CTTI IND Safety Advancement Project

Agenda of the Multi-Stakeholder Meeting held July 21-22, 2015

DoubleTree by Hilton Hotel Washington, D.C. – Silver Spring

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:

- Present findings and conclusions from the project evidence gathering activities
- Discuss opportunities for improving the efficiency and value of the expedited IND safety reporting process
- Understand opportunities for educating stakeholders on expedited IND safety reporting best practices

CLINICAL TRIALS TRANSFORMATION INITIATIVE

Tuesday July 21st, 2015

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

9:00am **CTTI Introduction**
Pamela Tenaerts (CTTI)

Session I **Project History and Overview**
Session Facilitator: Nancy Roach (Fight Colorectal Cancer)
Session Objectives:
- Understand past and current efforts to improve the efficiency of expedited IND safety reporting

9:15am **Patient Perspective on Safety Reporting**
Nancy Roach

9:25am **CTTI Project History and Current Guidance**
Jose Vega (Merck)

9:40am **Expedited IND Safety Reports Submitted to FDA's Office of Hematology and Oncology Products**
Sean Khozin (FDA)

9:55am **Project Overview and Meeting Objectives**
Michael Jones (Eli Lilly)

10:10am **Discussion**

10:30am **Break**

Session II **Presentation of Project Findings**
Session Facilitator: Raymond Perez (University of Kansas)
Session Objectives:
- Present and discuss findings and conclusions from the project evidence gathering activities

10:50am **Investigative Site Survey and Interview Findings**
Raymond Perez

11:10am **Sponsor Survey and Interview Findings**
Robert Goodwin

11:30am **Discussion**

12:15pm **Lunch (Provided)**

Tuesday July 21st, 2015 (Continued)

Session III **Impact of FDA Inspection Practices on Expedited IND Safety Reporting**

Session Facilitator: Robert Goodwin

Session Objectives:

- Clarify and discuss conduct of FDA inspections for expedited IND safety reporting
- Understand forces that have shaped the culture around expedited IND safety reporting
- Understand cultural issues sponsor organizations face in changing expedited IND safety reporting processes

1:15pm **FDA Policy, Processes and Inspections: Expedited IND Safety Reporting**
Chrissy Cochran (FDA)

1:30pm **Cultural Issues and Barriers to Changing Reporting Practice: Sponsor Perspective**
Robert Goodwin

1:45pm **Discussion**

2:30pm **Break**

Session IV **Implementation of the FDA Final Rule on Expedited IND Safety Reporting**

Session Facilitator: Patrick Archdeacon (FDA)

Session Objectives:

- Understand challenges and opportunities related to aggregate reporting of expedited IND safety reporting
- Describe some sponsor methods for determining what/when/how to submit expedited ICSR or aggregate reports
- Discuss what is needed in reports to be valuable and interpretable to FDA and investigators
- Identify future opportunities for educating sponsors

2:45pm **Overview of Expedited IND Safety Reporting**
Patrick Archdeacon

2:55pm **Sponsor Experience with Implementing the FDA Final Rule on Expedited IND Safety Reporting**
Nina Stuccio (Merck)

3:15pm **Sponsor Experience with Implementing the FDA Final Rule on Expedited IND Safety Reporting**
Kenneth Lipetz (Eli Lilly)

3:35pm **Investigator Perspective on Expedited IND Safety Reporting**
Jeffrey Infante (Tennessee Oncology Physicians)

Tuesday July 21st, 2015 (Continued)

3:45pm **Round Table Discussion – Challenges with Implementing the FDA Final Rule on Expedited IND Safety Reporting**

5:00pm **Adjourn to Dinner Reception**

DAY 2

Wednesday July 22nd, 2015

8:30am **Welcoming Remarks**
Raymond Perez (University of Kansas)

Session V **Desired Attributes of Electronic Portals for Expedited IND Safety Reporting**
Session Facilitator: Raymond Perez
Session Objectives:

- Solicit feedback on proposed recommendations for ideal attributes of electronic reporting portals for expedited IND safety reporting

8:45am **Presentation of Proposed Recommendations**
Krupa Patel (Merck)

9:00am **Small Group Discussion of Proposed Recommendations**

- Would these recommendations solve your current challenges with Sponsor safety mailing systems/processes? If not, what other recommendations would you like to have considered?
- How would these recommendations work with your organization's current processes/procedures?
- What are some of the benefits you see for your organization if these recommendations were implemented?

9:30am **Large Group Discussion**

10:00am **Break**

CLINICAL TRIALS TRANSFORMATION INITIATIVE

Wednesday July 22nd, 2015 (Continued)

Session VI **Innovative Opportunities for Communicating Safety Information**

Session Facilitator: Michael Jones (Eli Lilly)

Session Objectives:

- Consider alternative methods for reporting of IND safety information, including related challenges and opportunities
- Understand alternate safety reporting processes that would be of value to investigators

10:15am **Describe and Discuss Different Types of Safety Communication**
Patrick Archdeacon

10:30am **Sponsor Experience with Periodic Reporting**
Maria Luisa Bonura (Pfizer)

10:45am **Sponsor Experience with Periodic Reporting**
Marsha Millikan (Eli Lilly)

11:00am **Investigator Perspective on Periodic Reporting**
Mohamed Salem (Georgetown)

11:10am **Round Table Discussion**

12:15pm **Wrap Up**

12:30pm **Adjourn (Boxed Lunch Provided)**