



Agenda: Pregnancy Testing in Clinical Trials Expert Meeting

Hosted by the Clinical Trials Transformation Initiative (CTTI)

Purpose: “To develop consensus on factors to be considered to select appropriate pregnancy testing protocols”

July 15 & 16, 2013

*DoubleTree by Hilton Hotel Bethesda - Washington DC
8120 Wisconsin Avenue, Bethesda, Maryland 20814*

Ballroom C, Level 2

MEETING BACKGROUND

Designing a pregnancy testing protocol for a clinical trial requires balancing the performance characteristics of a given test, the baseline risk of pregnancy in a given subject population, the potential risks to the fetus from study interventions, and the effect of the testing protocol on overall study implementation in terms of burden to subjects, burden on staff, and direct costs. There are no published data on the consistency of sponsors, investigators, or institutional review boards (IRBs) in applying these criteria to designing and evaluating pregnancy testing protocols. However, anecdotal reports indicate that there is widespread variability.

Development of evidence-based guidance that explicitly considers the level of acceptable risk to suggest appropriate pregnancy testing protocols will ultimately improve protection of research subjects, reduce the risk of unintended fetal exposure, and reduce the workload of sponsors, investigators, IRBs, and other stakeholders in the clinical trial enterprise.

MEETING OBJECTIVES

- Present survey findings and computer simulation model results from the CTTI project entitled, *Developing Rational Guidance for Pregnancy Testing in Clinical Trials*
 - Discuss practices and challenges in assessing the acceptable risk of pregnancy and implementing a pregnancy testing protocol for a clinical trial
 - Solicit additional feedback and develop consensus on factors to consider when assessing acceptable risk of pregnancy in clinical trials
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DAY 1 – MONDAY, JULY 15, 2013
BALLROOM C, LEVEL 2

7:30 – 8:30 am Breakfast - Harmony Room, Level 2

WELCOMING REMARKS

- 8:30 – 8:40 am Welcome
 Sara Calvert, CTTI, Senior Clinical Project Manager
- 8:40 – 9:00 am Origin and rationale of the project, “*Developing Rational Guidance for Pregnancy Testing in Clinical Trials*”
 Evan R. Myers, Duke University Medical Center, Dept. of Obstetrics & Gynecology

SESSION I: Background on Pregnancy Testing in Clinical Trials

Session Facilitator: Melissa S. Tassinari, FDA, CDER, OND, Pediatric & Maternal Health Staff

Objectives:

- Review the history of embryo/fetal exposure to teratogens/teratogenic risk
- Review the biology and clinical chemistry of pregnancy testing
- Discuss the regulatory perspective on attributes of a cleared pregnancy test

- 9:00 – 9:20 am Why do we worry about pregnancy testing? – Teratogens and teratogenic risk
 Melissa S. Tassinari
- 9:20 – 10:00 am The Analytical & Clinical Complexities of Measuring hCG
 Ann M. Gronowski, Washington University School of Medicine in St. Louis
- 10:00 – 10:20 am What does having a FDA cleared pregnancy test mean?
 Denise Johnson-Lyles, FDA, CDRH, Office of InVitro Devices
- 10:20 – 10:30 am Questions/Discussion
 All Attendees

10:30 – 10:45 am BREAK

SESSION II: Current Practices and Survey Findings

Session Facilitator: Claire Jurkowski, Medical Director, Global Pharmacovigilance and Epidemiology, Bristol Myers Squibb

Objectives:

- Discuss examples of pharmaceutical industry process for selecting pregnancy testing protocols in clinical trials
- Review survey results of current factors considered in selecting a pregnancy testing protocol

- 10:45 – 11:05 am Pharmaceutical industry process for selecting a pregnancy testing protocol
 Sheila Ronkin, Pfizer, Inc.
- 11:05 – 11:15 am Questions/Discussion
 All Attendees
- 11:15– 11:45 am Summary of Results from CTTI Pregnancy Testing in Clinical Trials Survey
 Evan Myers
- 11: 45– 12:30 pm Discussion of survey results
 All Attendees

12:30 – 1:30 pm **LUNCH (PROVIDED) - Harmony Room, Level 2**

SESSION III: Helping make evidence-based decisions about pregnancy testing—potential resources

Facilitator: Evan Myers

Session Objectives:

- Describe the use of computer simulation models to estimate likely outcomes of different pregnancy testing protocols based on subject age, contraceptive effectiveness, and sensitivity and timing of pregnancy test
- Discuss results of initial simulations in different populations
- Review potential resources or tools that can be used to select appropriate pregnancy testing protocols for clinical trials

1:30 – 2:15 pm Modeling approach background and initial simulation results
Potential resources/tools to guide selection of pregnancy testing protocols
Evan Myers

2:15 – 2:30 pm Discussion
All Attendees

2:30 – 2:45 pm **BREAK**

SESSION IV: Break Out Sessions - Jasmine, Juniper, Lilac Rooms, Level 3

2:45 – 2:55 pm Survey results recap & Goals and logistics of breakout sessions
Sara Calvert

3:00 – 4:00 pm Break-out sessions to discuss proposed resources

- Are there other factors that should be considered in the modeling approach and for resource development?
- What resources do you currently use and what additional resources are needed to help support the development of pregnancy testing protocols for clinical trials?
- What are the patients' perspectives on the proposed resources?
- How do you envision using these resources in designing pregnancy testing protocols for clinical trials?
- What would be the most useful format for the potential resources (e.g., broad guidelines or recommendations, tables, webpage or smart phone application to enter trial specific data?)

4:00 – 5:00 pm Break-out groups report (approximately 10 minutes for each group to present and 5 minutes for questions after each group's presentation)

5:00 – 5:15 pm Full group discussion and wrap-up

Please use comment cards provided at your table to submit additional questions/comments that were not covered as part of the breakout session reports.

6:00 – 8:00 pm **RECEPTION - Harmony Room, Level 2**

DAY 2 – Tuesday, July 16, 2013
Ballroom C, Level 2

8:00 – 9:00 am **Breakfast – Harmony Room, Level 2**

SESSION V: Develop Consensus

Session Facilitator: Evan Myers

Session Objectives:

- Discuss proposed recommendations and develop consensus on factors to be considered for assessing acceptable risk of pregnancy and implementing a pregnancy testing protocol for a clinical trial

9:00 – 10:30 am Summary of Day 1 recommendations for designing and evaluating pregnancy testing protocols
Evan Myers

10:30 – 10:45 am **BREAK**

10:45 – 12:00 pm Develop consensus on factors to be considered when assessing acceptable risk of pregnancy in clinical trials in order to suggest appropriate pregnancy testing protocols
Panel: Evan Myers, Claire Jurkowski, Melissa Tassinari
All Attendees

12:00 – 12:15 pm Summarize consensus
Evan Myers

12:15 – 12:30 pm Q&A

12:30 – 12:45 pm Closing remarks: (Boxed lunch available in Foyer)

1:00pm Adjourn