CTTI Data Monitoring Committees Project Expert Meeting

Agenda of the Expert Meeting held July 28-29, 2015

DoubleTree by Hilton Hotel Washington DC – Silver Spring

8727 Colesville Road, Silver Spring, MD

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 survey and focus groups
- Share and solicit feedback on proposed Data Monitoring Committees (DMCs) recommendations

CLINICAL TRIALS TRANSFORMATION INITIATIVE

Tuesday July 28th, 2015

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

9:00am **CTTI Introduction**
Annemarie Forrest (CTTI)

9:10am **Issue, Project Overview, and Meeting Objectives**
Dave DeMets (University of Wisconsin)

Session I: **Presentation of the Survey and Focus Group Results**
Session Facilitator: Jane Perlmutter (Patient Advocate)
Session Objectives:
- Present and discuss findings from the DMC project survey and focus groups

9:30am **Introduction to the Project Survey and Focus Groups**
Patrick Archdeacon (FDA)
- Description of survey and focus groups
- DMC purpose, rationale, roles and responsibilities

9:50am **DMC Communication Practices Among Key Stakeholders**
Ray Bain (Merck)
- Charter
- Reports to the DMC
- Reports from the DMC

10:10am **DMC Composition, Member Qualification and Training**
Jane Perlmutter
- DMC committee composition
- DMC member qualification
- Training DMC members and stakeholders

10:30am **Discussion**

11:00am **Break**

Session II **Data Monitoring Committee Purpose and Rationale**
Session Facilitator: Roger Lewis (Harbor-UCLA Medical Center)
Session Objectives:
- Solicit feedback on the role and function of DMCs and factors that influence their use in clinical trials
- Solicit feedback on other types of trial oversight committees, particularly ones whose responsibilities overlap with those of DMCs

11:15am **DMC Purpose and Rationale**
Roger Lewis

11:20am **Current Use of DMCs and Other Types of Trial Oversight Committees**
Jonathan Seltzer (ACI Clinical)

11:40am **Facilitated Discussion**

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

CLINICAL TRIALS TRANSFORMATION INITIATIVE

Tuesday July 28th, 2015

Session III **Formation and Organization of Data Monitoring Committees**

Session Facilitator: Ray Bain

Session Objectives:

- Solicit feedback on proposed recommendations related to
  - Forming a DMC
    - Committee qualification
    - Committee make-up
- Operationalization of the DMC
  - Charter preparation and maintenance

1:30pm **Proposed Recommendations for Formation of DMCs**
John McEachern (Parexel)

1:45pm **Discussion**

2:15pm **A Proposed DMC Charter Checklist**
Karim Calis (FDA)

2:30pm **Discussion**

3:00pm **Break**

Session IV **Communication Between the Data Monitoring Committee and Stakeholders**

Session Facilitator: Jason Connor (Berry Consultants)

Session Objectives:

- Solicit feedback and develop consensus on proposed recommendations related to
- Best Practices for communication between the Statistical Analysis Center and other stakeholders
- Best practices for communication between DMCs and regulatory bodies
- Best practices for communication between the DMC and sponsor and/or steering committee

3:15pm **Best Practices for Communication Among DMC Stakeholders**
Jason Connor

3:35pm **Panel Discussion**
Janet Wittes (Statistics Collaborative, Inc.)
Joseph Heyse (Merck Research Laboratories)
Robert Smith (Brown University)

4:45pm **Wrap-up**
Dave DeMets

5:00pm **Dinner Reception**

CLINICAL TRIALS TRANSFORMATION INITIATIVE

Wednesday July 29th, 2015

8:30am **Welcoming Remarks**
Annemarie Forrest

8:35am **Summary of Day 1**
Dave DeMets (University of Wisconsin)

Session V **Preparation of Data Monitoring Committee Members**
Session Facilitator: M. Khair ElZarrad (NIH)
Session Objectives:
- Solicit feedback and develop consensus on proposed recommendations related to DMC member training

8:45am **NIAID DMC Training Program**
Judy Zuckerman (NIAID)

9:05am **MRCT DMC Training Program**
Barbara Bierer (MRCT)

9:25am **Proposed Recommendations for Training DMC Members**
M. Khair ElZarrad

9:45am **Discussion**

10:15am **Break**

Session VI **Actionable Opportunities for Transformative Change**
Session Facilitator: Karim Calis (FDA)
Session Objectives:
- Discuss existing barriers to change and strategies for overcoming those barriers
- Consider ways to facilitate adoption of proposed project recommendations

10:30am **Break-Out Group Discussion: Actionable Opportunities for Transformative Change**

12:00pm **Working Lunch (Provided)**

12:30pm **Report Out and Large Group Discussion: Actionable Opportunities for Transformative Change**

2:00pm **Adjourn**