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
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)
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
  o Forming a DMC
    • Committee qualification
    • Committee make-up
► Operationalization of the DMC
  o 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
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

For more information, contact the CTTI Informed Consent project manager, Annemarie Forrest, at annemarie.forrest@duke.edu or visit http://www.ctti-clinicaltrials.org.