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
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)
**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 21\textsuperscript{st}, 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 22\textsuperscript{nd}, 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
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)