Cardiovascular Safety and State-of-the-art Development Issues

Tutorials: April 16, 2012
Conference: April 17-18, 2012
Washington Marriott, Washington, DC, USA

PROGRAM CHAIRPERSON

Philip T. Sager, MD, FACC, FAHA, FHRS
President, Sager Consulting Experts Inc.
Chair, Scientific Programs Committee,
Cardiac Safety Research Consortium

PROGRAM COMMITTEE

CV Safety Track

Norman Stockbridge, MD, PhD
Director, Division of Cardiovascular and Renal Products
Office of Drug Evaluation I, Office of New Drugs
CDER, FDA

Peter Kowey, MD, FACC
Chief of Cardiology, Main Line Health System
Professor of Medicine and Clinical Pharmacology
Jefferson Medical College

Mitchell W. Krucoff, MD, FACC
Professor of Medicine/Cardiology;
Director, Cardiovascular Devices Unit;
Director, eECG Core Lab
Duke University Medical Center/Duke Clinical Research Institute

Diabetes Track

Mary Jane Geiger, MD, PhD, FACP
Medical Fellow
Diabetes Business Unit
Eli Lilly & Company

Orville G. Kolterman, MD
Senior Vice President, Chief Medical Officer
Amylin Pharmaceuticals

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA
Regional Offices
Basel, Switzerland Tokyo, Japan
Mumbai, India Beijing, China

Type 2 Diabetes Mellitus Medications, QT, Benefit/Risk Assessment, Arrhythmias, Thrombosis, and Cardiotoxicity

Join Industry Experts and Regulators to Improve Your Safety Analysis During Drug Development, Analyze and Mitigate Potential Risks, and Explore New Solutions and Approaches to Developing Safe and Effective Medications, including those to treat Type 2 Diabetes Mellitus.

Participate in debate-style presentations and hear commentary and presentations from international industry, academic, and regulatory speakers to help you optimize your cardiovascular safety assessment and improve the development of medications to treat Type 2 Diabetes Mellitus and other diseases.

FEATURES

- This meeting will offer plenary sessions and two tracks – one for Diabetes topics and one for CV safety topics
- Interact with FDA and other regulatory agency participants
- Scientific abstract presentation sessions
- Robust networking opportunities

WHO SHOULD ATTEND

- Pharmaceutical executives
- Academic scientists
- Pharmaceutical cardiac safety experts
- Clinical diabetology experts
- Clinical epidemiology experts
- Regulatory affairs specialists
- Biostatisticians and data managers
- Project teams working in Endocrine/Metabolic areas
- Preclinical safety experts
- Biomarker professionals
- ECG lab and equipment vendors
- Regulatory specialists

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Heart Rhythm Society℠
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Cardiac Safety Research Consortium
Duke Clinical Research Institute (DCRI)

FDA

LEARNING OBJECTIVES

PLENARY SESSION:
At the conclusion of this session, participants should be able to:
- Define the Benefit:Risk considerations confronting regulators and payors/providers.
- State the role of social norms in the determination of Benefit:Risk
- Recognize quantitative approaches to assessing Benefit:Risk

CV SAFETY TRACK:
At the conclusion of this track, participants should be able to:
- Describe how to evaluate drugs for CV risk
- Explain the major issues in clinical CV safety evaluation.
- Describe new approaches to evaluating post-marketing safety assessment.

DIABETES TRACK:
At the conclusion of this track, participants should be able to:
- Summarize the evidence for cardiovascular risk with new and existing T2DM drugs.
- Recognize the current and evolving regulatory initiatives for CV Safety of T2DM drugs.
- Discuss how new regulations will impact clinical development of new T2DM drugs.
- Evaluate scientific data from preclinical and clinical sources, pre- and post-marketing strategies, and other innovative approaches to drive future efforts to develop efficient approaches to the development of T2DM drugs.
- Identify approaches to assure CV safety is appropriately defined in the development of T2DM drugs.

CONTINUING EDUCATION

This activity has been planned and implemented in accordance with the Essential Areas and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Postgraduate Institute for Medicine (PIM) and the Drug Information Association. PIM is accredited by the ACCME to provide continuing medical education for physicians.

PIM designates this live activity for a maximum of 15.25 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 18.25 contact hours or 1.825 continuing education units (CEU's).

Drug Information Association has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102.

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer up to 1.8 CEUs for this program. Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you must attend the program (and tutorial, if applicable), scan your name badge at each session you attend, and complete the on-line credit request process through My Transcript at **www.diahome.org**. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on **May 2, 2012**.

Please Note: *If you do not scan your badge at each session you attend, you will not be able to request continuing education credits for that portion of the program.*

This program is part of DIA's Certificate Program and is awarded the following:
- Clinical Research Certificate Program: 8 Elective Units

For more information go to www.diahome.org/certificateprograms

Disclosure Policy
The Postgraduate Institute for Medicine (PIM) and DIA require instructors, planners, managers and other individuals who are in a position to control the content of this activity to disclose any real or apparent conflict of interest they may have as related to the content of this activity. All identified conflicts of interest are thoroughly vetted by PIM and DIA for fair balance, scientific objectivity of studies mentioned in the materials or used as the basis for content, and appropriateness of patient care recommendations.

CONTINUING EDUCATION CREDIT ALLOCATION

TUTORIALS:
Tutorial 1 – Introduction to CV Safety Issues: Pharmacy 3.25 contact hours or .325 CEUs, 286-000-12-062-L04-P, Type of Activity: Knowledge; IACET .3 CEUs

Tutorial 2 – Lesions Learned, Unlearned and to be Learned in Successful Development of Drugs for Diabetes Mellitus: Pharmacy 3.25 contact hours or .325 CEUs, 286-000-12-063-L04-P, Type of Activity: Application; IACET .3 CEUs

CONFERENCE:
Session 1 - Plenary Session: 3.5 contact hours or .35 CEUs, 286-000-12-064-L04-P, Type of Activity: Knowledge; IACET .3 CEUs

CV SAFETY TRACK
Session 2 – Key Drug Development Issues: 1 contact hour or .1 CEU, 286-000-12-065-L04-P, Type of Activity: Knowledge; IACET .1 CEU

Session 3 – QT and Arrhythmia Assessment: 2.25 contact hours or .225 CEUs, 286-000-12-066-L04-P, Type of Activity: Knowledge; IACET .2 CEUs

Session 4 – Drug-induced Heart Rate Increases – Is this a Risk Factor for CV Events?: 1 contact hour or .1 CEU, 286-000-12-067-L04-P, Type of Activity: Knowledge; IACET .1 CEU

Session 5 – Innovation in Clinical Trials and Safety Assessment: 1.5 contact hours or .15 CEUs, 286-000-12-068-L04-P, Type of Activity: Knowledge; IACET .2 CEUs

Session 6 – Abstract Presentations: 1.5 contact hours or .15 CEUs, 286-000-12-069-L04-P, Type of Activity: Knowledge; IACET .2 CEUs

Session 7 – Devices Lessons Learned and Future Innovation & Closing Remarks: 4.25 contact hours or .425 CEUs, 286-000-12-070-L04-P, Type of Activity: Knowledge; IACET .4 CEUs

DIABETES TRACK
Session 2 – Current Considerations in Diabetes Drug Development: 4.25 contact hours or .425 CEUs, 286-000-12-071-L04-P, Type of Activity: Knowledge; IACET .4 CEUs

Session 3 – Facilitating the Use of Diabetic Devices to Improve Diabetic Outcomes: 1.5 contact hours or .15 CEUs, 286-000-12-072-L04-P, Type of Activity: Knowledge; IACET .2 CEUs

Session 4 – Abstract Presentations: 1.5 contact hours or .15 CEUs, 286-000-12-073-L04-P, Type of Activity: Knowledge; IACET .2 CEUs

Session 5 – Expanding the Science in DM Drug Development: New Collaborative Research Efforts & Closing Remarks: 3.25 contact hours or .325 CEUs, 286-000-12-074-L04-P, Type of Activity: Knowledge; IACET .3 CEUs

FEATURED REGULATORY SPEAKERS

Robert Temple, MD
Deputy, Center Director for Clinical Science, CDER, FDA

Mary Parks, MD
Director, Division of Endocrinology and Metabolism Products
Office of Drug Evaluation II
Office of New Drugs, CDER, FDA

Norman Stockbridge, MD, PhD
Director, Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Office of New Drugs, CDER, FDA

Carlos Bell, MPH, Lieutenant Commander, USPHS
Program Manager, Sentinel Initiative
Office of Medical Policy, CDER, FDA

Christine E. Garnett, PharmD
Associate Director
Pharmacometric Operation
Office of Clinical Pharmacology
CDER, FDA

Danica Marinac-Dabic, MD, PhD
Director, Division of Epidemiology
CDRH, FDA

J. Todd Sahlroot, PhD
Deputy Director and Team Leader
Division of Biometrics II
Office of Biostatistics, CDER, FDA

Mary Ross Southworth, PharmD
Deputy Director for Safety, Division of Cardiovascular and Renal Products
Office of New Drugs, CDER, FDA

Colette Strnadova, PhD
Senior Scientific Advisor
Therapeutic Products Directorate
Health Canada

Markus Yap, PhD, MPH
Business Informatics Manager
Office of Business Informatics
CDER, FDA

Joanne Zhang, PhD
Lead Statistician in QT Team
Division of Biometrics VI
Office of Biostatistics, CDER, FDA

MONDAY | **APRIL 16, 2012**

12:00-5:00 PM REGISTRATION

1:30-5:00 PM TUTORIALS

Tutorial #1 – Introduction to CV Safety Issues

INSTRUCTOR

Borje Darpo, MD, PhD
Associate Professor of Cardiology
Karolinska Institute
Pharmaceutical Consultant, Sweden

This workshop serves as an introduction to the area of drug-induced QT prolongation and proarrhythmias. It is intended to provide participants with a background to the topic and is focused on clinical assessment of the 'QT liability' of drugs in development and which expectations regulatory authorities in different regions will have on programs in this regard.

Tutorial Learning Objectives

- Describe the basis for proarrhythmias related to drug-induced prolonged cardiac repolarization
- Recognize basic concepts related to the collection, analysis and interpretation of clinical ECG data, taking into consideration the effect of study design and conduct on these parameters
- Design a program for QT assessment in early as well as late stage clinical trials
- Describe how to design, conduct, analyze and interpret data from a "thorough QT/QTc study"
- Describe the role of concentration effect modeling and whether the 'thorough QT/QTc study can be replaced/waived
- Recognize the underlying regulatory thinking in terms of QT prolongation and patient safety
- Discuss emerging new concepts and technologies for QT assessment, such as highly automated measurement methods and concentration effect modeling and their potential role
- Discuss the epidemiology of drug-induced proarrhythmias and the role of observational studies in assessing the risk for marketed products

Tutorial #2 – Lessons Learned, Unlearned and to be Learned in Successful Development of Drugs for Diabetes Mellitus

INSTRUCTORS

Orville G. Kolterman, MD
Senior Vice President, Chief Medical Officer
Amylin Pharmaceuticals

Michael Lincoff, MD
Cleveland Clinic

Jay S. Skyler, MD
Professor of Medicine, Deputy Director, Diabetes Research Institute
University of Miami Miller School of Medicine

Alexander Fleming, MD
CEO, Kinexum

This will be a highly interactive workshop among the multidisciplinary experts and attendees before, during, and after the conference. Challenging case studies will be presented and discussed by the panel and critiqued by the audience. .

- Explain the key changes in the regulatory and development environment that are driving specific clinical trial challenges
- Examine where the expectations of regulators, payers and patients, are going and the challenges and opportunities for addressing them.
- Differentiate getting to go/no go decisions at each phase based on available readouts and other considerations
- Examine new and novel indications for diabetes-related therapies
- Recognize key differences in the development of T1 and T2DM therapies and potential for drugs that target both major indications

TUESDAY | **APRIL 17, 2012**

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

8:00-8:15 AM WELCOME AND OPENING REMARKS

Philip T. Sager, MD, FACC, FAHA, FHRS
President, Sager Consulting Experts Inc.
Chair, Scientific Programs Committee
Cardiac Safety Research Consortium

Susan Cantrell
Director
DIA North America

8:15-10:00 AM SESSION 1 – PLENARY SESSION

Benefit:Risk Consideration and CV Safety

Debate: What is the Right Balance with Respect to Focusing on CV Safety - Do we have it Right? (50 min)

Robert Temple, MD
Deputy, Center Director for Clinical Science
CDER, FDA

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

Case Example: Benefit:Risk Assessment of Dronedarone (15 min)

Industry Speaker Invited

Quantitative Approaches to Assessing Benefit:Risk; Can we Get Beyond Subjective Approaches? (25 min)

Thomas R. Fleming, PhD
Professor of Biostatistics
University of Washington

10:00-10:20 AM REFRESHMENT BREAK

10:20 AM-12:00 PM SESSION 1 – PLENARY SESSION (CONTINUED)

Benefit:Risk Consideration and CV Safety

How do we integrate social norms and preferences into the Benefit:Risk determination? (20 min)

Markus Yap, PhD, MPH
Business Informatics Manager
Office of Business Informatics
CDER, FDA

Benefit and Risk - What is the Patient's Perspective? (15 min)

Rebecca Killion
Patient Representative

Viewpoint on Integrating Patient Preferences into the Benefit: Risk Analysis (10 min)

Robert Temple, MD
Deputy, Center Director for Clinical Science
CDER, FDA

Benefit and Risk - What is the Payer's Perspective? (15 min)

Marcel E. Salive, MD, MPH
Division of Geriatrics and Clinical Gerontology
National Institute on Aging

Panel Discussion (40 min)

All Session Speakers

12:00-1:30 PM LUNCHEON

1:30-6:00 PM CONCURRENT TRACKS

CV SAFETY TRACK

1:30-2:35PM SESSION 2

Key Drug Development Issues

Disparate Effects of Anticoagulation and Anti-thrombotic Medications: Does it Make Mechanistic Sense? (20 min)

Richard C. Becker, MD
Professor of Medicine
Duke University School of Medicine

What Should we Focus on - Population-based Safety Margins or Individualized Safety? (20min)

Academic Speaker Invited

Lessons Learned from Device Development (25 min)

Mitchell W. Krucoff , MD, FACC
Professor of Medicine/Cardiology;
Director, Cardiovascular Devices Unit;
Director, eECG Core Lab
Duke University Medical Center/Duke Clinical Research Institute

2:35-3:15 PM SESSION 3

QT and Arrhythmia Assessment

FDA IRT Experience with Novel QT Study Designs (20 min)

Joanne Zhang, PhD
Lead Statistician in QT Team
Division of Biometrics VI
Office of Biostatistics
CDER, FDA

FDA Update on the Expansion of the ECG Warehouse to Include Holter Technologies (20 min)

Christine E. Garnett, PharmD
Associate Director, Pharmacometric Operation,
Office of Clinical Pharmacology
CDER, FDA

3:15-3:30 PM REFRESHMENT BREAK

DIABETES TRACK

1:30-3:15 PM SESSION 2

Current Considerations in Diabetes Drug Development

Benefit:Risk of Diabetic Medications - Microvascular Benefits and Macrovascular Concerns - How do we Integrate Different Effects (20 min)

Academic Speaker Invited

Integrating the Multiple Metabolic Effects of Diabetic Agents into Clinical Development and Practice and the Implications of what are Appropriate Measures of Glycemic Control (20 min)

Academic Speaker Invited

Identified challenges in developing drugs, including diabetic agents

Venture Capitalist Perspective (10 min)

Speaker Invited

Industry Perspective (10 min)

Murray Stewart, DM, FRCP
SVP Therapy Area Head for Metabolic and Cardiovascular Pathways
GlaxoSmithKline

What are the Best Endpoints for Evaluating DM Drugs (20 min)

Industry Speaker Invited

Panel Discussion (25 min)

All Session Speakers

1:30-6:00 PM CONCURRENT TRACKS

CV SAFETY TRACK

3:30-5:00 PM SESSION 3 (CONTINUED)

QT and Arrhythmia Assessment

Use of the Early Clinical Data - can QT Risk be Adequately Determined During the SAD and MAD Trials and Potential Implications for Oncology Drug Development? (15 min)

Borje Darpo, MD, PhD
Associate Professor of Cardiology
Karolinska Institute
Pharmaceutical Consultant, Sweden

The Conundrum of Drug-induced Heart Rate Increases - What are the Optimal Approaches to Deal with this During the TQT? (15 min)

Marek Malik, PhD, MD, DSc, FACC, FESC, FHRS
Professor of Cardiac Electrophysiology,
St. Paul's Cardiac Electrophysiology and St. George's, University of London, UK

What is the Optimal Approach to Phase 3 when a Drug has a Moderate QT Effect (15 min)

Jay W. Mason, MD
Professor of Medicine
University of Utah

An Update on QT Assessment in Japan (15 min)

Boaz Mendzelevski, MD
Vice President of Cardiology
CoreLab Partners Inc., UK

Panel (30 min)

All Session Speakers

5:00-6:00 PM SESSION 4

Drug-induced Heart Rate Increases - Is this a Risk Factor for CV Events?

Mechanisms of Drug-induced HR Increases: Might the Mechanism Impact the Clinical Relevance? (15 min)

Gary A. Gintant, PhD
Research Fellow
Chairman, Abbott QT Working Group
Global Pharmaceutical Research and Development
Abbott

What is the Data (Sibutramine, Beta-agonists, Topiramate and Phentermine) Showing Patient Risk; what is Meaningful - Central Tendency, Outliers, or a Threshold Effect? (15 min)

Academic Speaker Invited

Panel Discussion - What is the Clinical Significance of HR Increases and what Might be Reasonable Next Steps to Explore the Clinical Implications of Increases in Heart Rate? (30 min)

All Session Speakers and

Peter Kowey, MD, FACC
Chief of Cardiology, Main Line Health System
Professor of Medicine and Clinical Pharmacology
Jefferson Medical College

6:00 PM END OF DAY 1

6:00-7:00 PM NETWORKING RECEPTION

DIABETES TRACK

3:30-6:00 PM SESSION 2 (CONTINUED)

Current Considerations in Diabetes Drug Development

FDA Experience with the Diabetes Guidance - What have we Learned and how does the FDA Evaluate Safety Data (35 min)

Mary Parks, MD
Director, Division of Endocrinology and Metabolism Products, Office of Drug Evaluation II
Office of New Drugs, CDER, FDA

FDA Statistical Update (25 min)

J. Todd Sahlroot, Ph.D.
Deputy Director and Team Leader, Division of Biometrics II
Office of Biostatistics
CDER, FDA

Health Canada Viewpoint (20 min)

Colette Strnadova, PhD
Senior Scientific Advisor
Therapeutic Products Directorate
Health Canada

Panel discussion (70 min)

All Session Speakers

WEDNESDAY | **APRIL 18, 2012**

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

8:00-9:30 AM CONCURRENT TRACKS

CV SAFETY TRACK

8:00-9:30 AM SESSION 5

Innovation in Clinical Trials and Safety Assessment

The Challenges to Implementing Innovation in Drug Development – What can be Done? (25 min)
FDA Speaker Invited

The Uses of Devices to Foster Innovation in Safety Assessment of Drugs (20 min)
Industry Speaker Invited

Internet-based Strategies to run Clinical Trials and Potentially Collect Safety Information (20 min)
Speaker Invited

Debate-adjudication of CV Endpoints in Clinical Trials - Is it Really Necessary? (25 min)
Jonathan Seltzer, MD, MBA, MA, FACC
President, Applied Clinical Intelligence, LLC
Director, Clinical Research Main Line Health Heart Center
Academic Speaker Invited

DIABETES TRACK

8:00-9:30 AM SESSION 3

Facilitating the use of Diabetic Devices to Improve Diabetic Outcomes

State-of-the-art talk (20 min)
Academic Speaker Invited

JDRF Experience - How Collaboration can Directly Benefit Public Health (20 min)
Speaker Invited

Patient Perspective on the Need for Device-oriented Therapy (15 min)
Kelly L. Close
President
Close Concerns, Inc

FDA Perspective (15 min)
FDA Speaker Invited

Panel Discussion (20 min)
All Session Speakers

9:30-10:00 AM REFRESHMENT BREAK

10:00-11:30 AM CONCURRENT TRACKS

CV SAFETY TRACK

10:00-11:30 AM SESSION 6

Abstract Presentations

DIABETES TRACK

10:00-11:30 AM SESSION 4

Abstract Presentations

11:30 AM-12:00 PM WORKING LUNCH (Boxed lunches will be provided)

12:00-2:00 PM CONCURRENT TRACKS

CV SAFETY TRACK

12:00-2:00 PM SESSION 7

Devices Lessons Learned and Future Innovation

Innovations in Device Development (25 min)

FDA Speaker Invited

Current Case Examples of Innovative Approaches, Including the Use of Registries (25 min)

Academic Speaker Invited

Panel - Are the Lessons in Device Development Generalizable and can Safety be Incentivized? (30 min)

All Session Speakers and

Philip T. Sager, MD, FACC, FAHA, FHRS
President, Sager Consulting Experts Inc.
Chair, Scientific Programs Committee, Cardiac Safety Research Consortium

Peter Kowey, MD, FACC
Chief of Cardiology, Main Line Health System
Professor of Medicine and Clinical Pharmacology
Jefferson Medical College

Post-marketing Safety Assessment

The Utility of Electronic Data Capture to Assess Post-approval Product Safety (20 min)

Paul D. Varosy, MD, FACC, FHRS
Director of Cardiac Electrophysiology
VA Eastern Colorado Health Care System
Assistant Professor of Medicine
University of Colorado Denver

The Continuum of Safety Pre-market to Post-market and Assessment of Costs (20 min)

Roseann M. White, MA
Senior Director, Biometrics
Abbott Vascular

DIABETES TRACK

12:00-2:00 PM SESSION 5

Expanding the science in DM Drug development: New Collaborative Research Efforts

The CSRC Collaboration Between Stakeholders and What can be Achieved (15 min)

Philip T. Sager, MD, FACC, FAHA, FHRS
President, Sager Consulting Experts Inc.
Chair, Scientific Programs Committee, Cardiac Safety Research Consortium

Patient and Physician Values - How can the Science be Driven to Permit Modification of the Approach to the Benefit:Risk Evaluation

The Role of the Patient and Physician Values in the Evaluation of the Benefit:Risk Analysis (20 min)

Speaker Invited

Scientific Approach to Assessment and Integration of Patient and Physician Values into the Benefit:Risk Analysis (20 min)

Speaker Invited

Novel approaches to CV Safety assessment in DM

The Need and Benefits of Developing Novel Approaches to Studies Assessing the Medical and Safety issues of Diabetic Medications (10 min)

Anders Svensson, MD, PhD
Head of Global Clinical Development - Metabolism
F. Hoffmann-La Roche

The CSRC DM White Paper: Novel Design and Development Approaches (20 min)

Mary Jane Geiger, MD, PhD, FACP
Medical Fellow
Diabetes Business Unit
Eli Lilly & Company

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

FDA Perspective (10 min)

J. Todd Sahlroot, Ph.D.
Deputy Director and Team Leader, Division of Biometrics II
Office of Biostatistics
CDER, FDA

Utility of analyzing large databases from completed studies and data-pooling

What can be Gained and the Impact on Product Development; is this a POC for other Therapeutic Areas; What are the Obstacles (15 min)

Speaker Invited

What are the Necessary Steps to Make this a Reality (10 min)

Mary Parks, MD
Director, Division of Endocrinology and Metabolism
Products, Office of Drug Evaluation II
Office of New Drugs, CDER, FDA

2:00-2:15 PM REFRESHMENT BREAK

CV SAFETY TRACK

2:15-4:15 PM SESSION 7 (CONTINUED)

Post-marketing Safety Assessment

Sentinel Effort - What has been and will be Achieved (20 min)

Carlos Bell, MPH
Lieutenant Commander, USPHS
Program Manager, Sentinel Initiative
Office of Medical Policy
CDER, FDA

Epidemiologic Assessment of Safety, the FDA MD Epinet Effort and the Use of Registries (20 min)

Danica Marinac-Dabic, MD, PhD
Director, Division of Epidemiology
CDRH, FDA

Extensive Data Acquisition, what is a Signal and what is Noise? (20 min)

Speaker Invited

Can Careful Post-market Safety Assessment Speed Development and Reduce the Burdens During Phase 3 Development (20 min)

Mary Ross Southworth, PharmD
Deputy Director for Safety, Division of Cardiovascular and Renal Products, Office of New Drugs
CDER, FDA

Panel (40 min)

All Session Speakers and

Eric L. Michelson, MD
Senior Director, Clinical Research
AstraZeneca LP

4:15-4:30 PM CLOSING REMARKS

4:30 PM CONFERENCE ADJOURNED

DIABETES TRACK

2:15-3:15 PM SESSION 5 (CONTINUED)

Expanding the Science in DM Drug Development: New Collaborative Research Efforts

Panel Discussion (60 min)

All Session Speakers

3:15-3:30 PM CLOSING REMARKS

3:30 PM CONFERENCE ADJOURNED

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

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Cardiovascular Safety and State-of-the-art Development Issues

Event #12009

- **Tutorials: April 16, 2012**
- **Conference: April 17-18, 2012**

Washington Marriott Hotel, Washington, DC, USA

Registration Fees

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TUTORIALS: MONDAY, April 16, 2012 1:30-5:00 PM

#1	Introduction to CV Safety Issues	US $405 ❑
#2	Lessons Learned, Unlearned and to be Learned in Successful Development of Drugs for Diabetes Mellitus	US $405 ❑

PAYMENT OPTIONS:
Register online at www.diahome.org or check payment method.

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❑ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

❑ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

Participants with Disabilities: *DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.*

TRAVEL AND HOTEL The most convenient airports are Ronald Reagan National or Dulles International and attendees should make airline reservations as early as possible. The Washington Marriott is holding a block of rooms at the reduced rate below until March 26, 2012, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $255 **Double $255**

Attendees must make their own hotel reservations. Contact the Washington Marriott Hotel by telephone at +1.888.236.2427 and mention the DIA event. The hotel is located at 1221 22nd St. NW, Washington, DC 20037, USA.

CANCELLATION POLICY: On or before APRIL 9, 2012
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

Participants with Disabilities: DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

EVENT INFORMATION

For registration questions, please contact **Marilyn Ginsberg** by phone at **+1.215.442.6135** or by email at **Marilyn.Ginsberg@diahome.org**.
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Company

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email **Required for confirmation**

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