



The Use of Antibacterial Drugs Developed via Streamlined Approaches for Serious Infections Where There is Unmet Need: Understanding Patient and Physician Perspectives and Considerations to Take Forward

Agenda of the Multi-Stakeholder Expert Meeting to be held March 1, 2016

Sheraton Silver Spring Hotel
8777 Georgia Avenue
Silver Spring, MD 20910

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

MEETING OBJECTIVES:

- ▶ Present perspectives from patients, caregivers and physicians on antibacterial drugs developed using streamlined approaches
- ▶ Identify focus group themes and discuss topics which should be further explored or where draft recommendations could be made
- ▶ Obtain feedback to improve labeling, risk communication, public understanding and stewardship

Tuesday, March 1, 2016

7:15 **Breakfast (*Provided*)**

8:00 **Welcoming Remarks**

Introduction to the Clinical Trials Transformation Initiative and the ABDD Program
Pamela Tenaerts, Clinical Trials Transformation Initiative (CTTI)

8:15 Project Overview and Scope
Jamie Roberts, CTTI

8:30 9:15 **Session I: Current Landscape of Antibacterial Drug Development for Serious and Unmet Medical Need**

Session I Facilitator: Deborah Collyar, Patient Advocates in Research (PAIR)

Session I Objectives:

- ▶ Current landscape and pipeline
- ▶ Streamlined development approaches

8:30 Current Landscape and Pipeline of Antibacterial Products
Vance Fowler, Duke University School of Medicine
Q & A

8:45 Streamlined Development Approaches
Joseph Toerner, Food and Drug Administration, CDER
Q & A

9:05 Open Discussion

9:15 **Break**

9:30 11:30 **Session II: CTTI ABDD Unmet Need Project & Presentation of Findings**

Session II Facilitator: Jamie Roberts, CTTI

Session II Objectives:

- ▶ Background and current status of project
- ▶ Findings from focus groups and interviews

9:30 Findings: Perspectives of Patients, Caregivers and Healthy People
Diane Bloom, InFocus Research

9:55 Open Discussion

10:15 Findings: Perspectives of Providers and Investigators
Thomas Holland, Duke University School of Medicine

10:45 Open Discussion

11:30 **Working Lunch (*Provided*)**

Tuesday, March 1, 2016 (Continued)

12:00 1:00 Session III: Presentation of Focus Group Themes and Considerations

*Session III Facilitators: Rosemary Tiernan, Food and Drug Administration, CDER;
Stephen Mikita, Patient Representative*

Session III Objectives:

- ▶ Review draft themes, considerations and questions for discussion
- ▶ Identify gaps and challenges
- ▶ Discuss implications for stakeholders

12:00 Focus Group Themes and Questions for Consideration
Stephen Mikita

12:20 Open Discussion
Facilitator: Rosemary Tiernan

12:45 Introduction and Instructions for Breakouts
Jamie Roberts

1:00 2:00 Session IV: Breakout Sessions

- ▶ **Breakout 1: Risk communication with the Public & Providers**
Facilitators: Deborah Collyar, PAIR & Amy Corneli, Duke
- ▶ **Breakout 2: Real-time Clinical Data Use Collection**
Facilitators: Pamela Tenaerts, CTTI & Jeff Loutit, The Medicines Company
- ▶ **Breakout 3: Stewardship Issues**
Facilitators: Thomas Holland, Duke & Diane Bloom, InFocus Research

2:00 Break

2:15 2:45 Session VI: Breakout Sessions Report Outs

2:15 Breakout 1: Speakers: *TBD by Breakout Group*

- *Open Discussion*

2:30 Breakout 2: Speakers: *TBD by Breakout Group*

- *Open Discussion*

2:45 Breakout 3: Speakers: *TBD by Breakout Group*

- *Open Discussion*

3:00 Highlights, Wrap-Up & Next Steps
Speakers: Pamela Tenaerts, Rosemary Tiernan, Jamie Roberts

3:15 Adjourn