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 Transcatheter Heart Valve, EDWARDS LIFESCIENCES
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 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

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

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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<tr>
<td>1:00</td>
<td>CREATE AN EFFECTIVE DMC CHARTER FOR BETTER OUTCOMES</td>
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<td>- Master technique and timing of providing interim reports to the DMC</td>
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<td>- Design a schedule, meeting format, and arrangement for presentation of data</td>
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<td>- Plan who will have access to interim data and attend all or part of DMC meetings</td>
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<td>- Determine processes for evaluating conflict of interest of DMC members</td>
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<td><strong>Frank Rockhold, Professor of Biostatistics, DUKE UNIVERSITY</strong></td>
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<tr>
<td>2:30</td>
<td>STATISTICAL DATA ANALYSIS CENTER AND THE ROLE OF INDEPENDENT STATISTICIAN</td>
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<td>- Define the roles and objectives of the SDAC relative to the DMC</td>
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<td>- Discuss the accessibility of real-time study data by treatment group</td>
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<td>- Outline standards for SDAC reports</td>
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<td><strong>Michael Pencina, Director, Biostatistics, DUKE CLINICAL RESEARCH INSTITUTE</strong></td>
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<td>3:15</td>
<td>RISK- BENEFIT CONSIDERATIONS IN DMC FUNCTIONS</td>
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<td>- Improve the current state of R-B evaluation in interim data monitoring</td>
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<td>- Discuss Recent advances in R-B methodology</td>
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<td>- Recognize potential applications for DMCs</td>
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<td><strong>Robert Bigelow, Associate Director, DUKE CLINICAL RESEARCH INSTITUTE</strong></td>
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### 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

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

GROUP DISCOUNT PROGRAM
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.

SAVE 25%
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