley Randolph-Cooley, GLO Preemies
• JaNeen Cross, Howard University School of Social Work
• Wakako Eklund, Pediatrix Medical Group

Moderated Discussion and Q&A

4:30 PM  Closing Remarks and Day One Adjournment
Mark McClellan, Duke-Margolis Center for Health Policy

Adjourn
Day Two | Considerations for the Development of Therapies for the Prevention of Preterm Birth

1:00 PM  **Opening Remarks and Summary of Day 1**
Nancy Allen LaPointe, Duke-Margolis Center for Health Policy

1:10 PM  **Session 4: Assessing Efficacy and Safety in Clinical Programs for Therapeutics for Spontaneous Preterm Birth Prevention**
Experts will discuss the efficacy and safety assessments used in clinical programs as well as opportunities to improve and address the challenges within these programs. The discussion will consider how researchers can identify clinically relevant neonatal outcomes.

Moderator: Lynne Yao, U.S. Food and Drug Administration

Panelists:
- Mark Hudak, University of Florida College of Medicine
- Tamorah Lewis, University of Toronto
- Anjali Kaimal, University of South Florida
- Christina Chang, U.S. Food and Drug Administration
- An Massaro, U.S. Food and Drug Administration
- Robert Nelson, Johnson & Johnson

Moderated Discussion and Q&A

2:20 PM  Break

2:35 PM  **Session 5: Dose-Finding and Clinical Trial Design Considerations**
Field experts will discuss the importance of identifying a target drug for development and the data needed to support clinical trials for both novel and approved products, emphasizing consideration of different study populations and control groups in clinical trials. They will also discuss dose finding while considering physiologic changes in pregnancy and drug metabolism.

Moderator: Michal Elovitz, Icahn School of Medicine at Mount Sanai

Presentations:
- Kimberly Hatfield, U.S. Food and Drug Administration
- Doanh (Donny) Tran, U.S. Food and Drug Administration

Panelists:
- Kimberly Hatfield, U.S. Food and Drug Administration
- Doanh (Donny) Tran, U.S. Food and Drug Administration
- Kevin Prohaska, U.S. Food and Drug Administration
- Steve Caritis, University of Pittsburgh Medical Center
- Kelle Moley, Ferring Pharmaceuticals
Moderated Discussion and Q&A

3:45 PM  **Wrap-up with Workshop Moderators**
Panel members will discuss the key takeaways from each session and provide next steps in advancing drug development for the prevention of preterm birth.

Moderator: Nancy Allen LaPointe, Duke-Margolis Center for Health Policy

4:25 PM  **Closing Remarks and Meeting Adjournment**
Nancy Allen LaPointe, Duke-Margolis Center for Health Policy

4:30 PM  **Adjourn**

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