Pharmaceutical companies applying for new drug approval in Japan are now required to satisfy the ICH-E14 guideline. The hallmark of the ICH-E14 guidance is the Thorough QT (TQT) Study, or its alternatives for drugs that do not lend themselves to the E14 TQT paradigm (e.g., oncology drugs).

While experience in conducting and analyzing TQT studies in Japan is rapidly developing, some issues remain open. Some of these issues are specific to Japan, including the potential for ethnic differences in QT pharmacodynamics and the need to extrapolate QT data from foreign studies into Japanese subjects. Other issues are universal and reflect the ongoing discussion within the global pharmaceutical research, academic and regulatory community, including the future of the TQT study, the emerging intensive QT studies, the use of positive controls for assay sensitivity, the risks involved in TQT studies, etc.

The 3rd Cardiac Safety Workshop in Japan will explore these topics and others, bringing together experts and members of academia, regulatory and drug development organizations for 2 days of intensive discussion, debates and updates.

**WHO SHOULD ATTEND**
- Drug development and clinical research managers and associates
- Pharmaceutical physicians and medical directors
- Safety pharmacology and nonclinical scientists
- Drug safety and drug surveillance personnel
- Clinical pharmacology scientists
- Pharmacovigilance managers
- Regulatory affairs managers
- Biostatisticians
- Data managers
- IT/technology managers
- Outsourcing and marketing managers
- Decision makers in cardiac drug safety, including toxicology, pharmacology and compliance

**Simultaneous Interpretation Available**

**Tabletop Exhibit Opportunity**
Please contact DIA Japan for details about tabletop exhibits.

Tel: +81-3-5575-2130
Fax: +81-3-3583-1200
email: diajapan@diajapan.org
DAY 1 | MONDAY, MAY 28, 2012

9:00-9:30 REGISTRATION 2nd Floor Lobby

DAY 1
ADVANCING THE SCIENCE OF CARDIAC SAFETY ASSESSMENTS

9:30-10:00 SESSION 1 Togen (2F)
OPENING SESSION

9:30
Opening Remarks
Boaz Mendzelevski, MD
Vice President of Cardiology, CoreLab Partners, UK

9:30-10:00 Keynote Presentation
Assessing the Drug-induced Electrophysiological Effects on the Heart
Atsushi Sugiyama, MD, PhD
Professor of Pharmacology, School of Medicine
Toho University, Japan

10:00-12:00 SESSION 2 Togen (2F)
REGULATORY SCIENCES AND CV SAFETY
SESSION CO-CHAIRS
Colette Strnadova, PhD
Senior Scientific Advisor, Therapeutic Products Directorate
Health Canada
Yoshiaki Uyama, PhD
Director, Regulatory Science Research Division, Office of Regulatory Science, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

A. REGULATORY UPDATES BY PMDA, FDA, HC AND EMA

10:00-10:30
Implementation of ICH-E14 in Japan and Review Issues
Kaori Shinagawa, MD, PhD
Senior Scientist for Clinical Medicine, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

10:30-10:45
Novel Approaches to TQT Study Design and Analysis
Joanne Zhang, PhD (Presentation by pre-recorded video)
Lead Statistician for QT-IRT, Office of Biostatistics / Office of Translational Sciences, CDER, FDA, USA

10:45-11:00
Overall Experience to Date and Review of Special Cases
Krishna Prasad, MB, BS, MD, FRCGP
Consultant Cardiologist, Clinical Assessor, Chair of QT Subgroup & CO-Rapp ICH-E14 Implementation Working Group, MHRA, UK

11:00-11:15
Cardiac Safety Beyond the QT Interval
Colette Strnadova, PhD
Senior Scientific Advisor, Therapeutic Products Directorate, Health Canada

11:15-11:30
QT Drug Labeling
Monica Fiszman, MD, PhD (Presentation by pre-recorded video)
Clinical Reviewer, FDA, USA

B. REGULATORY ROUNDTABLE – PMDA, FDA, EMA, HEALTH CANADA

11:30-12:00
The Asian Regulatory Consortium Update
• TQT Studies in Different Populations and Regions – Benefits/Challenges
• Consolidating the Regulatory Cardiac Safety Approaches Across Regions

All speakers for Session 2 and
Jie Hou, MD, PhD
Professor and Director, Phase I Clinical Trial Unit, TEDA, International Cardiovascular Hospital, China

Haiyan Li, MD
Professor of Cardiology, Director of Clinical Trial Center, Peking University Third Hospital and Deputy Director, Peking University Research Institute, China

12:00-13:00 LUNCH BREAK
Free lunch is available in Heian (2F)

13:00-14:00 SESSION 3 Togen (2F)
ABSTRACT SESSION
SESSION CO-CHAIRS
Koki Nakamura, MD, PhD
Senior Medical Director, Japan Development Center, Pharmaceutical Development Division, Takeda Pharmaceutical Company Limited, Japan
Atsushi Sugiyama, MD, PhD
Professor of Pharmacology, School of Medicine, Toho University, Japan

13:00-13:15
The Effect of Food on the QTc Interval In Thorough QT Studies Conducted in Healthy Japanese and Caucasian Subjects
Jörg Täubel, MD, FFPM
Chief Executive Officer, Richmond Pharmacology Ltd., UK

13:15-13:30
Discriminating QT/QTc Changes Induced by Moxifloxacin and Vardenafil Using Dynamic QT Beat-to-beat Analysis
Börje Darpö, MD, PhD
Pharmaceutical Consultant, Karolinska Institute, Sweden

13:30-13:45
A Robust and Reliable Ex-Vivo Method for Assessing Cardiac Repolarization Using “Living” Human Hearts
Jack A. Reynolds, DVM
CEO, AnaBios Corporation, USA

13:45-14:00
Assessing Cardiotoxicity via Ion Channels and Human Induced Pluripotent Stem Cell-derived Cardiomyocyte Functional Assays
Rick Turner, PhD
Senior Director, Cardiac Safety, Quintiles, USA
### SESSION 4  
**THOROUGH QT STUDIES AND INTENSIVE PHASE 1 QT STUDIES**

**Session Co-Chairs**
- **Maki Ito, MD, PhD**  
  Head, Medical Affairs Office, Drug Safety Management Department  
  Shionogi & Co., Ltd., Japan
- **Kaori Shinagawa, MD, PhD**  
  Senior Scientist for Clinical Medicine, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

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| 14:00-14:15 | The Future of the TQT Study — Are we there yet?                       | **Börje Darpö, MD, PhD**  
  Pharmaceutical Consultant, Karolinska Institute, Sweden |
| 14:15-14:30 | The Intensive Phase 1 QT Study: A Sponsor Point of View              | **Koki Nakamura, MD, PhD**  
  Senior Medical Director, Japan Development Center,  
  Pharmaceutical Development Division, Takeda Pharmaceutical Company Limited, Japan |
| 14:30-14:45 | The Risk of Failing a TQT Study and Risk Mitigation Strategies     | **Robert Kleiman, MD**  
  Chief Medical Officer, eRT, USA |
| 14:45-15:00 | False Positive and False Negative Results of QT Effects,            | **Atsushi Sugiyama, MD, PhD**  
  Based on Non-clinical Data  
  Professor of Pharmacology, School of Medicine, Toho University, Japan |
| 15:00-15:30 | Debate: Is Assay Sensitivity Still Required for all TQT Studies?     | **Yuji Kumagai, MD, PhD**  
  Director, Clinical Trial Center, Kitasato University East Hospital,  
  Professor of Kitasato University, Japan |

**15:30-16:00**  
**COFFEE BREAK**  
Heian (2F)

### SESSION 5  
**ETHNIC DIFFERENCES AND EXTRAPOLATION OF FOREIGN QT DATA**

**Session Co-Chairs**
- **Yasuhiko Imai**  
  Bristol-Myers K.K., Japan
- **Kaori Shinagawa, MD, PhD**  
  Senior Scientist for Clinical Medicine, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

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<th>Speaker</th>
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| 16:00-16:20 | Moxifloxacin Cardiac Safety Study in Japanese Subjects               | **Hiroyuki Fukase, MD**  
  Director, CPC Clinical Trial Hospital, Medipolis Medical Research Institute, Japan |
| 16:20-17:00 | What is the Evidence to Support Ethnic Differences in Drug           | **Jörg Täubel, MD, FFPM**  
  Induced QT Prolongation  
  Chief Executive Officer, Richmond Pharmacology Ltd., UK |
| 17:00-17:30 | Roundtable: Is there Sufficient Evidence to Support Ethnic           | **Krishna Prasad, MB, BS, MD, FRCP**  
  Differences in QT PD? — A  
  Consultant Cardiologist, Clinical Assessor, Chair of QT Subgroup &  
  CO-Rapp ICH-E14 Implementation Working Group, MHRA, UK  
  **Colette Strnadova, PhD**  
  Senior Scientific Advisor, Therapeutic Products Directorate,  
  Health Canada |

**17:30-19:00**  
**RECEPTION**  
Heian (2F)
DAY 2 | TUESDAY, MAY 29, 2012

8:30-8:45 REGISTRATION 2nd Floor Lobby

DAY 2
CARDIOVASCULAR SAFETY BEYOND THE QT INTERVAL

8:45-10:15 SESSION 6 Togen (2F)
DRUG INDUCED HR, PR AND QRS CHANGES

SESSION CO-CHAIRS
Yuji Kumagai, MD, PhD
Director, Clinical Trial Center, Kitasato University East Hospital, Professor of Kitasato University, Japan
Atsushi Sugiyama, MD, PhD
Professor of Pharmacology, School of Medicine, Toho University, Japan

8:45-9:15
Drug Induced HR Changes: Clinical Implications and Safety Assessments
Pierre Maison-Blanche
Bio Medical Systems, France

9:15-9:35
Drug Induced QRS Changes: Does it Matter and how Should it be Assessed?
Tsuyoshi Shiga, MD, PhD
Associate Professor, Department of Cardiology, the Heart Institute of Japan, Tokyo Women’s Medical University, Japan

9:35-9:55
Profiling Drug Induced PR Effects in Drug Development
Colette Strnadova, PhD
Senior Scientific Advisor, Therapeutic Products Directorate, Health Canada

9:55-10:15
Panel Discussion
Speakers for Session 6 and

Krishna Prasad, MB, BS, MD, FRCP
Consultant Cardiologist, Clinical Assessor, Chair of QT Subgroup & CO-Rapp ICH-E14 Implementation Working Group, MHRA, UK

Kohei Shinagawa, MD, PhD
Senior Scientist for Clinical Medicine, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

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

10:15-10:45 COFFEE BREAK Heian (2F)

10:45-12:35 SESSION 7 Togen (2F)
CARDIO-ONCOLOGY: AVOIDING ONCOLOGY DRUG CARDIOTOXICITY

SESSION CO-CHAIRS
Maki Ito, MD, PhD
Head, Medical Affairs Office, Drug Safety Management Department, Shionogi & Co., Ltd., Japan
Boaz Mendzelevski, MD
Vice President of Cardiology, CoreLab Partners, UK

10:45-11:15
Overview: Cardiovascular Safety in Oncology Drug Development
Chau T. Dang, MD
Medical Oncologist Memorial Sloan-Kettering Cancer Center, USA

11:15-11:35
Cardiac Toxicities Associated with VEGF Signaling Pathway Inhibitors
Richard Steingart, MD, FACC
Chief, Cardiology Service, Memorial Sloan-Kettering Cancer Center, USA

11:35-11:55
Imaging Strategies for Early Detection of Oncology Cardiotoxicity
Polina Voloshko, MD
Vice President, Medical Operation, CardioCore, USA

11:55-12:15
Risk Mitigation Strategies in Oncology Drug Development
Boaz Mendzelevski, MD
Vice President of Cardiology, CoreLab Partners, UK

12:15-12:35
Panel Discussion
Speakers for Session 7 and

Kohei Amakasu
Reviewer, Office of New Drug V, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Krishna Prasad, MB, BS, MD, FRCP
Consultant Cardiologist, Clinical Assessor, Chair of QT Subgroup & CO-Rapp ICH-E14 Implementation Working Group, MHRA, UK

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

12:35-13:40 LUNCH BREAK
Free lunch is available in Heian (2F)
**General Information**

**REGISTRATION:** Registration will start at 9:00 on Day 1, and at 8:30 on Day 2, on the 2nd floor.

**EXHIBITS:** Exhibit Hall, “Heian” located next to the workshop room on the 2nd floor, will open from 12:00 to 19:00 for Day 1 and from 8:45 to 13:40 for Day 2.

**RECEPTION:** Reception will be held in the Exhibit Hall at 17:30 on Day 1.

**Upcoming Events**

**JUNE 11, 2012**
Nakano Sunplaza, Tokyo, Japan
1st CMC Forum in Japan

**JUNE 14-15, 2012**
Yamano Hotel, Hakone, Japan
1st DIA FDA IND/NDA Training Course in Japan

**NOVEMBER 19-21, 2012**
Toshi Center Hotel, Tokyo, Japan
9th DIA Japan Annual Meeting

**Private Social Function Policy**

DIA does not allow hospitality functions to be held during any DIA meeting sessions, scheduled exhibit hours, or social events. Therefore, the hours noted below are the only hours that are acceptable for hospitality functions.

- **Sunday, May 27:** All time are acceptable
- **Monday, May 28:** Before 8:00 and after 20:00
- **Tuesday, May 29:** Before 8:00 and after 16:30

**13:40-15:10 SESSION 8  Togen (2F)**

**CARDIO-METABOLIC: ASSESSING CV SAFETY OF DIABETES DRUGS**

**SESSION CO-CHAIRS**
Boaz Mendzelevski, MD  
Vice President of Cardiology, CoreLab Partners, UK
Koki Nakamura, MD, PhD  
Senior Medical Director, Japan Development Center, Pharmaceutical Development Division, Takeda Pharmaceutical Company Limited, Japan

13:40-14:10
**Overview: CV Risks of Anti-diabetic Agents**
Masatsugu Hori, MD, PhD  
President, Osaka Medical Center for Cancer and Cardiovascular Diseases, Japan

14:10-14:30
**Recent Diabetes Guidelines and Current Regulatory Experience**
Eckhard Leifke, MD, PhD  
Senior Medical Director, Takeda Global Research & Development Center Inc., USA

14:30-14:50
**Trial Designs for CV Outcome Studies in Diabetes Drug Development**
Boaz Mendzelevski, MD  
Vice President of Cardiology, CoreLab Partners, UK

14:50-15:10
**Panel Discussion**

**Speakers for Session 8 and**
Masakazu Hirata  
Deputy Review Director, Office of New Drug I, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Krishna Prasad, MB, BS, MD, FRCP  
Consultant Cardiologist, Clinical Assessor, Chair of QT Subgroup & CO-Rapp ICH-E14 Implementation Working Group, MHRA, UK

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

Maki Ito, MD, PhD  
Head, Medical Affairs Office, Drug Safety Management Department, Shionogi & Co., Ltd., Japan

15:10-15:15
**CHAIRMAN’S CLOSING REMARKS**
Boaz Mendzelevski, MD  
Vice President of Cardiology, CoreLab Partners, UK

15:15  **WORKSHOP ADJOURNED**

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.
REGISTRATION FORM: Register online or forward to DIA Japan, Nisso 22 Building, 7F, 1-11-10 Azabudai, Minato-ku, Tokyo 106-0041 Japan
tel +81-3-5575-2130 • fax +81-3-3583-1200

3rd DIA Cardiac Safety Workshop in Japan
Event #12305 • May 28-29, 2012 • Tokyo, Japan
DIA will send participants a confirmation letter within 3 to 5 business days after receipt of their registration.

Registration Fees If DIA cannot verify your membership, you will be charged the nonmember fee. Registration fee includes refreshment breaks and reception (if applicable), and will be accepted by mail, fax, or online.

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All fees listed below include the 5% consumption tax.

Member Early-bird Opportunity Available on nondiscount member fee only.

Join DIA now to save on future meetings and to enjoy the benefits of membership for a full year!

www.diajapan.org/Membership

Discount Fees

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If paying a nonmember fee, please indicate whether you want membership.

I DO want to be a DIA member  I DO NOT want to be a DIA member

TO RECEIVE AN EXHIBIT APPLICATION, PLEASE CHECK ❑

Please check the applicable category:

- Academia
- Government
- Industry
- CSO (Contract research/service organization)
- Student (Call for registration information)

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TRAVEL AND HOTEL
There are a limited number of rooms at the Hotel Grand Palace at the reduced rates shown below. Room availability at this rate is guaranteed only until April 26, 2012 or until the room block is filled. Attendees should make their airline and room reservations as soon as possible.

- Single ¥ 18,050/night
- Twin ¥ 21,525/night

Address: 1-1-1 Iidabashi, Chiyoda-ku, Tokyo 102-0072, Japan
Telephone: +81-(0)3-3264-3078 / Fax: +81-(0)3-3230-6822
e-mail: toru-ishikawa@grandpalace.co.jp
URL: http://www.grandpalace.co.jp/english/index.html

To reserve your room, please contact the Hotel Grand Palace above and mention the DIA Workshop or click here for the Hotel Reservation Form.

CANCELLATION POLICY: On or before May 21, 2012
Administrative fee that will be withheld from refund amount:
Member or Nonmember = ¥21,400
Government/Academia/Nonprofit (Member or Nonmember) = ¥10,700

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.

TABLETOP EXHIBIT INFORMATION
For information, contact DIA Japan
Nisso 22 Bldg. 7F, 1-11-10 Azabudai, Minato-ku, Tokyo 106-0041 Japan

Telephone +81-(0)3-5575-2130
Fax +81-(0)3-3583-1200
e-mail diajapan@diajapan.org

If you are interested in obtaining space for an exhibit, please check the box in the REGISTRATION FEE area on the left.

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

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  CITIBANK, N.A. Akasaka Branch, Prudential Plaza,
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  7585284, SWIFT CODE # CITIJPJT.

Your name and company, as well as the above event I.D. number, must be included on the transfer document to ensure payment to your account.

All local and overseas charges incurred for the bank transfer must be borne by payer.

Please include BANK TRANSFER REFERENCE #

PAYMENT BY CREDIT CARD is available online only – www.diahome.org
第3回 DIAカーディアック・セイフティ・ワークショップ

2012年5月28日（月）～5月29日（火）
タワーホール船堀

日本における新薬の承認申請の際には、ICH-E14ガイドラインの規定を満たすことが義務付けられています。このガイドラインの特徴は、Thorough QT（TQT）試験、もしくはTQT試験の実施が不実行できる薬剤（抗がん剤など）では、それに代わる試験データの提出が求められていることです。

国内でのTQT試験の実施と研究は急速に進展していますが、まだいくつかの課題が残されています。日本特有の問題としては、QTファーマコダイナミックスにおける潜在的な民族間差や海外の臨床試験で得られたQTデータの外挿性などがあります。また、世界的に産官学の間で議論されている問題では、TQT試験の将来性、Intensive QT試験の動向、陽性対照の使用、TQT試験に関するリスクなどがあります。

第3回カーディアック・セイフティ・ワークショップでは、2日間にわたって産官学の専門家を招き、このような問題について議論、意見交換を行います。

参加対象者
- 臨床開発担当者
- 医師、医療従事者
- 安全性薬理学、非臨床研究従事者
- 安全管理、信頼性保証担当者
- 臨床薬理学研究者
- 薬事担当者
- 生物統計担当者
- データマネージャー
- IT担当者
- アウトソーシング、マーケティング担当者
- 心臓の安全性に関する薬事関連（毒物学、薬理学、コンプライアンス等を含む）の政策決定者

卓上展示申込受付中
詳細については、下記までお問い合わせください。
一般社団法人 ディー・アイ・エー ジャパン
〒106-0041 東京都港区麻布台1-11-10 日総第22ビル7F
Tel: 03-5575-2130
Fax: 03-3583-1200
e-mail: diajapan@diajapan.org

日本語・英語間の同時通訳あり
1日目 | 2012年 5月28日（月）

9:00 – 9:30 受付 2階 ロビー

DAY 1 - 心臓安全性評価学の進展

9:30-10:00 セッション 1 2階 桃源

オープニングセッション

9:30
はじめに
CoreLab Partners
Boaz Mendzelevski

9:30-10:00 基調講演
Assessing the Drug-induced Electrophysiological Effects on the Heart
東邦大学
杉山 篤

10:00-12:00 セッション 2 2階 桃源

レギュラトリーサイエンスと心臓の安全性について
座長
Health Canada
Colette Strnadova

独立行政法人 医薬品医療機器総合機構
宇山 佳明

A. PMDA、FDA、EMA、HEALTH CANADAにおける動き

10:00-10:30
日本におけるICH E14ガイドラインの実施状況と審査のポイント
独立行政法人 医薬品医療機器総合機構
品川 香

10:30-10:45
Novel Approaches to TQT Study Design and Analysis
FDA （録画ビデオによる講演）
Joanne Zhang

10:45-11:00
Overall Experience to Date and Review of Special Cases
Medicines and Healthcare products Regulatory Agency
Krishna Prasad

11:00-11:15
Cardiac Safety Beyond the QT Interval
Health Canada
Colette Strnadova

11:15-11:30
QT Drug Labeling
FDA （録画ビデオによる講演）
Monica Fiszman

B. レギュラトリーサイエンス - PMDA、SFDA、FDA、EMA、HEALTH CANADA

11:30-12:00
アジアの規制当局間の連携についての動向
・異なる地域、民族でのTQT試験について - 利点と課題
・アジア地域における、心臓安全性の問題に対する規制当局のアプローチ
パネリスト:
セッション2の演者及び
TEDA International Cardiovascular Hospital
Jie Hou
Peking University Third Hospital
Haiyan Li

12:00-13:00 ランチブレイク 2階 平安
軽食をご用意しております。

13:00-14:00 セッション 3 2階 桃源

A. PMDA、FDA、EMA、HEALTH CANADAにおける動き

13:00-13:15
The Effect of Food on the QTc Interval In Thorough QT Studies Conducted in Healthy Japanese and Caucasian Subjects
Richmond Pharmacology Ltd.
Jörg Täubel

13:15-13:30
 Discriminating QT/QTc Changes Induced by Moxifloxacin and Vardenafil Using Dynamic QT Beat-to-beat Analysis
Karolinska Institute
Börje Darpö

13:30-13:45
A Robust and Reliable Ex-Vivo Method for Assessing Cardiac Repolarization Using “Living” Human Hearts
AnaBios Corporation
Jack A. Reynolds

13:45-14:00
Assessing Cardiotoxicity via Ion Channels and Human Induced Pluripotent Stem Cell-derived Cardiomyocyte Functional Assays
Quintiles
Rick Turner
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<td>14:00-14:15</td>
<td>The Future of the TQT Study — Are we there yet?</td>
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<td>Karolinska Institute</td>
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<td>Börje Darpö</td>
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<td>14:15-14:30</td>
<td>The Intensive Phase 1 QT Study: A Sponsor Point of View</td>
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<td>武田薬品工業株式会社</td>
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<td>中村 浩己</td>
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<td>14:30-14:45</td>
<td>The Risk of Failing a TQT Study and Risk Mitigation Strategies</td>
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<td>Robert Kleiman</td>
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<td>14:45-15:00</td>
<td>False Positive and False Negative Results of QT Effects, Based on Non-clinical Data</td>
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<td>東邦大学</td>
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<td>杉山 篤</td>
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<td>15:00-15:10</td>
<td>ディベート “Assay sensitivityは、また全てのTQT試験に必要か”</td>
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<td>15:00-15:10</td>
<td>賛成の立場から: Assay sensitivity is required and can take many forms</td>
<td>北里大学 東病院</td>
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<td>北里大学</td>
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<td>熊谷 雄治</td>
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<td>15:10-15:20</td>
<td>反対の立場から: Assay sensitivity is obsolete and should be replaced with alternative approaches</td>
<td>Eli Lilly</td>
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<td>Charles Benson</td>
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<td>15:20-15:30</td>
<td>規制当局からのコメント</td>
<td>FDA</td>
<td>Nitin Mehrotra</td>
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<tr>
<th>Time</th>
<th>Session 5</th>
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<td>15:30-16:00</td>
<td>コーヒーブレイク</td>
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<td>16:00-17:30</td>
<td>民族間差と海外QTデータの評価</td>
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<td>独立行政法人 医薬品医療機器総合機構</td>
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<td>品川 香</td>
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<td>16:00-16:20</td>
<td>Moxifloxacin Cardiac Safety Study in Japanese Subjects</td>
<td>財団法人メディポリス医学研究財団 シーピーシー治験病院</td>
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<td>深瀬 広幸</td>
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<td>16:20-16:40</td>
<td>What is the Evidence to Support Ethnic Differences in Drug Induced QT Prolongation</td>
<td>Richmond Pharmacology Ltd.</td>
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<td>Jörg Täubel</td>
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<td>16:40-17:00</td>
<td>Is Extrapolation of Foreign QT Data Required? — A Regulatory Perspective</td>
<td>独立行政法人 医薬品医療機器総合機構</td>
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<td>安藤 友紀</td>
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<td>17:00-17:30</td>
<td>ラウンドテーブル “QT PDにおける民族間差を裏付ける十分な証拠はあるのか”セッション5の演者及び</td>
<td>Medicines and Healthcare products Regulatory Agency</td>
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<td></td>
<td>Krishna Prasad</td>
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<td>Health Canada</td>
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<td>Colette Strnadova</td>
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<td>17:30-19:00</td>
<td>レセプション</td>
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DAY 2 - QT間隔の先にある心臓安全性の問題

8:45-10:15  セッション 6  2階 桃源
薬剤誘発性のHR, PR, QRSの変化
座長
北里大学東病院
北里大学
熊谷 竜治
東邦大学
杉山 篤

8:45-9:15
Drug Induced HR Changes: Clinical Implications and Safety Assessments
Bio Medical Systems
Pierre Maison-Blanche

9:15-9:35
Drug Induced QRS Changes: Does it Matter and how Should it be Assessed?
東京女子医科大学
志賀 剛

9:35-9:55
Profiling Drug Induced PR Effects in Drug Development
Health Canada
Colette Strnadova

9:55-10:15
パネルディスカッション
セッション6の演者及び
Medicines and Healthcare products Regulatory Agency
Krishna Prasad
Health Canada
Colette Strnadova

10:15-10:45 コーヒーブレイク  2階 平安

10:45-12:35 セッション 7  2階 桃源
カーディオ・オンコロジー：抗がん剤の心毒性を防ぐために
座長
塩野義製薬株式会社
伊藤 眞紀
CoreLab Partners
Boaz Mendzelevski

10:45-11:15
Overview: Cardiovascular Safety in Oncology Drug Development
Memorial Sloan-Kettering Cancer Center
Chau T. Dang

11:15-11:35
Cardiac Toxicities Associated with VEGF Signaling Pathway Inhibitors
Memorial Sloan-Kettering Cancer Center
Richard Steingart

11:35-11:55
Imaging Strategies for Early Detection of Oncology Cardiotoxicity
CardioCore
Polina Voloshko

11:55-12:15
Risk Mitigation Strategies in Oncology Drug Development
CoreLab Partners
Boaz Mendzelevski

12:15-12:35
パネルディスカッション
セッション7の演者及び
Medicines and Healthcare products Regulatory Agency
Krishna Prasad
Health Canada
Colette Strnadova

独立行政法人 医薬品医療機器総合機構
品川 香

12:35-13:40 ランチブレイク  2階 平安
軽食をご用意しております。
13:40-15:10 セッション8

カーディオ・メタボリック: 糖尿病治療薬の心臓安全性評価について

座長
CoreLab Partners
Boaz Mendzelevski
武田薬品工業株式会社
中村 浩己

13:40-14:10
Overview: CV Risks of Anti-diabetic Agents
独立行政法人 大阪府立病院機構大阪府立成人病センター
塚 正二

14:10-14:30
Recent Diabetes Guidelines and Current Regulatory Experience
Takeda Global Research & Development Center Inc.
Eckhard Leifke

14:30-14:50
Trial Designs for CV Outcome Studies in Diabetes Drug Development
CoreLab Partners
Boaz Mendzelevski

14:50-15:10
パネルディスカッション
セッション8の演者及び
独立行政法人 医薬品医療機器総合機構
平田 雅一
Medicines and Healthcare products Regulatory Agency
Krishna Prasad
Health Canada
Colette Strnadova
塩野義製薬株式会社
伊藤 眞紀

15:10-15:15
閉会の挨拶
CoreLab Partners
Boaz Mendzelevski

15:15 閉会
第3回DIAカードィアック・セーフティ・ワークショップ
【カンファレンスID #12305】

2012年5月28日～29日
タワーホール船堀 東京都江戸川区船堀4-1-1

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