**Programme Chairperson**
Boaz Mendzelevski, Director of Cardiology, Covance Inc., UK

**Programme Co-Chairs**
John A. Camm, Professor of Cardiac & Vascular Sciences, St. George's Hospital Medical School, UK
Borre Darpo, Pharmaceutical Consultant, Sweden
Rashmi Shah, Pharmaceutical Consultant, UK

**Programme Overview**
Recent high profile cardiovascular adverse effects of newly approved drugs triggered public concerns and resulted in increased regulatory focus and new guidance concerning cardiac safety of drugs under development. The new guidance documents, ICH topics S7B (non-clinical) and E14 (clinical), are primarily concerned with investigating the effect of new drugs on cardiac repolarisation and the QT interval. At the centre of these initiatives is the need for a well designed, well executed “thorough QT/QTC study” with relevant statistical power to characterise the pro-arrhythmic risk of drugs in development. However, experience with the new QT assessment study is limited and its impact on the late stage development and regulatory approval process are not yet fully understood.

In addition, recent concerns involving certain COX-2 selective non-steroidal anti-inflammatory drugs (NSAIDs) have highlighted the need for broader cardiac safety surveillance and cardiac risk management programmes, extending well beyond regulatory approval into the post-marketing period. These concerns have now triggered further regulatory reviews of the drug development process and are expected to introduce additional requirements to the drug approval process and the post-marketing commitments from drug manufacturers.

This programme will review and address the above cardiac safety topics and will bring academic, regulatory and industry experts together to exchange ideas and share information with the audience.

**Conference Objectives**
- Discuss the emerging trends in drug development Cardiac Safety
- Summarise new regulatory guidance for QT analysis and reporting
- Recognise the requirements and methods for QT assessment and reporting
- Discuss the science behind drug induced repolarisation AEs
- Recognise the cardiovascular risks of drugs with pro-thrombotic propensity
- Evaluate late phase Cardiac Risk Assessment & Management Strategies

**Conference Themes**
- Cardiac Safety Strategies in Early and Late Phase Development
- The Global Implementation of ICH-E14 Clinical QT Guidance
- Design and Analysis Considerations For Thorough QT Studies
- ICH-E14 Regional Variations - Further Challenges for Compliance
- Role of S7B Non-Clinical Data & Correlation with Clinical Outcomes
- Drug Safety Surveillance and Cardiac Risk Management Programmes

**Accreditation and Credit Designation**
The Drug Information Association is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. The Drug Information Association designates this educational activity for a maximum of 12 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity. The American Medical Association has determined that physicians not licensed in the US who participate in this CME activity are eligible for AMA PRA category 1 credit.

The Drug Information Association (DIA) has been reviewed and approved as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1020 I Street, NW, Suite 615, Washington, DC 20006. The DIA has awarded up to 1.2 continuing education units (CEUs) to participants who successfully complete the program. To receive a statement of credit, please visit www.diahome.org. Detailed instructions on how to complete your CEU request and download your certificate will be provided onsite.

**Disclosure Policy**
It is Drug Information Association policy that all faculty participating in continuing education activities must disclose to the program audience (1) any real or apparent conflict(s) of interest related to the content of their presentation and (2) discussions of unapproved or unapproved uses of drugs or medical devices. Faculty disclosure will be included in the course materials.

**CALL FOR ABSTRACTS**
The deadline for submitting an abstract is the 30th of September 2006.
To submit an abstract, send an email to: tatjana.topalovic@diaeurope.org
- Non-Clinical Safety Pharmacology and Electrophysiology
- Clinical QT assessment - Study Design, Analysis and Outcome
- Clinical Cardiac Safety Assessments
- Peri-Approval and Post Marketing Cardiac Safety Strategies

**REGISTER ONLINE! VISIT OUR WEBSITE WWW.DIAHOME.ORG**
Monday, December 4, 2006

07:00 Registration and Welcome Coffee

08:00 Welcome Address by Boaz Mendzelevski, Director of Cardiology, Covance Inc., UK

08:15 Session 1A
Evolving Trends in Cardiac Safety
Session Chairperson: John A. Camm, Professor of Cardiac & Vascular Sciences, St. George’s Hospital Medical School, UK

The cardiovascular risk associated with new drugs has recently become a major public concern and a regulatory focus. This session will provide an up-to-date overview of the scientific, clinical, genomic, pharmacology and public health background concerning drug induced repolarisation and vascular abnormalities.

Evolving Trends in Cardiac Safety
John A. Camm, Professor of Cardiac & Vascular Sciences, St. George’s Hospital Medical School, UK

QT Genomics: State-of-the-Art
Dan Roden, Professor of Medicine and Pharmacology, Director, Oates Institute for Experimental Therapeutics Assistant Vice-Chancellor for Personalized Medicine, Vanderbilt University, USA

Drug Induced QT/QTc Prolongation: Overview
Rashmi Shah, Pharmaceutical Consultant, UK

10:30 Coffee Break in Exhibition Area

11:00 Session 1B
Evolving Trends in Cardiac Safety Continued
Session Chairperson: John A. Camm, Professor of Cardiac & Vascular Sciences, St. George’s Hospital Medical School, UK

Cardiovascular Risk Associated with COX-2 Inhibitors
Curt D. Furbeg, Professor of Public Health Sciences, Wake Forest University School of Medicine, USA

Moderated Abstract Session:
Repolarisation Based Cardiac Risk Assessment
TQT Studies and Clinical Cardiac Risk Assessment Methods

12:30 Lunch Break

14:00 Session 2A
Regulatory Review & Roundtable
Session Chairperson: Rashmi Shah, Pharmaceutical Consultant, UK

The ICH S7B non-clinical guidance and ICH E14 clinical guidance were finalised in May 2005 and are now in advanced stages of regulatory implementation in the three ICH regions – USA, Europe and Japan. This session will discuss the regional and global regulatory issues concerning implementation of cardiac safety assessments and compliance with the new requirements.

Review of Final E14 Guidance
Borje Darpo, Pharmaceutical Consultant, Sweden

Review of Final S7B Guidance
Klaus Olejnizack, Scientific Director - Head for the Department Geno – and Reproductive Toxicity, BfArM, Germany

Update from the E14 Implementation Working Group
Colette Strnadova, Senior Scientific Advisor Therapeutic Products Directorate, Health Canada, Canada

15:30 Coffee Break in Exhibition Area

16:00 Session 2B
Regulatory Review & Roundtable Continued
Session Chairperson: Rashmi Shah, Pharmaceutical Consultant, UK

Regional Updates:
USA - Mehul Desai, Medical Expert, FDA, USA
Europe - speaker invited
Japan - Maki Ito, Head, Medical Advisers Office, Drug Safety Management Department, Shionogi & Co., Ltd., Japan

Regulatory Round Table
Moderator - Rashmi Shah
Participants - All

17:30 Reception in Exhibition Area

18:30 End of Day 1

Hotel Information

The DIA has blocked a number of rooms at the:
Maritim proArte Hotel Berlin
Friedrichstrasse 151
10117 Berlin
Tel: + 49 (0)30 2033 4410
Fax: + 49 (0)30 2033 4092
e-mail: info.bpa@maritim.de

at a special rate of:
Comfort single € 129,00
Comfort double € 138,00

The rates above includes VAT and service charges.

IMPORTANT
To be assured of accommodation in the Maritim proArte Hotel Berlin, registrants are recommended to complete their reservation form by November 3, 2006, using reference code: DIA

In case of cancellation:
Cancellation must be in writing. One night deposit will be kept as cancellation fee. All no shows will be billed for the entire stay.

Travel Information

The Maritim proArte Hotel is ideally located in the in the vicinity of the German Reichstag, the Brandenburg Gate, the Potsdamer Platz, the Museumsinsel (Museum Island), the German State Opera, concert halls and theaters as well as Europe’s largest variety theater, the Friedrichstadtpalast.

HOW TO GET TO THE HOTEL
The nearest airport is Berlin Tegel (TXL) 15 km (other airport option is Berlin Schönefeld (SXF) 25 km). Transportation from Tegel possible by public bus: marked with TXL, stops at "Unter den Linden" Transportion from Schönefeld possible by public train: marked with "Airport Express", stops at station "Friedrichstrasse"
10:30 Session 3B  
CARDIAC RISK ASSESSMENT STRATEGIES – EARLY DEVELOPMENT  
Session Chairperson:  
Borje Darpo, Pharmaceutical Consultant, Sweden

The adopted ICH E14 guideline has a clear focus on clinical assessment of QT interval prolongation, and specifically on the ‘thorough QT study’ in healthy volunteers. Several recent collaborative initiatives have, however shown that non-clinical assays, including pro-arrhythmia models, have a high predictive value for pro-arrhythmias in patients. In addition, concentration / effect modelling using all available data in clinical trials may be a more effective way than the ‘thorough QT study’ to define the risk for targeted patients with impaired clearance or other risk factors. This session addresses the role of non-clinical standard assays, pro-arrhythmia models and clinical QT assessment in early trials, including the use of pooled concentration / effect data.

Novel Methods for Predicting Drug Induced Arrhythmia  
Marc Vos, Professor of Medical Physiology, Heart Lung Centre, University of Utrecht, The Netherlands

Bridging The Gap - Correlation Between Non-Clinical and Clinical Cardiac Risk Assessments  
Wilhelm Haverkamp, Cardiologist, Charite University, Germany

QT Assessment in Early Clinical Trials - Can it Replace the TQT Study?  
Nenad Sarapa, Executive Director, Translational Medicine, Daiichi Sankyo Pharma Development, USA

Moderated Abstract Session  
Repolarisation Based Cardiac Risk Assessment  
Non-Clinical and Early Clinical Methods

12:00 Lunch Break

TOPICS FOR ABSTRACT SUBMISSION

Clinical Cardiac Safety Assessments  
- Genetic screening/other biomarkers for drug-induced TdP  
- Novel algorithms for ECG interval measurement/assessment  
- Selection of ECG data collection technology and methodology  
- Manual vs. automated ECG data analysis methods and outcome  
- Inter and intra-reader techniques to interpret quality of ECG data

Peri-Approval and Post Marketing Cardiac Safety Strategies  
- Spontaneous reporting systems and CV outcomes  
- Novel post-marketing risk management strategies  
- Cardiovascular Adverse Event classification and reporting  
- Surveillance of drug utilisation and prescribing patterns  
- Epidemiologic assessment of observational clinical trial registry data  
- Capturing clinical outcomes data using post market surveillance (ADR) data
### DIA Workshop on Cardiac Safety December 4-5, 2006, Maritim proArte Hotel Berlin, Germany

**REGISTRATION FORM - I.D. CODE # 06116**
**Fax to: +41 61 225 51 52**

**Member Industry Early-Bird Opportunity**

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**Membership**
Join DIA now to qualify for the early-bird member fee! [www.diahome.org/docs/Membership](http://www.diahome.org/docs/Membership)

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government or academia/nonprofit members.

A one-year membership to DIA is available to those paying a NONMEMBER meeting registration fee.

**Payable in Euros**

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**Payment Methods**

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- Cheques should be made payable to: Drug Information Association. Mail your cheque together with the registration form to facilitate identification of attendee to: DIA, Elisabethen-Anlage 11, Postfach, 4002 Basel, Switzerland.
- Bank Transfers

Persons under 18 are not allowed to attend DIA meetings.

**Cancellations and Substitutions**

- Cancellations received in writing on or before November 27, 2006, will be refunded at the member rate.
- Any cancellation after this date will result in loss of registration fee.
- Substitutions are allowed at any time. 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.

**Workshop Cancellation Policy**

All cancellations must be in writing and be received at the DIA office by 17:00 on November 27, 2006.

**Non-Member Industry Early-Bird Opportunity**

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**Group Discount Available! Send 3, the 4th is FREE**

Register 3 individuals from the same company and receive complimentary registration for a 4th! All 4 individuals must be registered and prepay at the same time. DIA will apply the value of the lowest applicable fee to this complimentary registration. It does NOT include fees for optional events or DIA membership. Substitutions of enrolled delegates of similar membership may be made at any time. Group registration is not available online. To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company and return them together to DIA.

Please indicate that this form is part of a group registration by ticking this box. Please indicate the full names of the other three registrants from your company.

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**REGISTRANT**

Last Name
First Name
Company
Job Title
Street Address / P.O. Box
Postal Code
City
Country
Telephone
Telefax (Required for confirmation)
Email (Required for confirmation)

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Exp. Date
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**Signature**.................................................................Date ........................................

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