exl events

October 19-20, 2017
Sheraton Philadelphia University City
Philadelphia, PA

2017

DMC DATA MONITORING COMMITTEE OPTIMIZATION Summit

Understand the Emerging Issues Regarding Data Monitoring Committees in Clinical Trials While Examining the Roles, Responsibilities and Operating Procedures of DMCs

LEARNING OBJECTIVES

- Discuss the management, operation, and formation of your data monitoring committee
- Identify the appropriate procedures to enhance DMC independence
- Establish charters that include well-defined standard operating procedures
- Examine the confidentiality of interim data and analyses
- Discover the processes of collecting, cleaning, and summarizing data, which are required for your DMC

FEATURED SPEAKERS

Frank Rockhold,
Professor of Biostatistics,
DUKE UNIVERSITY

Joe Massaro,
Professor, Biostatistics,
BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH

Joseph Scherer,
Senior Associate Director, Biostatistics,
BOEHRINGER INGELHEIM

Keith Usiskin,
Executive Director,
CELGENE

Lynn Navale,
Vice President, Biometrics,
KITE PHARMA

Wendel Smith,
Director Global Safety Transcather Heart Valve,
EDWARDS LIFESCIENCES

SPONSOR

ACI CLINICAL

2017 DMC DATA MONITORING COMMITTEE OPTIMIZATION Summit

DEAR COLLEAGUE,

With the increasing use of Data Monitoring Committees during randomized clinical trials, sponsors and stakeholders are now facing new challenges. Their roles have changed over the years and are involved in increasingly varied types of trials. DMC duties may be limited to analyses of efficacy and safety, or extended to review of data quality and additional trial operations. Unclear roles and responsibilities can add to confusion between DMCs and trial stakeholders. Study protocols are becoming increasingly complex, and a lack of understanding and ineffective communication techniques are issues that need to be resolved.

The DMC Optimization Summit, taking place on October 19-20, 2017 in Philadelphia, will bring together clinical health professionals to address the current landscape of DMC use and conduct, while clarifying the purpose of using a DMC. Our skilled staff will discuss preparing statistical reports, charter planning, regulatory reporting, and much more. Attendees will gain a better understanding of how to form committees of qualified members who communicate in a way that is understood by all stakeholders and increases the quality of trial oversight.

WHO SHOULD ATTEND

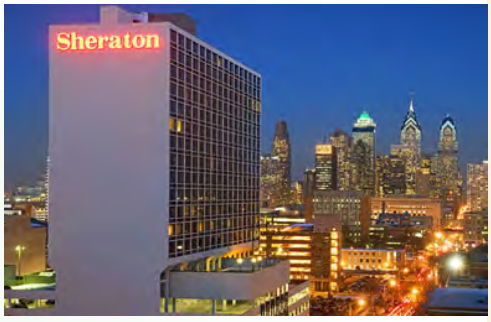
This conference is designed for representatives from pharmaceutical, medical device and biotechnology companies with responsibilities in the following areas:

- DMCs
- Medical/Clinical Safety
- Medical/Scientific Affairs
- Clinical Operations
- Biostatistics
- Pharmacovigilance
- Protocol Management
- Clinical Monitoring
- Data Management
- Safety Operations
- Electronic Data Capture
- Clinical Development
- Project/Trial Management
- Regulatory
- Study Design
- Informatics
- Principal Scientist
- Medical Products Safety
- Endpoints
- Biometrics

This event is also of interest to:

- Consultancies
- Technology Solution Providers
- Medical Imaging Vendor
- Data Management Companies
- Academic Research Organizations
- Medical Research institutions
- Site Management Networks
- Investigative Site Networks

VENUE INFORMATION



Sheraton Philadelphia University City Hotel
3549 Chestnut St
Philadelphia, PA 19104

To make reservations, please call 1-888-627-7071 and request the negotiated rate for **ExL's October Meetings**. You may also make reservations online using the following weblink: http://bit.ly/2sHCy0s. The group rate is available until **September 27, 2017**. Please book your room early, as rooms available at this rate are limited.

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AGENDA DAY ONE THURSDAY, OCTOBER 19, 2017

8:00 Registration and Continental Breakfast

9:00 CHAIRPERSON'S OPENING REMARKS

9:15 MANAGE THE OPERATION AND FORMATION OF YOUR DATA MONITORING COMMITTEE

- Discuss logistical aspects of the DMC and the DSMB, such as the qualifications and responsibilities of members
- Identify how and to whom communication of study results should be disseminated by after the review of interim data
- Examine potential biases formed during ongoing studies

Joe Massaro, *Professor, Biostatistics,* **BOSTON UNIVERSITY SCHOOL OF PUBLIC HEALTH**

10:00 SPONSOR INTERACTIONS WITH STATISTICAL DATA ANALYSIS CENTERS (SDACS)

- Define timelines for cutoff of data, quality checks of data and delivery to SDAC
- Explore different frameworks for interacting with ISTAT and transfer of data to SDAC
- Manage quality checks of output by sponsor
- Examine considerations when changes are requested to DMC SAP by DMC members

Joseph Scherer, *Sr. Associate Director Biostatistics,* **BOEHRINGER INGELHEIM PHARMACEUTICALS**
Dongmei Liu, *Associate Director Biostatistics,* **ACERTA PHARMA**

10:45 Networking Break

11:15 PANEL SESSION: ESTABLISH A SUCCESSFUL RELATIONSHIP WITH PERSPECTIVES FROM DMC MEMBERS

- Recommendations for effective DMC management
- Best practices your experience has identified
- Suggested methods for recruiting DMC members
- What NOT to do as a trial sponsor

Jonathan Seltzer, *President and CEO,* **ACI Clinical**

12:00 Luncheon

"EXCELLENT MEETING - GREAT CONTENT AND KNOWLEDGE OF THE TOPIC " *–PROJECT LEAD,* **DCRI**

PROVIDING THE RIGHT DATA TO ANSWER THE RIGHT QUESTIONS AT THE RIGHT TIME

1:00 CREATE AN EFFECTIVE DMC CHARTER FOR BETTER OUTCOMES

- Master technique and timing of providing interim reports to the DMC
- Design a schedule, meeting format, and arrangement for presentation of data
- Plan who will have access to interim data and attend all or part of DMC meetings
- Determine processes for evaluating conflict of interest of DMC members

Frank Rockhold, *Professor of Biostatistics,* **DUKE UNIVERSITY**

2:30 STATISTICAL DATA ANALYSIS CENTER AND THE ROLE OF INDEPENDENT STATISTICIAN

- Define the roles and objectives of the SDAC relative to the DMC
- Discuss the accessibility of real-time study data by treatment group
- Outline standards for SDAC reports

Michael Pencina, *Director, Biostatistics,*
DUKE CLINICAL RESEARCH INSTITUTE

3:15 RISK- BENEFIT CONSIDERATIONS IN DMC FUNCTIONS

- Improve the current state of R-B evaluation in interim data monitoring
- Discuss Recent advances in R-B methodology
- Recognize potential applications for DMCs

Robert Bigelow, *Associate Director,* **DUKE CLINICAL RESEARCH INSTITUTE**

4:00 Networking Break

4:30 ENHANCE DMC INTERACTION AND INTERFACE WITH THE SPONSOR

- Overview of regulatory and scientific expectations for DMC and Sponsor interactions
- Sponsor and DMC interface when there is an external trial steering committee
- Common interactions that a DMC would have with specific Sponsor teams
- Sponsor handling of the DMC recommendations; regulatory implications

Keith Usiskin, *Executive Director,* **CELGENE**

5:15 Day One Concludes

AGENDA DAY TWO FRIDAY, OCTOBER 20, 2017

8:00 Continental Breakfast

9:00 CHAIRPERSON'S RECAP OF DAY ONE

9:15 INCORPORATE REGULATORY AUTHORITIES IN THE DMC PROCESS

- Manage prompt reporting to FDA of certain serious and unexpected adverse event
- Discuss regulatory guidelines that offer an important set of principles for the DMC process
- Enhance the regulatory understanding of the DMC process

10:00 SPONSOR EXPOSURE TO INTERIM COMPARATIVE DATA AND THE POTENTIAL RISKS

- Potential of compromising objective safety monitoring, equipoise, recruitment, administration of the intervention, or other aspects of the trial
- The sponsor's ability to manage the trial without introducing bias
- Conferring access to interim data with the FDA in advance
- Development of appropriate stopping rules before performing unblinded interim analysis

Peter Zhang, PhD, *Head of Biostatistics Department,* **OTSUKA**

10:45 Networking Break

11:15 DATA MONITORING COMMITTEES IN ADAPTIVE CLINICAL TRIALS

- Address the issue and take a leading role in the implementation of adaptive design studies
- Discuss pre-planned and defined adaptations in the protocol
- Find members of the committee that have the technical expertise to implement such changes and provide assurance of the scientific validity of any adaptation

Lynn Navale, *Vice President, Biometrics,* **KITE PHARMA**

12:00 Luncheon

1:00 THE FUTURE OF DMC AND OVERVIEW OF THE PARADIGM CHANGE

- Traditional DMCs – Benefits & Pitfalls
- 21st century DMCs – New Insights & Evolving Scopes Moving Forward
- Improved Effectiveness of DMCs
- Benefit-Risk Paradigm

Amit Bhattacharyya, PhD, *Vice President, Biometrics,* **ACI CLINICAL**

1:45 DMCS OUTSOURCING OR IN-SOURCE: USE IN EARLY FEASIBILITY STUDIES, TIME FOR A PARADIGM CHANGE ?

- Discuss the use of monitoring committees in EFS versus pivotal regulatory trials
- Analyze real-world examples of logistic problems and solutions to planning and running your IMR and DMCs
- Propose your safety regulatory submission: what does a regulatory body consider?
- Manage closing out a DMC, points to consider

Wendel Smith, *Director Global Safety Transcather Heart Valve,* **EDWARDS LIFESCIENCES**

2:45 Conference Concludes

DATA MONITORING COMMITTEE FACTS

- DMCs have been a component of some clinical trials since at least the early 1960s
- In 1967, an NIH external advisory group first introduced the concept of a formal committee charged with reviewing the accumulating data as the trial progressed to monitor safety, effectiveness, and trial conduct issues in a set of recommendations to the then-National Heart Institute
- Few trials sponsored by the pharmaceutical/medical device industry incorporated DMC oversight until relatively recently
- Some government agencies that sponsor clinical research have required the use of DMCs in certain clinical trials

REGISTRATION FEES FOR ATTENDING THE DMC OPTIMIZATION SUMMIT

EARLY BIRD PRICING
Register Before Friday, September 15, 2017

Conference	$1,895

STANDARD PRICING
Register After Friday, September 15, 2017

Conference	$2,095

ONSITE PRICING

Conference	$2,195

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Offers may not be combined. Early Bird rates do not apply. To find out more on how you can take advantage of these group discounts, contact our offices at (201) 871-0474.

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