



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 Tchong, 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: Nicole 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