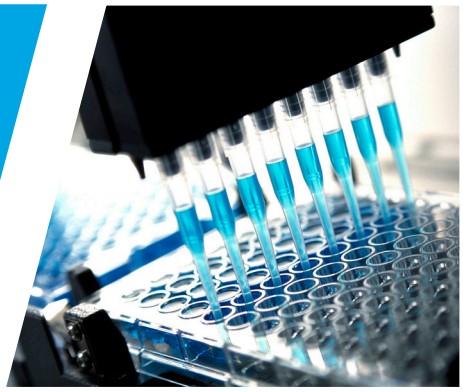
Data Monitoring Committees: Best Practices and Future Directions

November 29-30, 2012

Hyatt Regency Washington, DC



PROGRAM CHAIRPERSON

Jonathan Seltzer, MD, MBA, MA, FACC
Applied Clinical Intelligence, LLC
President and CEO

PROGRAM COMMITTEE

Carmen Bozic, MD
Senior Vice President and Global Head
Safety and Benefit-Risk Management
Biogen Idec

Robert M. Califf, MD
Vice Chancellor for Clinical Research, Duke Univ. Medical Center;
Director Duke Translational Medicine Institute,
United States

Dave DeMets, PhD
Professor, Department of Biostatistics & Medical Informatics
University of Wisconsin

John Orloff, MD
Senior Vice President
Chief Medical Officer
Novartis Pharmaceuticals Corporation

Robert Temple, MD
Deputy Center Director for Clinical Science
Acting Director
Office of Drug Evaluation I (ODE-I)
CDER, FDA

Janet Wittes, PhD
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Statistics Collaborative

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DATA MONITORING COMMITTEES: BEST PRACTICES AND FUTURE DIRECTIONS

For those who sponsor, serve on, or report to Data Monitoring Committees, this meeting promises to provide the tools to help participants in their job. In addition, it will provide some groundwork about the evolving role of DMCs in clinical trial world which is being transformed by electronic data collection. The first part of the meeting will examine current best practices. Leading academic, government and industry leaders, as well as clinicians and statistician DMC members, will discuss the optimal approaches for constituting committees, developing charters, presenting data presentation, training members, and resourcing. The second part of the meeting will focus on the impact of real-time data analytics on DMCs, the evolving roles of DMCs in risk-based monitoring, and a look toward the potential future roles DMCs might play in overall safety monitoring. As a bonus, a special section will discuss the role of DMCs in clinical trials with adaptive designs.

Day 1 Theme: After a Decade of Guidance: Best Practices of Data Monitoring Committees

1. After a Decade of Guidance: The Current Role of DMCs
2. Best Practices for Data Monitoring Committees (DMCs)
3. Best Practices for Independence: Financial, Academic, and Statistical
4. Relationships of DMCs with Other Committees and DMC Roles for Global Companies vs. Small Organizations
5. Joint Session: Role of DMC in Adaptive Designs

Day 2 Theme: The Future of Data Monitoring Committees in the World of Real Time Data and Risk Based Clinical Trials

1. Impact of Real-Time Data Analytics on DMC Structure and Function
2. Implications and New Models for DMCs in the World of Risk Based Monitoring

WHO SHOULD ATTEND

Pharmaceutical, academic and government senior-level professionals and decision-makers involved in all areas drug development including:

- Academic health centers
- Investigator sites
- Good clinical practices
- Clinical research & development
- Clinical safety and pharmacovigilance
- Outsourcing
- Project management
- Regulatory affairs/operations
- Statistics

LEARNING OBJECTIVES

At the conclusion of this conference, participants should be able to:

1. Discuss the evolving role of the Data Monitoring Committee(DMCs) and the infrastructure required in the current pharmaceutical environment
2. Explain the differing roles of Data Monitoring Committees and Steering Committees
3. Identify the limitations of a DMC for smaller companies versus larger companies
4. Describe the proper role of a DMC based on the global infrastructure of the clinical trial

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THURSDAY, NOVEMBER 29

Day 1 Theme: After a Decade of Guidance: Best Practices of Data Monitoring Committees

7:00-8:30AM PROGRAM REGISTRATION AND CONTINENTAL BREAKFAST

8:30-8:45AM WELCOME AND OPENING REMARKS

Jonathan Seltzer, MD, MBA, MA, FACC
Applied Clinical Intelligence, LLC
President and CEO

8:45-10:00AM SESSION 1

After a Decade of Guidance: The Current Role of DMCs

This session sets the stage for our examination of DMC best practices. We will start with an overview, detailing the current status of DMCs. Following this, Dr. Temple will review the FDA's original expectations for the use of DMCs and offer a perspective on the success of the guidance. Likewise, Dr. DeMets, an internationally known expert on DMCs, will offer his perspective on the growth and use of DMCs. Both speakers will discuss what has worked well and what still needs improvement. These topics will form the basis of the morning's discussion.

Current State of DMCs

Jonathan Seltzer, MD, MBA, MA, FACC
Applied Clinical Intelligence, LLC
President and CEO

Reactor Panel:

Academic Perspective: What has Happened over the Last Decade

Dave DeMets, PhD
Professor, Department of Biostatistics & Medical Informatics
University of Wisconsin

FDA Perspective: What was Expected, What is Happening

Robert Temple, MD
Deputy Center Director for Clinical Science
Acting Director
Office of Drug Evaluation I (ODE-I)
CDER, FDA

Academic Perspective

Robert M. Califf, MD
Vice Chancellor for Clinical Research,
Duke Univ. Medical Center;
Director Duke Translational Medicine Institute, United States

10:00-10:15AM REFRESHMENT BREAK

10:15-11:45AM SESSION 2

Best Practices for Data Monitoring Committees (DMCs)

Session Chairperson

Janet Wittes, PhD
President
Statistics Collaborative

This panel discussion will focus on practicalities of DMCs. The panel members, who are physicians and statisticians, all have had considerable experience sitting on, presenting to, or acting as the study chair or the sponsor representative to whom the DMC reports. The panel members will first describe some problems they have actually encountered with a DMC. They will then address such questions as how a DMC should be constituted, whether or not a DMC should remain masked, to whom a DMC should report, and what the reports to the DMC should contain. For committees charged solely with monitoring safety, the panel members will express their opinions about the need to review efficacy as well.

Session Presenters

Kevin Buhr, PhD
Associate Scientist
Statistical Data Analysis Center
University of Wisconsin – Madison

Lawrence M. Friedman, MD
Consultant, Former Director, Division of Epidemiology and Clinical Applications
National Heart Lung & Blood Inst/ NIH

Paul Gallo, PhD
Biometrical Fellow
Novartis

Jay Herson, PhD
Senior Associate Biostatistics
Johns Hopkins University

John H. Powers III, MD
Senior Medical Scientist, Collaborative Clinical Research Branch, NIAID
SAIC/National Institutes of Health

David Stump, MD
Executive Director, Research and Development
Human Genome Sciences

11:45AM–12:30PM LUNCHEON AND NETWORKING OPPORTUNITY

12:30-1:45PM SESSION 3

Best Practices for Independence: Financial, Academic and Statistical

Session Chairpersons

Carmen Bozic, MD
Senior Vice President and Global Head
Safety and Benefit-Risk Management
Biogen Idec

The Data Monitoring Committee (DMC) plays an integral role in protecting patient safety and maintaining the integrity and validity of a clinical trial. The DMC must also assure the public that conflict of interest does not compromise either patient safety or clinical trial integrity. This session will examine the importance and challenges of DMC independence from multiple perspectives, including statistical and financial.

Session Presenters

Marian Fisher, PhD
Distinguished Scientist, Department of Biostatistics and Medical Informatics
The University of Wisconsin

Matthew Downs
Statistical Scientist
Statistics Collaborative, Inc

Gil Price, MD
CEO
Drug Safety Solutions

Thomas Fleming, PhD, MA
Professor, Biostatistics
University of Washington

1:45-3:00PM SESSION 4

Relationships of DMCs with Other Committees, and DMC Roles for Global Companies vs. Small Organizations

John Orloff, MD
Senior Vice President
Chief Medical Officer
Novartis Pharmaceuticals Corporation

This session will examine best practices and opportunities relating to DMC and sponsor interactions with Steering / Executive Committees for pivotal and mega-trials. It will also explore the different roles that DMCs may play in supporting projects and programs for large and small pharmaceutical companies.

Session Presenters

Markus Abt, PhD
Deputy Global Head Statistics Metabolism and CNS
F. Hoffmann-La Roche Ltd.

Raymond P. Bain, PhD
Vice President
Biostatistics and Research Decision Sciences (BARDS)
Global Clinical Development (GCD)
Merck Research Laboratories (MRL)

Marc de Somer, MD
Vice President, Clinical Development
Alkermes, Inc.

Robert Wise, MD
Professor Medicine
Johns Hopkins School of Public Health
Johns Hopkins Medicine

3:00-3:30PM AFTERNOON BREAK

3:30-5:30PM SESSION 5

Joint Session on DMCs in Adaptive Design

Joint Session 4: Role of DMC in Adaptive Designs

Session Chairperson:

Lisa M. LaVange, PhD
Director, Office of Biostatistics
Office of Translational Sciences
CDER, FDA

Adaptive designs present additional challenges to the role of a DMC. The primary role of a DMC is patient safety. Yet some interim decisions in an adaptive design, such as dose selection, may lie in a domain which is traditionally a sponsor responsibility. Concerns about restricting access to interim results need to be addressed, and operational bias needs to be minimized. In this session, views will be presented from the sponsor and DMC member perspective. Case studies will be discussed followed by a panel discussion.

Session Presenters

Paul Gallo, PhD
Biometrical Fellow
Novartis

Dave DeMets, PhD
Professor, Department of Biostatistics
& Medical Informatics
University of Wisconsin

Case Study: A Seamless 2/3 Design

Brenda L. Gaydos, PhD
Research Fellow, Advanced Analytics
Head of Clinical Trial Optimization
Eli Lilly and Company

Ray Carroll, PhD (via teleconference)
Distinguished Professor
Texas A&M University

Panel Discussion

Moderator:

Lisa M. LaVange, PhD
Director, Office of Biostatistics
Office of Translational Sciences
CDER, FDA

Panelists:

Gregory Campbell, PhD
Director, Division of Biostatistics
CDRH, FDA

Bram Zuckerman, MD
Director, Cardiovascular Devices
CDRH, FDA

John Orloff, MD
Senior Vice President
Chief Medical Officer
Novartis Pharmaceuticals Corporation

Dave DeMets, PhD
Professor, Department of Biostatistics and Medical Informatics
University of Wisconsin

Janet Wittes, PhD
President
Statistics Collaborative

Marc K. Walton, MD, PhD
Associate Director for Translational Medicine Office of Translational Sciences CDER, FDA

5:30-6:30PM NETWORKING RECEPTION

Participants from DMC and Adaptive Design meetings

FRIDAY, NOVEMBER 30

Day 2 Theme: The Future of Data Monitoring Committees in the World of Real Time Data and Risk Based Clinical Trials

8:30-10:00AM SESSION 6

Potential Models for DMCs

Session Chairperson

Jonathan Seltzer, MD, MBA, MA, FACC
Applied Clinical Intelligence, LLC
President and CEO

This session is meant to demonstrate some possible directions that DMCs might be able to take in the evolving world of clinical research. Presenters will focus on areas in which they feel that DMCs might be able to improve their performance or potentially, new roles for DMCs.

Session Presenters

Real Time Data Analysis: Potential Opportunities for DMCs

Geoffrey Mann, PhD
Product Manager, Health and Life Sciences
SAS Institute Inc. JMP Division

Moving Toward More Clinically Meaningful DMC Data Displays

Alan Smith
Vice President, Biometrics
Applied Clinical Intelligence

A Model for Cross Company/Cross Compound DMCs: In Loco Parentis - One Sponsor's View of the Role of DMC/DSMB in Maintaining Patient Safety

Gregory Fiore, MD
Chief Medical Officer
The Medicines Company

10:00-10:30AM MORNING REFRESHMENT BREAK

10:30AM-12:00PM SESSION 7

Data Monitoring Committees –After a Decade of the DMC Guidance, Where Do We Go From Here?

Session Co-Chairpersons

Carmen Bozic, MD
Senior Vice President and Global Head
Safety and Benefit-Risk Management
Biogen Idec

John Orloff, MD
Senior Vice President
Chief Medical Officer
Novartis Pharmaceuticals Corporation

This session will be a discussion of the evolving role of DMCs from both a practical perspective as well as from that of the regulatory agencies.

Panel Discussion

Session Panelists

Robert M. Califf, MD
Vice Chancellor for Clinical Research, Duke University Medical Center;
Director Duke Translational Medicine Institute,
United States

Dave DeMets, PhD
Professor, Department of Biostatistics &
Medical Informatics
University of Wisconsin

Robert O'Neill, PhD
Senior Statistical Advisor
Office of Translational Sciences
CDER, FDA

Jonathan Seltzer, MD, MBA, MA, FACC
Applied Clinical Intelligence, LLC
President and CEO

Janet Wittes, PhD
President
Statistics Collaborative

12:00PM FINAL REMARKS AND CONFERENCE ADJOURNED

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

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Event #12018 • November 29-30
Hyatt Regency • Washington, DC

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EVENT CONTACT INFORMATION

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Contact **Benjamin Zaitz, Event Planner,** Phone **+1.215-293-5803**
Fax **+1.215.442.6199,** email **Benjamin.zaitz@diahome.org**

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First Name _____ M.I.

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