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)
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
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<th>Time</th>
<th>Session Title</th>
<th>Speaker/Company</th>
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<tbody>
<tr>
<td>10:15am</td>
<td>Describe and Discuss Different Types of Safety Communication</td>
<td>Patrick Archdeacon</td>
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<tr>
<td>10:30am</td>
<td>Sponsor Experience with Periodic Reporting</td>
<td>Maria Luisa Bonura (Pfizer)</td>
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<td>10:45am</td>
<td>Sponsor Experience with Periodic Reporting</td>
<td>Marsha Millikan (Eli Lilly)</td>
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<td>11:00am</td>
<td>Investigator Perspective on Periodic Reporting</td>
<td>Mohamed Salem (Georgetown)</td>
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<td>11:10am</td>
<td>Round Table Discussion</td>
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<tr>
<td>12:15pm</td>
<td>Wrap Up</td>
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<tr>
<td>12:30pm</td>
<td>Adjourn (Boxed Lunch Provided)</td>
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