

# QT and Drug Development

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The year's most comprehensive safety pharmacology strategy congress  
24th – 25th October 2007, Copthorne Tara Hotel, London

## Keynote Session Speakers include:



**Dr Charles M Beasley Jr., MD.**  
Chief Scientific Officer, Global Product Safety,  
**Eli Lilly & Company**



**Professor A J Camm**, Chairman of the Department of Cardiovascular Sciences and the Division of Cardiological Sciences  
**St George's Hospital, UK**

## Additional presentations from:

**Dr Philip Sager**, Executive Director, Global QT Strategy Leader and Medical Science Director, Cardiovascular Development, **AstraZeneca**

**Dr Rob Wallis**, Executive Director, Head of Global Product Safety, **Pfizer**

**Dr Martin Bedigian**, Global Head, Cardiovascular Assessment Group, **Novartis**

**Dr Gerde Bode**, Consultant and Lecturer

**Dr Guido Hanauer**, Director, Early Safety Pharmacology, **Altana Pharma AG**

**Dr Martin Traebert**, Safety Pharmacology, **Novartis Pharma AG**

**Dr Michael Markert**, Lab Head, Pharmacology, **Boehringer Ingelheim**

**Dr Gary Gintant**, Senior Group Leader, Integrative Pharmacology, **Abbott Laboratories**

**Dr Dhiraj Naruwala**, Medical Director, **Quintiles**

**Dr Collette Strnadova**, Senior Scientific Advisor, Therapeutics Product Directorate, **Health Canada**

**Dr Malcolm Mitchell**, Medical Director, **Eli Lilly & Co**

**Dr Daniel Bloomfield**, Director, Cardiovascular Clinical Research, **Merck Research Laboratories**

**Dr John Davis**, Senior Director, Clinical Pharmacology, **Pfizer**

**Dr Corina Dota**, ECG Centre Manager, **AstraZeneca**

**Dr Nenad Sarapa**, Executive Director, Translational Medicine, **Daiichi Sankyo Pharma Development**

**Annie Stylianou**, Manager, Statistics, **GlaxoSmithKline**

**Dr Venkat Sethuraman**, Associate Director, Group Head, Clinical Pharmacology Statistics, **Novartis Pharmaceuticals**

## Important issues to be addressed include:

- Regulatory and Industry review of S7 and E14 guidelines
- Selecting predictable preclinical assays
- Preclinical safety testing strategies
- Conduct and design of a TQT Study
- Integrating preclinical and clinical data
- QT labelling
- ECG in clinical safety evaluation
- Exposure QT modelling

## Plus Pre conference workshop:

Conducting a Definitive and Thorough QTc Study

23rd October, Copthorne Tara Hotel  
London

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# QT and Drug Development

24th – 25th October,  
Cophthorne Tara Hotel, London

## The year's most comprehensive safety pharmacology strategy congress

Cardiovascular adverse effects continue to dominate the industry agenda. A well designed and executed QTc study has the potential to characterise pro-arrhythmic risk of products in development. This major conference will bring together industry, regulators and academic bodies to discuss the scientific and regulatory challenges in QT analysis and reporting. Topics to be addressed include:

- Regulatory and Industry review of S7 and E14 guidelines
- Selecting predictable preclinical assays
- Preclinical safety testing strategies
- Conduct and design of a TQT Study
- Integrating preclinical and clinical data
- QT labelling
- ECG in clinical safety evaluation
- Exposure QT modelling

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### Day one Wednesday 24th October 2007

08:30 Registration & Coffee

09:00 Opening remarks from the chair

#### Non Clinical Safety Pharmacology

09:10 Regulatory Review of S7 Guidelines for Preclinical Safety Studies

- QT as part of Safety Pharmacology
- Guidelines ICH S7 A and B
- Strategy for testing QT prolongation potential
- Optimal Timing of studies
- Practice and future

**Dr Gerde Bode**, Consultant and Lecturer

09:40 S7B Guidelines: Impact on Preclinical Testing – An Industry Perspective

- summary of the guideline
- handling S7B in the industrial practice

**Dr. Guido Hanauer**, Director, Early Safety Pharmacology **Altana Pharma AG**

10:10 Tea

10:40 Selecting Predictable Preclinical Assays

- Review of in silico, in vitro and in vivo cardiac safety assays
- Novartis cardiac safety test strategy
- Predictivity of preclinical assays
- Case study

**Dr. Martin Traebert**, Safety Pharmacology  
**Novartis Pharma AG**

11:10 Latest Models in preclinical in vivo cardiac safety testing

- challenges in vivo testing
- novel in vivo methodologies and technologies
- limitations and applications in non clinical safety pharmacology

**Dr Michael Markert**, Lab Head, Pharmacology  
**Boehringer Ingelheim**

11:40

**Preclinical Safety Testing Strategies**

- what should we test?
- in vitro vs. in vivo assays: early vs. later studies
- testing for business and regulatory decisions
- the need to match approaches with evolving information

**Dr Gary Gintant**, Senior Group Leader, Integrative Pharmacology, **Abbott Laboratories**

12:10

Lunch

#### Clinical QT Assessment

13:20

**Integrating Preclinical & Clinical Data**

- the inter-relationship of in vitro and in vivo assays
- effects on the QT interval observed in pre-clinical and clinical studies
- recommendations on how to integrate pre-clinical and clinical data

**Dr Rob Wallis**, Executive Director, Head of Global Safety Pharmacology  
**Pfizer**

13:50

**Update from the ICH E14 Implementation Working Group**

- The Questions and Answers document
- The questions being addressed
- The process of answer of development
- Controversies and considerations undergoing discussion

**Colette Strnadova**, Senior Scientific Advisor, Therapeutics Products  
Directorate, **Health Canada**

14:20

**Implementation of E14 Guidelines – An Industry Perspective**

- Examples of studies performed in accordance with the evolution of E14
- The current implementation strategy concerning studies being planned
- How one company has tried to deal with the continuing development of TQT studies

**Dr Malcolm Mitchell**, Medical Director, **Eli Lilly & Co**

15:10

Tea

**Bookings Hotline: +44 (0)20 8785 5640**

**Keynote Presentations**

15:50	<p><b>Keynote address: Conduct &amp; Design of a TQT Study</b></p> <ul style="list-style-type: none"> <li>• The magnitude of intrasubject variability in QTc exceeds by some 2- to 10-fold the magnitude of the point estimate of the difference in change in QT between groups that might be considered clinically predictive of potential harm. Therefore “proving” the absence of a difference that might predict harm is quite difficult.</li> <li>• Regulators seem to be considering progressively smaller differences as potentially predictive of harm – label a compound negatively with respect to smaller and smaller differences observed in a TQTS.</li> <li>• Therefore, TQTS are difficult and labour intensive to perform.</li> <li>• A number of design alternatives may improve on the ability of a TQTS to “prove” the absence of a difference that might predict harm. Unfortunately, there are few empirical results that guide decisions about these alternatives.</li> </ul> <p><b>Dr Charles M. Beasley, Jr., M.D.</b>, Chief Scientific Officer, Global Product Safety, <b>Eli Lilly &amp; Company</b></p>	11:50	<p><b>Electrocardiography in clinical safety evaluation</b></p> <ul style="list-style-type: none"> <li>• ECG in cardiac safety evaluation</li> <li>• The impact on ICH E14 on Phase I studies</li> <li>• The thorough QT study: what is important to know about the collection and analysis of ECG data?</li> <li>• ECG collection for a compound with positive QT signal</li> </ul> <p><b>Dr Corina Dota</b>, ECG Centre Manager, Medical Science Sweden, <b>AstraZeneca</b></p>
16:20	<p><b>Keynote address: Drug induced interference with cardiac ion channels – a CV safety risk</b></p> <p><b>Professor AJ Camm</b>, Chairman of the Department of Cardiovascular Sciences and the Division of Cardiological Sciences, <b>St George's Hospital, UK</b></p>	12:20	<p><b>ECG Data Quality</b></p> <p><b>Dr Dhiraj Narula</b>, Medical Director, ECG Services, <b>Quintiles</b></p>
17:10	<p><b>Closing remarks from the chair</b></p>	12:50	<p><b>Lunch</b></p>
17:30	<p><b>Drinks reception</b></p>	13:50	<p><b>The next generation of QT and non-invasive cardiac ion channel assessment</b></p> <p><b>Dr Tony Hunt</b>, Medical Director and Cardiovascular Specialist <b>PSI HeartSignals (Global) Ltd</b></p>
18:30	<p><b>End of day one</b></p>	14:10	<p><b>QT Assessment in Early Clinical Trials</b></p> <p>Phase 1 clinical studies aim to characterize the safety, tolerability, pharmacokinetics and pharmacodynamics of a drug candidate over wide dose ranges (usually up to the maximum tolerated dose), and define the therapeutic index relative to potential efficacy and safety profiles. Regulatory opinion on the predictive value of the negative non-clinical cardiovascular safety tests for the risk of QTc prolongation in the clinic is not harmonized. Robust ECG assessment is thus one of the critical objectives of early stage clinical development. Replicate serial ECGs, standardized experimental conditions and the ICH E14 statistical measures of the central tendency in Phase 1 dose ascending studies can detect early the potential for QTc prolongation by a drug candidate. When coupled with concentration-QTc effect modeling, the QTc data from Phase 1 studies will guide the strategy for risk-benefit assessment and determine the timing of the thorough QTc study. The presenter will illustrate these principles with examples from single and multiple ascending dose studies in healthy subjects.</p> <p><b>Dr Nenad Sarapa</b>, Executive Director, Translational Medicine, <b>Daiichi Sankyo Pharma Development</b></p>
<b>Day two Thursday 25th October 2007</b>			
08:30	<p><b>Registration &amp; Coffee</b></p>	14:40	<p><b>Cardiac Risk Assessment in Phase II/III Trials</b></p> <ul style="list-style-type: none"> <li>• What factors in early clinical development influence the cardiovascular assessments in late phase?</li> <li>• How should ECG's and biomarkers be used to help define the cardiovascular safety profile?</li> <li>• How should the data be interpreted and what are the pitfalls</li> <li>• How is cardiac safety defined?</li> <li>• Why has it emerged to the forefront of development?</li> <li>• What cardiovascular assessments are utilized in R and D?</li> <li>• Why should CV safety be rigorously monitored in phase II and III?</li> <li>• What should be considered when developing the CV safety monitoring and assessment plan?</li> <li>• Which CV modalities should be included routinely and which for special situations?</li> <li>• Designing the CV safety plan for the phase II and III program</li> <li>• Logistics and operational considerations in acquiring and collecting data</li> <li>• Data analyses and pooling. Examples of adverse event data and ECG data.</li> <li>• Interpreting and troubleshooting the data</li> <li>• Summary and key points to take away</li> </ul> <p><b>Dr Martin Bedigian</b>, Global Head, Cardiovascular Assessment Group, <b>Novartis</b></p>
09:00	<p><b>Opening remarks from the chair</b></p>	15:10	<p><b>Late stage development and post marketing – implications on QT assessment</b></p> <ul style="list-style-type: none"> <li>• Late stage development- implications and QT assessment</li> <li>• Post-marketing issues</li> <li>• Post-marketing risk management strategies</li> </ul> <p><b>Dr Philip Sager</b>, Executive Director, Global QT Strategy Leader and Medical Science Director, Cardiovascular Development, <b>AstraZeneca</b></p>
09:10	<p><b>QT Labelling</b></p> <p><b>Daniel Bloomfield, M.D.</b>, Director, Cardiovascular Clinical Research, <b>Merck Research Laboratories</b></p>	15:40	<p><b>Closing remarks from the chair</b></p>
09:40	<p><b>The use of concentration modelling on QT data</b></p> <ul style="list-style-type: none"> <li>• data collection</li> <li>• understanding the concentration effect relationship</li> <li>• applications in drug development</li> </ul> <p><b>Dr John Davis</b>, Senior Director, Clinical Pharmacology, <b>Pfizer</b></p>	16:00	<p><b>Tea</b></p>
10:10	<p><b>Tea</b></p>	16:30	<p><b>End of conference</b></p>
10:50	<p><b>Statistical Design Considerations for Drug Induced QT and QTc Prolongation in the Clinic</b></p> <p><b>Annie Stylianou</b>, Manager, Statistics, <b>GlaxoSmithKline</b></p>		
11:20	<p><b>Exposure-QT Modelling to Characterize Cardiac Safety: Some Practical Issues to Consider</b></p> <p>The current guidelines, ICH E14, for the evaluation of non-antiarrhythmic compounds requires a “thorough” QT study (TQT) conducted during clinical development. However, this may not be feasible for certain class of drugs, e.g., oncology or cytotoxic drugs. In this presentation, we explore the use of exposure-QT (serum concentration vs QTcF) modeling to address the TQT objective “the largest time-matched mean active - placebo is less than 10 ms”. We assume the exposure-QT relationship to be linear or nonlinear (such as Emax, 4-parameter logistic model) to estimate the changes from baseline at mean Cmax. We compare the above results using simulation under the assumption that a placebo-control was employed and “the largest time-matched mean” hypotheses were to be tested. We describe the impact of other QT interval parameters (e.g., RR) on the modeling in addition to the number of time points, design (parallel vs crossover) and baseline methods (time-matched, time-averaged) used. We use the data from positive control (moxifloxacin 400 mg) to illustrate the impact of ECG collection around tmax to characterize the linear PK-QT relationship. In general, guidance for sample size and precision around estimation of treatment effects using the above models will be discussed under various practical scenarios.</p> <p><b>Dr Venkat Sethuraman</b>, Associate Director, Group Head, Clinical Pharmacology Statistics, <b>Novartis Pharmaceuticals</b></p>		

## Your Expert Faculty Includes

### **Professor A J Camm**, Chairman of the Department of Cardiovascular Sciences and the Division of Cardiological Sciences, **St George's Hospital, UK**

After graduating from Guy's Hospital, London, Professor Camm pursued a career in Cardiology at St. Bartholomew's Hospital and in 1986 moved to the Chair of Clinical Cardiology at St. George's Hospital. Professor Camm is Chairman of the Department of Cardiovascular Sciences and the Division of Cardiological Sciences, and is past Chairman of the Department of Medicine at St. George's. In 1992 Professor Camm was appointed the Queens Honorary Physician.

Professor Camm is particularly interested in clinical cardiac electrophysiology, cardiac arrhythmias and implantable devices for rhythm control. He is past Chairman of the European Society of Cardiology Working Group on Cardiac Arrhythmias, past President of the British Pacing & Electrophysiology Group and a past council member of the Royal College of Physicians. He is a former Trustee of the North American Society of Pacing and Electrophysiology and he is the past President of the British Cardiac Society.

Professor Camm is currently Convener of Medicine, University of London and Chairman of the Joint Cardiology Committee (Royal College of Physicians). He has traveled extensively and is recognised internationally for his research and teaching. Professor Camm is a worldwide renowned trialist and holds memberships in 18 multicentre study committees, including DIAMOND (Danish Investigation of Arrhythmias and Mortality on Dofetilide), ATRAMI (Autonomic Tone and Reflexes after Myocardial Infarction), ELITE II (Effects of Losartan in the Elderly), ALIVE (Azimilide Post-Infarct Survival Evaluation), and DAPHNE (Dronedrone Atrial Fibrillation Post Conversion Evaluation).

### **Colette Strnadova**, Senior Scientific Advisor, Therapeutics Products Directorate, **Health Canada**

Dr. Colette Strnadova is a senior scientific advisor with the Therapeutic Products Directorate of Health Canada. Her professional responsibilities include review of drug submissions undergoing the reconsideration process, ECG assessment study consultations, and regulatory guideline development.

Dr. Strnadova served as the Health Canada representative on two International Conference on Harmonisation (ICH) guideline projects: the ICH S7B guideline, which deals with the assessment of the potential for delayed ventricular repolarization in safety pharmacology studies, and the ICH E14 guideline, which deals with the assessment of QT/QTc interval prolongation liability in clinical trials. Dr. Strnadova currently serves on the ICH E14 Implementation Working Group. She has also developed Health Canada guidance documents on the analysis and review of QT/QTc data and Product Monograph content for drugs with QT/QTc prolongation liability.

### **Dr Daniel Bloomfield**, Director, Cardiovascular Clinical Research, **Merck Research Laboratories**

Daniel M. Bloomfield M.D., M.Phil., F.A.C.C. currently works at Merck Research Laboratories in Clinical Cardiovascular Research. After finishing a BA in Chemistry at Haverford College, he studied Social Anthropology at Oxford University as a Rhodes Scholar. Upon return to the US, he attended Harvard Medical School and then did his Internal Medicine and Cardiology training at Columbia before joining the faculty. As an Associate Professor of Medicine in the Division of Cardiology, Dr. Bloomfield's academic research career was supported by a grants from the NIH, foundations, and industry and was an internationally recognized expert in syncope (fainting spells), and in identifying patients at risk for sudden cardiac death. Dr. Bloomfield's laboratory was also involved in studies related to the autonomic modulation of cardiac repolarization as well as characterizing U wave behavior in diverse autonomic states. Dr. Bloomfield joined Merck Research Laboratories in 2003 in Clinical Pharmacology, was involved in and co-chaired a number of early development teams. He has chaired the QT Task Force (multifunctional group of over 200 individuals involved in all aspects of Merck's response to the E14 guidance), created the Integrated Pre-clinical and Clinical Cardiovascular Safety Team (CVST) and the Cardiac Safety Board.

### **Dr Malcolm Mitchell**, Medical Director, **Eli Lilly & Co**

Dr Mitchell graduated from the University of Newcastle upon Tyne Medical School in 1972.

He has 10 years clinical experience in clinical medicine both in general medicine and radiotherapy. He has 25 years of drug development experience within the pharmaceutical industry and has worked in all phases of drug development. He currently works within clinical pharmacology and as Director of Clinical Pharmacology responsible for regulatory submissions for all products in the portfolio for Eli Lilly. He is thus involved in planning and implementation of QT studies primarily in healthy subjects. He sits on the Cardiovascular Safety Committee within the company which is a multidisciplinary group which discusses any issues seen in development relating to that area. As part of that review system he has input to all QT studies performed by Lilly independent of whether they are considered through QT studies.

### **Dr Corina Dota**, ECG Centre Manager, Medical Science Sweden, **AstraZeneca**

M.D. with 11 years of clinical and medical teaching experience from university hospitals and private medical practice in Romania and Germany, and 10 years of clinical research and management in the field of digital ECGs and use of computerised systems in dECG analysis at AstraZeneca in Sweden.

Currently provides scientific expertise and leadership for the AstraZeneca ECG Centre in Molndal, Sweden, as well as to the team who develops new systems and applications for digital ECG capture, transfer and analysis. Has provided dECG support for AstraZeneca's clinical trials for the past 6 years.

### **Dr Nenad Sarapa**, Executive Director, Translational Medicine, **Daiichi Sankyo Pharma Development**

Dr. Nenad Sarapa received his M.D. degree in 1986 from the University of Zagreb in Croatia. Dr. Sarapa completed residency in Internal Medicine with subsequent Board Certification in Clinical Pharmacology and Therapeutics. He completed PhD training at the University of Zagreb in Croatia. Following an 8-year experience as clinician and clinical research investigator in teaching hospitals, Dr. Sarapa joined Wellcome Foundation's Clinical Pharmacology group in London in January of 1995. He has since worked as a clinical pharmacologist at Glaxo Wellcome, Parexel, Pharmacia & Upjohn, SUGEN and Pharmacia. Dr. Sarapa worked on the Innovative Proof of Concept Team at Pharmacia that in 2003 conducted the first-ever microdosing study in the US, having obtained the FDA approval for the use of a non-GMP drug product and a significantly reduced nonclinical safety package. Dr. Sarapa worked for 2 years as Director of Clinical Pharmacology at Pfizer in San Diego, California. Within the Global QT Advisory Council at Pfizer, Dr. Sarapa has taken the lead in developing strategies for robust cardiovascular safety assessment on clinical trials and conducted exploratory research into the use of Holter ECG and novel endpoints of drug effects on cardiac repolarization. Dr. Sarapa has most recently been the Executive Director of Translational Medicine & Clinical Pharmacology at Daiichi Sankyo in Edison, NJ. In this role he had oversight of the preparation of IND dossiers and supervised the design and conduct of single- and multiple-dose ascending trials with NCEs in the antiplatelet, anticoagulant, diabetes, metabolic, oncology, anti-infective and anti-inflammatory areas. Dr. Sarapa was also in charge of cardiovascular safety assessment of all compounds at Daiichi Sankyo.

Throughout his career in pharmaceutical industry, Dr. Sarapa's main research interests include the innovative designs for early human studies, detection of safety signals in exploratory drug development (including drug-induced QTC prolongation) and translation of biomarkers into the clinic.

### **Dhiraj Narula**, MD, Medical Director, ECG Services, **Quintiles**

Dhiraj Narula, MD, joined Quintiles ECG Services in 2004 as medical director. A board certified cardiologist and electrophysiologist, he is a member of the Royal College of Physicians in the United Kingdom and a Fellow of the American College of Cardiology. At Quintiles, he advises customers on ECG matters, updates ECG interpretation guidelines and writes protocol specific criteria. Responsible for the overall medical direction and quality of Quintiles ECG services, he focuses on training cardiologists and their associates to interpret ECGs for standardized reporting. Having trained in London, Bombay, New York and Hartford, Connecticut, Dr. Narula has treated a broad spectrum of patients in cardiology, renal transplant and internal medicine units. As a practitioner, he has completed more than 2,500 procedures, such as surgical implants, angioplasties, valvuloplasties and biopsies. To keep abreast of practical application of the newest clinical developments, he continues to see patients at his practice in Las Vegas. Dr. Narula is widely published, with numerous articles in the New England Journal of Medicine, American Heart Journal, European Heart Journal, and Indian Heart Journal, as well as contributing to medical textbooks. He has received more than a dozen professional honors, including prizes, scholarships, a fellowship and a teaching award.

### **Martin Traebert**, Group Head Safety Pharmacology, **Novartis Pharma**

Martin has a Ph.D. in Biology/Biochemistry with 10 years of experience in the field of electrophysiology. Martin Traebert studied biology in at the Ruhr-University of Bochum (Germany) and finished with a diploma thesis on cardiac electrophysiology. He obtained his Ph.D. degree from the Institute of Physiology at the University of Zürich focussed on renal phosphate transport by histological and electrophysiological tools. He joined Novartis as a post doc working on histological and electrophysiological analysis of rat brain slices. Afterwards he built up the hERG channel patch clamp laboratory at Novartis and is currently the Group Head of the in vitro Safety Pharmacology group at Novartis dealing with a variety of cardiac safety assays related to cardiac safety testing (patch clamp, repolarization assays, cytotoxicity etc.) Additionally, he is involved in the integrated safety assessment for several research projects and clinical submissions

### **Dr Gary Gintant**, Senior Group Leader, Dept of Integrative Pharmacology, **Abbott Laboratories**

Gary Gintant, Senior Group Leader in the Dept. of Integrative Pharmacology, Global Pharmaceutical Research and Development, Abbott Laboratories, where he heads the Early Preclinical Studies Group. He is actively involved in various cardiac risk assessment / QT interval committees (including the ILSI/HESI Cardiovascular Risk Assessment Committee and Abbott QT Working Group) and has served on various NIH study sections and as advisor to the National Institutes for Drug Abuse regarding cardiac toxicity. Gary also reviews for numerous cardiovascular journals, and is a member of the Editorial Advisory Board for JPET. Research interests are centered on cardiac electrophysiology, ion channels, arrhythmias, and cardiovascular pharmacology, with numerous publications. He gained his M.A., M.Phil. and Ph.D. degrees from Columbia University (College of Physicians and Surgeons) and was a member of the Depts. of Cardiology and Pharmacology at Wayne State University School of Medicine prior to joining Abbott. Gary is a member of the Safety Pharmacology Society, Biophysical Society, a Fellow of the American Heart Association, and an Associate Research Fellow of the Volwiler Society.

### **Dr Gerde Bode**

- Physician with board certification for Pathology, Neuropathology, Legal Medicine, Pharmacology and Toxicology
- 15 years scientific assistant and lecturer at the University of Goettingen, Germany
- 25 years leading positions in the pharmaceutical industry at Boehringer, Hoechst Marion Roussel/ Aventis in Paris and finally Altana, Hamburg
- Currently, Consultant and lecturer at different universities
- 16 years Topic leader for many guidelines for Safety
- chairman of ad hoc Safety group of EFPIA
- Member of the Drug Commission A at BfARM, Germany
- Co-Chair at DIA Annual Meeting in Vienna 2007
- Outstanding Service Award from DIA in 2002.

## Pre Conference Workshop

### Key Issues and Best Practice in Conducting a Definitive Thorough QTc Study

Tuesday 23rd October 2007, Copthorne Tara Hotel, London

*Hosted by; Richmond Pharmacology, the Department of Cardiac & Vascular Sciences, St Georges University of London and leading industry experts.*

Adverse effects of newly approved drugs have triggered public concerns, which have resulted in increased regulatory focus and new guidelines concerning cardiac safety of drugs in development.

This one day workshop will identify key issues and best practice in conducting a definitive thorough QTc study.

#### Agenda

##### 09.15 am: Regulatory review

- Covering ICH S7B non clinical guidance and ICH E14 clinical guidance – this session will discuss the regional and global regulatory issues concerning the implementation of cardiac safety assessments and compliance with the new requirements
- Update on recent submissions and approvals
- Outlook – how will this affect drug development over the next 10 years

##### 10.15 am: How to ensure clinical efficiency and speed in the conduct of a thorough QTc study

- Understanding the clinical perspective in conducting a QTc study and how to ensure efficiency and speed in the process
- The benefits of using a CRO with a complete QTc solution under one roof
- How to minimize the effort in creating a meaningful data set

##### 11.15 am: Break

##### 11.30 am: At what stage of the research process should a QTc study be considered?

- When should a QTc study be considered in your drug development process

##### 12.30 pm: Data capture compliance and ECG measurement

- Understanding ECG core laboratories, and the unique MUSE

platform. How to ensure data capture is accurate, meaningful and FDA CFR part 11 compliant.

- How to make the most of the ECG data

##### 13.30 pm: Lunch

##### 14.15 pm: 6 steps to a successful QTc study

This session will cover the 6 steps involved in conducting a thorough QTc study including:

- o Concept and QTc study design
- o Clinical conduct
- o ECG Data management
- o QTc measurement and analysis
- o Report
- o Regulatory acceptance

##### 15.15 pm: Creating cost effectiveness without substituting quality

- This session will focus on the unique private and public partnership between the Department of Cardiac & Vascular Sciences St George's University of London, and Richmond Pharmacology
- How utilising the benefits of academia within a commercial setting can offer pharmaceutical organizations the best of both worlds

##### 16.15 pm: Close of seminar and tea

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This event will attract a highly targeted audience of decision makers in Safety Pharmacology. There are a wide range of promotional opportunities available at this event. For an informal discussion please call + 44 (0) 20 8785 5638 or email [sponsorship@healthnetworkcommunications.com](mailto:sponsorship@healthnetworkcommunications.com).

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## QT and Drug Development

The year's most comprehensive safety pharmacology strategy congress

**Conference:** 24th – 25th October 2007

**Workshop:** 23rd October 2007

**Venue:** Copthorne Tara Hotel London Kensington, Scarsdale Place, Kensington, London W8 5SR  
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Please notify us at least one month before the course date if you have any additional requirements e.g. wheelchair access, large print etc.

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Please complete fully and clearly in capital letters. Please photocopy for additional delegates.

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Town/City: \_\_\_\_\_ Post/Zip Code: \_\_\_\_\_

Country: \_\_\_\_\_

Direct Telephone: \_\_\_\_\_

Direct Fax: \_\_\_\_\_

Mobile: \_\_\_\_\_

Switchboard: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

#### TERMS AND CONDITIONS OF BOOKING

This booking is a legally binding agreement. Payment must be received before the event. Please contact us if you have not received confirmation of your booking within 14 days, as we cannot be held responsible for non-arrival of conference information.

**What Happens If I Have to Cancel?** If you confirm your cancellation in writing (letter or fax) at least 28 days before the event the fee will be waived, less a 10% service charge. Cancellations received between 28 and 14 days prior to the event will be subject to a 50% service charge. All cancellations received within 14 days of the event will be subject to the full delegate fee. A substitute delegate is welcome at no extra charge.

**Data Protection** The personal information you provide is gathered in accordance with the Data Protection Act 1998 and held on a database by Health Network Communications Ltd. We may use this information to communicate with you about our products and services. If you do not wish to receive this type of information please email: marketing@healthnetworkcommunications.com.

We may also make your information available to other carefully selected companies with products and services related to your business activities. If you do not wish to receive communications from these companies, please tick the box

### THREE EASY WAYS TO PAY

#### CREDIT CARD

Please debit my:  VISA  MASTERCARD  VISA ELECTRON

Card No:

Valid from:   /   Expiry Date:   /

Cardholders name \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Card billing address \_\_\_\_\_

\_\_\_\_\_

**CHEQUE** Enclosed is our cheque for £ \_\_\_\_\_ in favour of Health Network Communications Ltd. Please ensure that the Event Code C1012 is written on the back of the cheque.

**BANK TRANSFER** Should be made to: Barclays Bank plc, Clapham High Street, London SW4 4UF, UK.  
Account name: Health Network Communications Ltd. Account No: 10668907.  
Sort code: 20-21-80. Swift code: BARCGB22

**IBAN** IBAN: GB68 BARC 2021 8010 6689 07. Please include the delegate's name and the conference code C1012 in the transmission details.

### ACCOMMODATION

Special rates for accommodation are available. For details please contact Venue Search on +44 (0) 20 8541 5656 or fax +44 (0) 20 8547 3427 or email [beds@venuesearch.co.uk](mailto:beds@venuesearch.co.uk) and quote the reference **Health Network**.

### MAIL

Mail this completed form together with payment information to:

#### Customer Services

Health Network Communications Ltd  
Erico House  
93 - 99 Upper Richmond Road  
Putney, London  
SW15 2TG

### INCORRECT MAILING

If you are receiving multiple mailings or you would like us to change any details or remove your name from our database, please contact our Marketing Department on +44 (0) 20 8785 5640 Alternatively, fax this brochure to the mailing department on fax number +44 (0) 20 8785 5641 or email: marketing@healthnetworkcommunications.com.

Amendments can take up to six weeks so please accept our apologies for any inconvenience caused in the meantime.