REGISTRY TRIALS PROJECT
A Brave New World: Registry-Based Clinical Trials

Agenda of the Multi-Stakeholder Expert Meeting held March 30, 2016

DoubleTree Silver Spring Hotel by Hilton
8727 Colesville Road
Silver Spring, MD 20910

CTTI MISSION: To identify and promote practices that will increase the quality and efficiency of clinical trials

MEETING OBJECTIVES:

- **Identify essential elements of registries needed to successfully embed and conduct registry-based clinical trials**
- **Present findings from CTTI's Registry Trials Project: Literature Review and Expert Interviews**
- **Receive feedback on potential benefits of and existing barriers to the use of registries in clinical trials**
- **Reach consensus on best practices to increase adoption of clinical trials within registries**

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8:00 **Breakfast** *(Provided)*

8:30 **Welcoming Remarks**

8:30 Welcome, Meeting Agenda
Stephen Mikita, Registry Trials Project Manager

8:35 Introduction to the Clinical Trials Transformation Initiative
Sara Calvert, Clinical Trials Transformation Initiative

8:50 9:30 **Session I: The Registry Trials Project Scope, Overview, and Regulatory Pathways**

Session I Facilitator: John Laschinger; Food and Drug Administration, CDRH
Session I Objectives:
- *Describe project background, overview, and scope*
- *Review U.S. regulatory pathways*

8:50 Registry Trials Project Overview and Scope
Stephen Mikita

9:00 Regulatory Pathways: Devices vs. Drugs - Are There Roles for Registries?
John Laschinger, FDA

9:15 Open Discussion

9:30 10:45 **Session II: Presentation of Project Findings**

Session II Facilitator: James Tcheng, Duke University
Session II Objectives:
- *Present findings from literature review*
- *Present findings from expert interviews*
- *Discuss findings, barriers and solutions*

9:30 Registry Trials Project Literature Review
Sara Calvert, CTTI

9:45 **Break** *(Refreshments Provided)*

10:00 Registry Trials Project Expert Interviews
Ted Lystig, Medtronic

10:20 Open Discussion

10:45 12:15 **Session III: Expert Panel, Registry Trials Lessons Learned**

Session III Facilitator: John Laschinger, FDA
Session Objectives:
- *Provide examples of previous experience with registry trials*
- *Identify major challenges/barriers to registry trial implementation*
- *Discuss generalizability and actionable solutions*

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10:45 12:15	**Session III** *(Continued)*
10:45	Registry-based RCTs: Lessons from the TASTE Trial *Ole Frøbert, Örebro University Hospital*
11:05	Utility of Industry-Sponsored Oncology Registries for Clinical Trials *Dawn Flick, Celgene Corporation*
11:20	The VA's Point of Care Clinical Trial and Precision Oncology Programs *Louis Fiore, Department of Veterans Affairs*
11:35	Open Discussion
12:15	**Working Lunch** *(Provided)* *Introduction to Breakout Sessions and Group Assignments*
1:15 2:15	**Session IV: Breakout Sessions, Best Practices**
	Session IV Facilitator: Ted Lystig, Medtronic *Session IV Objective: Propose best practices to increase adoption of registry-based clinical trials* **Breakout 1: Data Quality** *Facilitator: Jules Mitchel, Target Health* **Breakout 2: Registry Design** *Facilitator: Nicolle Gatto, Pfizer* **Breakout 3: Regulatory** *Facilitator: Kristen Miller, Food and Drug Administration* **Breakout 4: Governance** *Facilitator: Arlene Swern, Celgene Corporation*
2:15	**Break** *(Refreshments Provided)*
2:30 4:00	**Session V: Breakout Sessions Report Outs, Best Practices**
2:30	Breakout 1: Data Quality *(Presenter TBD)*
2:45	Breakout 2: Registry Design *(Presenter TBD)*
3:00	Breakout 3: Regulatory *(Presenter TBD)*
3:15	Breakout 4: Governance *(Presenter TBD)*
3:30	Open Discussion/Consensus Recommendations
4:00 4:15	**Session VI: Call to Action and Wrap up**
	Session VI Facilitators: James Tcheng, John Laschinger, and Ted Lystig
4:15	Adjourn and Departures