Cardiovascular Safety, QT, and Arrhythmia in Drug Development

Co-sponsored by

FDA

Heart Rhythm Society

Conference: April 30-May 1, 2009 • Tutorial: April 29 | Hyatt Regency Bethesda, Bethesda, MD, USA

Join Regulatory, Industry, and Scientific Leaders from around the World to Discuss the Evolution of Drug Development, Cardiac Repolarization, and Cardiovascular (CV) Safety.

CONFERENCE HIGHLIGHTS

- CV Safety in Pharmaceutical Development
- Challenges in QT Assessment and Analysis
- Automatic ECG Analysis
- Regulatory and Consortium Update
- CV Safety Beyond QT/Torsade
- Case Studies
- Abstract Presentations

OVERVIEW

This open forum will discuss the new direction in the development of pharmaceutical agents, practical challenges and possible solutions, ways of challenging the current science, and regulatory approaches.

SPECIAL PRE-CONFERENCE TUTORIAL — Wednesday, April 29, 2009

An Introduction to Clinical Assessment of QT Prolongation in Drug Development

LEARNING OBJECTIVES

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

- 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;
- Design, conduct, analyze and interpret data from a 'thorough QT/QTc study
- Define the strategy behind choosing the optimal timing of the thorough QT study;
- Recognize the underlying regulatory thinking in terms of QT prolongation and patient safety;
- Identify relevant clinical, technological and statistical issues in the assessment of QT/QTc prolongation in clinical trials; and
- Discuss emerging new concepts and technologies for QT assessment, such as highly automated measurement methods and their potential role.

PROGRAM CHAIR

PHILIP SAGER, MD, FACC, FHRS
Chief Medical Officer
CardioDx, Inc
ICH E14 Implementation Group Topic Leader

PROGRAM COMMITTEE

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

WHO SHOULD ATTEND

- Academic scientists
- Industry management
- Clinical project physicians
- Quality assurance directors
- Preclinical/discovery scientists
- ECG safety data managers
- ECG lab and equipment vendors
- Regulatory specialists
- Clinical project management
- Safety assessment personnel

CONTACT INFORMATION

Conference: **Joanne Wallace, Program Manager,**
Phone 215-442-6180/Fax 215-442-6199
email Joanne.Wallace@diahome.org

No exhibit opportunities available at this conference.

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Learning Objectives: Please see cover page to see complete listing.

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

WEDNESDAY • APRIL 29

12:00-6:00 PM **TUTORIAL REGISTRATION**

1:30-5:00 PM TUTORIAL

An Introduction to Clinical Assessment of QT Prolongation in Drug Development

Tutoral Instructor

Borje Darpo, MD, PhD
Pharmaceutical Consultant, Sweden

The propensity to prolong cardiac repolarization is studied both in nonclinical and clinical development of a new drug. In clinical development this is currently mainly done through careful analysis of the drug's effect on the QT interval of the surface ECG. The QT interval is regarded as a biomarker, albeit imperfect, for proarrhythmic events and sudden death in patients. QT assessment is often performed both in early clinical trials in healthy volunteers, such as the first-in-man study, in a specific trial in healthy volunteers termed the 'thorough QT study' and to a varying degrees in patients. The centrepiece of the clinical QT assessment is the thorough QT study, which decides the level of subsequent ECG monitoring in late stage development.

This tutorial is designed for professionals who work with ECG data from clinical trials, especially clinicians, clinical writers, clinical data managers, statisticians, and clinical pharmacologists/pharmacokineticists and will:

- Provide attendees with the resources and information necessary to understand relevant concepts in the collection, analysis, and interpretation of ECG parameters in their own clinical trials;
- Discuss recent developments in terms of study design issues and interpretation of results; and
- Target the specific audience taking the course and include interactive case studies and interaction between participants and the presenter.

Learning Objectives

At the conclusion of this tutorial, attendees should be able to:

- 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;
- Design, conduct, analyze and interpret data from a 'thorough QT/QTc study
- Understand the strategy behind choosing the optimal timing of the thorough QT study;
- Understand the underlying regulatory thinking in terms of QT prolongation and patient safety;
- Identify relevant clinical, technological and statistical issues in the assessment of QT/QTc prolongation in clinical trials.
- Recognize emerging new concepts and technologies for QT assessment, such as highly automated measurement methods and their potential role.

THURSDAY • APRIL 30

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

8:00-8:05 AM WELCOME AND OPENING REMARKS

Program Chairperson

Philip Sager, MD, FACC, FHRS
Chief Medical Officer, CardioDx, Inc.
ICH E14 Implementation Group Topic Leader

8:05-8:35 AM SESSION 1

CV Safety in Pharmaceutical Development

SESSION CHAIRPERSON

Philip Sager, MD, FACC, FHRS
Chief Medical Officer, CardioDx, Inc.
ICH E14 Implementation Group Topic Leader

CV Safety in Pharmaceutical Development – FDA Perspective (30 min)
FDA Speaker Invited
Position, Company

8:35-9:55 AM SESSION 2

Challenges in QT Assessment and Analysis

SESSION CHAIRPERSON

Philip Sager, MD, FACC, FHRS
Chief Medical Officer, CardioDx, Inc.
ICH E14 Implementation Group Topic Leader

Use of the Early SAD and MAD Clinical Data to Assist Early Assessment During Drug Development (15 min)
Marek Malik, PhD, MD, DSc, DSc (Med), FACC, FESC, FHRS
Professor of Cardiac Electrophysiology, St. George's University of London & St. Paul's Cardiac Electrophysiology, UK

Commentary (10 min)
Nenad Sarapa, MD
Senior Director, East Coast Research & Early Development
Johnson & Johnson PRD

Moxifloxacin Can be Given Within the Placebo Cohort During a Parallel-Designed Thorough QT Study – FDA Perspective (15 min)
FDA Speaker Invited
Position, Company

QT Correction, Especially When There is an Increase in Heart Rate – Overview (20 min)
Marek Malik, PhD, MD, DSc, DSc (Med), FACC, FESC, FHRS
Professor of Cardiac Electrophysiology,
St. George's University of London & St. Paul's Cardiac Electrophysiology, UK

Use of PK/PD Modeling Principle to Address QT/QTc Interval Prolongation (15 min)
Jianguo (James) Li, PhD
Director of Clinical Pharmacology & DMPK, AstraZeneca LP

FDA Comment (5 min)
FDA Speaker Invited

9:55-10:15 AM REFRESHMENT BREAK

10:15-11:30 AM SESSION 2 *(Continued)*

Challenges in QT Assessment and Analysis

DEBATE: When is Enough? For drugs in which a thorough QT study cannot be performed and the preclinical and early clinical findings show no significant QT effect, analysis of digital ECGs in 60 pts in clinical trials is sufficient.

CON (10 min talk/5 min rebuttal)
Jeff Summers, MD
Deputy Director of Safety Division of Biologic Oncology Products, FDA

PRO (10 min talk/5 min rebuttal)
Ignacio Rodriguez, MD
Director, Drug Safety - Risk Management
Roche, Inc.

Panel Discussion (45 min)
All speakers above

11:30 AM-12:30 PM LUNCHEON

12:30-1:20 PM ABSTRACT PRESENTATIONS

Session Chairperson

Philip Sager, MD, FACC, FHRS
Chief Medical Officer
CardioDx, Inc.
ICH E14 Implementation Group Topic Leader

Repolarization Heterogeneity and T-wave Morphology
Joel Xue
Principal Scientist
GE Healthcare

Changes in T-Wave Morphology as a Covariate in the Assessment of Drug-Induced QT-interval Prolongation
Jorgen Matz
International Safety & Pharmacovigilance
H. Lundbeck A/S, Denmark

Differential Effects of D-Sotalol and a Flouroquinolone Antibiotic on T-wave Morphology and Ventricular Repolarization
Ihor Gussak, MD, PhD, FACC
Chief Medical Officer
NewCardio, Inc.

1:20-3:20 PM SESSION 3

Automatic ECG Analysis

Session Chairperson

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

Highly Automated QT Assessment from Holter by Optimized Extraction and Tailored ECG Review (10 min)
Fabio Badilini, PhD
Executive VP
AMPS-LLC, NY

eECG/ABBIOS: Validation of a Fully Automated QT Evaluation Program (10 min)
Adel Nada, MD, MS
Medical Director
Clinical Pharmacology and Pharmacometrics
Global Pharmaceutical R & D Abbott Laboratories

FDA Approach to Automatic Analysis and Validation (20 min)
FDA Speaker Invited

Structured Presentations to Cover the Following (20 min each speaker):

- Technical approach including how analysis is performed, # leads, outputs, etc.
- How was the automatic approach validated?
- Validation Data with variability measures including the population standard deviation
- How much over-reading is done for a healthy volunteer study?
- Morphology analysis approach and data
- Evaluation of novel TdP risk factors, if applicable

Jean-Philippe Couderc, PhD
Associate Professor of Medicine/Electrical and Computer Engineering; Heart Research Follow-Up Program, Cardiology Department
University of Rochester Medical Center

Jay W. Mason, MD
Professor of Medicine
University of Utah
Consultant to Oxford Medical

Vladislav Bukhman
Vice President, Chief Technology Officer
Monebo Technologies, Inc.

Ihor Gussak, MD, PhD, FACC
Chief Medical Officer and Vice President
Clinical Professor of Medicine,
UMDNJ-RWJ Medical School
NewCardio, Inc.

3:20-3:35 PM **REFRESHMENT BREAK**

3:35-4:20 PM SESSION 3 (continued)

Panel Discussion (45 min)
Speakers above

Philip Sager, MD, FACC, FHRS
Chief Medical Officer, CardioDx, Inc.
ICH E14 Implementation Group Topic Leader

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

Corina-Dana Dota, MD
ECG Centre Director, AZ ECG Centre
AstraZeneca R&D Mölndal, Sweden

4:20-6:00 PM SESSION 4

Regulatory and Consortium Update

Session Chairperson

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

FDA IRT Update Focusing on Identified Issues (20min)
FDA Speaker Invited

Canada Update (10 min)
Colette Strnadova, PhD
Senior Scientific Advisor, Therapeutic Products Directorate
Health Canada, Canada

CSRC Update (10 min)
Benjamin C. Eloff, PhD
Senior Scientific Program Manager,
Office of Scientific and Medical Programs,
Office of the Commissioner, FDA

THEW Update (10 min)
Jean-Philippe Couderc, PhD
Associate Professor of Medicine/Electrical and Computer Engineering; Heart Research Follow-Up Program, Cardiology Department
University of Rochester Medical Center

Process to Classify the Risk of Drug-associated Torsades de Pointes (10 min)
Klaus Romero, MD, MS
Clinical Pharmacologist
The Critical Path Institute

Validation and Acceptance of Pre-clinical Assessments and How They Correlate with Later QT Studies (10 min)
John Koerner
Senior Pharmacologist
Division of Cardiovascular and Renal Products
Office of New Drugs
CDER, FDA

Case Study: Oncology (15 min)
Boaz Mendzelevski, MD
Director of Cardiology, Medifacts International, UK

Case Study: Biologic (15 min)
Andrew Erdman, MD
Drug Safety Scientist
Genentech Inc.

6:00-7:00 PM **NETWORKING RECEPTION**

FRIDAY • MAY 1

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

8:00-10:30 AM SESSION 5

CV Safety Beyond QT/Torsade

Session Chairperson

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

CV Safety in Pharmaceutical Development – Academic Perspective (30 min)
Robert M. Califf, MD
Vice Chancellor for Clinical Research, Duke University Medical Center; Director Duke Translational Medicine Institute

The Role of Personalized Medicine in CV Safety Assessment and Drug Selection (30 min)
FDA Speaker Invited

Genetic Basis of Ventricular and Supraventricular Arrhythmias (15 min)
Dan M. Roden, MD, FACC
Professor of Medicine and Pharmacology, Director, Oates Institute for Experimental Therapeutics, Assistant Vice Chancellor for Personalized Medicine, Vanderbilt University School of Medicine

Using Genetics to Identify Patients with Heart Disease Who Have Increased Ventricular Arrhythmic Risk (15 min)
Amy J. Sehnert, MD
Director, Clinical Research and Development
CardioDx, Inc.

Non-torsade Ventricular and Supraventricular Arrhythmias and Increased Heart Rate as Risk Factors during Drug Development (20 min)
Jeremy N. Ruskin, MD, FACC
Director, Cardiac Arrhythmia Service
Massachusetts General Hospital

Assessment of Myotoxicity in Drug Development (20 min)
John K. Finkle, MD, FACP, FACC
Cardiovascular Therapeutic Area Director
Global Clinical Safety and Pharmacovigilance
GlaxoSmithKline

Assessment of Vascular Damage, Preclinical and Clinical Assessment, and Biomarker Use versus Routine Outcome Studies (20 min)
FDA Speaker Invited

10:30-10:50 AM **REFRESHMENT BREAK**

10:50 AM-12:15 PM SESSION 5 *(Continued)*

CV Safety Beyond QT/Torsade

DEBATE: The routine assessment of a thorough blood pressure study should be part of clinical development.

PRO (15 min talk/5 min rebuttal)
Michael A. Weber, MD
Professor of Medicine
State University of New York, Downstate Medical College

CON (15 min talk/5 min rebuttal)
Diane K. Jorkasky, MD, FACP
Independent Consultant, formerly Vice President, Worldwide Clinical Research Operations, Pfizer Inc.

Panel Discussion – What Thorough Studies Should Routinely be Required during Drug Development? (45 min)
All speakers above
Borje Darpo, MD, PhD
Pharmaceutical Consultant, Sweden

12:15-12:45 PM **WORKING LUNCH**
(Boxed lunches will be available.)

12:45-1:45 PM ABSTRACT PRESENTATIONS (12 MIN EACH SPEAKER)

Session Chairperson
Philip Sager, MD, FACC, FHRS
Chief Medical Officer
CardioDx, Inc.
ICH E14 Implementation Group Topic Leader

Does Over-encapsulation Alter Pharmacokinetics and Pharmacodynamics of Moxifloxacin?
Jay W. Mason, MD
Professor of Medicine
University of Utah
Consultant to Oxford Medical

QT/QTc Prolongation and Torsade de Pointes in Relation to Monoclonal Antibody Therapy
Victor V. Gogolak, MA
President
DrugLogic, Inc.

Concentration-QTc Analysis in the Presence of Pharmacokinetic and Potential Pharmacodynamic Interactions
FDA Speaker Invited

Impact of Delayed Effects in the Exposure-Response Analysis of Clinical QT Trials
Arne Ring, PhD
Team Leader Phase I/IIa Statistics
Medical Data Services, Boehringer Ingelheim Pharma, Germany

Isolated Heart Rate Effects on QTc Assessment
Lawrence Satin, MD, FACC
Chief Medical Officer
Cardiocore

1:45-2:35 PM SESSION 6

Future Approaches to Drug Development

Session Chairperson
Philip Sager, MD, FACC, FHRS
Chief Medical Officer
CardioDx, Inc.
ICH E14 Implementation Group Topic Leader

Future Challenges/Opportunities in QT Assessment (20 min)
Borje Darpo, MD, PhD
Pharmaceutical Consultant, Sweden

CV Safety and Accelerating Drug Development (30 min)
Robert J. Temple, MD
Associate Director for Medical Policy
Office of Drug Evaluation I
CDER, FDA

2:35-3:00 PM FINAL COMMENTS
Philip Sager, MD, FACC, FHRS
Chief Medical Officer
CardioDx, Inc.
ICH E14 Implementation Group Topic Leader

3:00 PM CONFERENCE ADJOURNED

Upcoming DIA Conferences and Training Courses

CONFERENCES

MARCH 20, 2009
Biotechnology Clinical Trials Outsourcing
Burlingame, CA

APRIL 20-21, 2009
Realizing Structural Change Management for Patient Recruitment Success
Horsham, PA

APRIL 26-29, 2009
3rd FDA/DIA Statistics Forum
Arlington, VA

MAY 2009
Early Drug Development: Navigating the Treacherous Rapids
Washington, DC

JUNE 21-25, 2009
45th DIA Annual Meeting
San Diego, CA

TRAINING COURSES

MARCH 9-11, 2009
Introduction to Good Clinical Practices and Auditing
Boston, MA

MARCH 9-11, 2009
Fundamentals of Clinical Research Monitoring
Philadelphia, PA

MARCH 9-11, 2009
EudraVigilance and Electronic Reporting of ICSR's in the EEA
Horsham, PA

MARCH 16, 2009
Overview of Drug Development
Philadelphia, PA

MARCH 17-18, 2009
Project Risk Management
Horsham, PA

MARCH 23-25, 2009
Regulatory Affairs Part I: The IND Phase
Baltimore, MD

APRIL 1-3, 2009
Practical Considerations in Drug Development
Horsham, PA

APRIL 15-17, 2009
Clinical Data Management
Horsham, PA

APRIL 22-24, 2009
Drug Safety Surveillance and Epidemiology
Philadelphia, PA

APRIL 27-30, 2009
Regulatory Affairs Part I: The IND Phase
and Part II: The CTD/NDA Phase
Atlanta, GA

APRIL 27-29, 2009
Essentials of Project Management
Baltimore, MD

APRIL 30-MAY 1, 2009
Utilizing Chemistry, Manufacturing & Controls in Drug Development
Horsham, PA

MAY 4-7, 2009
The Leadership Experience
San Francisco, CA

MAY 5-6, 2009
New Drug Development and Lifecycle Management
Horsham, PA

MAY 7-8, 2009
Project Information Communication and Knowledge Management
Horsham, PA

MAY 11-12, 2009
European Regulatory Affairs
Horsham, PA

MAY 13, 2009
Computer Systems Validation for the Non-computer Professional
Horsham, PA

MAY 14, 2009
Good Clinical Practices for the Clinical Research Professional
Horsham, PA

TRAVEL AND HOTEL The most convenient airport is BWI Airport or Dulles Airport and attendees should make airline reservations as early as possible to ensure availability. The Hyatt Regency Bethesda Hotel is holding a block of rooms at the reduced rate below until April 7, 2009, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single $249 **Double $274**

Please contact the Hyatt Regency Bethesda Hotel by telephone at 301-657-1234 or 800-233-1234 and mention the DIA event. The hotel is located at One Bethesda Metro Center, Bethesda, MD 20814, USA.

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.*

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Horsham, PA, USA
Tel: 215-442-6100
Fax: 215-442-6199
email: dia@diahome.org

Basel, Switzerland
Tel: 41-61-225-51-51
Fax: 41-61-225-51-52
email: diaeurope@diaeurope.org

Tokyo, Japan
Tel: 81-3-5833-8444
Fax: 81-3-5820-8448
email: diajapan@diajapan.org

DIA (India) Private Limited
Tel. 91.22.67653226
Fax 91.22.28594543
email: diaindia@diaindia.org

Cardiovascular Safety, QT, and Arrhythmia Assessment in Drug Development

Event ID #09009
Hyatt Regency Bethesda Hotel, Bethesda, MD, USA
April 29-May 1, 2009

Co-sponsored by

FDA

Heart Rhythm Society℠

Register online or fax this page to 215-442-6199

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CONTACT INFORMATION

Event information: Contact Joanne Wallace at the DIA office by telephone 215-442-6180, fax 215-442-6199 or email Joanne.Wallace@diahome.org.

Registration Fees

Registration fee includes refreshment breaks, luncheons, and reception (if applicable), and will be accepted by mail, fax, or online.

Industry Fee	US $1275 ❑
Discount Fees	
Government (Full-time)	US $ 265 ❑
Charitable Nonprofit/Academia (Full-time)	US $ 515 ❑

TUTORIAL: WEDNESDAY, APRIL 29

1:30 pm-5:00 pm
An Introduction to Clinical Assessment of QT Prolongation in Drug Development US $ 405 ❑

CANCELLATION POLICY: On or before APRIL 23, 2009

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.

❑ **I cannot attend but please keep me informed of DIA's future events.**
(requires completion of name, postal address and email address on this form)

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❑ **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.