



## **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 28<sup>th</sup>, 2015**

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- 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 28<sup>th</sup>, 2015**

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**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**

Wednesday July 29<sup>th</sup>, 2015

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- 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**

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