3rd DIA Cardiac Safety Workshop in Japan

May 28-29, 2012
Tower Hall Funabori, Tokyo

PROGRAM CHAIRPERSON

Boaz Mendzelevski, MD
CoreLab Partners, Inc., UK

PROGRAM SUB-CHAIRPERSON

Maki Ito, MD, PhD
Shionogi & Co., Ltd., Japan

PROGRAM COMMITTEE

Yasuhiko Imai
Bristol-Myers K.K., Japan

Yuji Kumagai, MD, PhD
Kitasato University East Hospital
Kitasato University, Japan

Koki Nakamura, MD, PhD
Takeda Pharmaceutical Company Limited, Japan

Kaori Shinagawa, MD, PhD
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Atsushi Sugiyama, MD, PhD
Toho University, Japan

PROGRAM ADVISOR

Yoshiaki Uyama, PhD
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

Regional Offices
Basel, Switzerland Tokyo, Japan
Mumbai, India Beijing, China

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**

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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, FRCP
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

14:00-15:30 **SESSION 4** Togen (2F)

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

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, Based on Non-clinical Data
Atsushi Sugiyama, MD, PhD
Professor of Pharmacology, School of Medicine, Toho University, Japan

15:00-15:30
Debate: Is Assay Sensitivity Still Required for all TQT Studies?

15:00-15:10
Pro position: Assay Sensitivity is Required and can Take Many Forms
Yuji Kumagai, MD, PhD
Director, Clinical Trial Center, Kitasato University East Hospital, Professor of Kitasato University, Japan

15:10-15:20
Con position: Assay Sensitivity is Obsolete and Should be Replaced with Alternative Approaches
Charles Benson, MD, PhD
Medical Fellow, Eli Lilly, USA

15:20-15:30
Regulatory Commentary
Nitin Mehrotra, PhD *(Presentation by pre-recorded video)*
Pharmacometrics Reviewer, QT-IRT Scientific Lead, Division of Pharmacometrics, Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA, USA

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

16:00-17:30 **SESSION 5** Togen (2F)

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

16:00-16:20
Moxifloxacin Cardiac Safety Study in Japanese Subjects
Hiroyuki Fukase, MD
Director, CPC Clinical Trial Hospital, Medipolis Medical Research Institute, Japan

16:20-16:40
What is the Evidence to Support Ethnic Differences in Drug Induced QT Prolongation
Jörg Täubel, MD, FFPM
Chief Executive Officer, Richmond Pharmacology Ltd., UK

16:40-17:00
Is Extrapolation of Foreign QT Data Required? — A Regulatory Perspective
Yuki Ando
Senior Scientist for Biostatistics, Pharmaceuticals and Medical Devices Agency (PMDA), Japan

17:00-17:30
Roundtable: Is there Sufficient Evidence to Support Ethnic Differences in QT PD?
Speakers for Session 5 and

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

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

Kaori 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, Caridiology 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)

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

15:10-15:20

INTRODUCTION TO THE CARDIAC SAFETY RESEARCH CONSORTIUM

Rick Turner, PhD
Senior Director, Cardiac Safety, Quintiles, USA

15:20-15:25

CHAIRMAN'S CLOSING REMARKS

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

15:25 WORKSHOP ADJOURNED

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

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.

All fees listed below include the 5% consumption tax.

	On or before MAY 11, 2012	After MAY 11, 2012
Member Early-bird Opportunity Available on nondiscount member fee only.		
Member Fee	¥ 61,950 ❑	¥ 67,200 ❑
Join DIA now to save on future meetings and to enjoy the benefits of membership for a full year! **www.diahome.org/Membership**		MEMBERSHIP ¥ 15,750 ❑
Nonmember Fee		¥ 82,950 ❑

A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

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Government (Full-time)	¥ 26,250 ❑	¥ 42,000 ❑
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**If paying a nonmember fee, please check one box above, indicating whether you want membership.*

TO RECEIVE AN EXHIBIT APPLICATION, PLEASE CHECK ❑

Please check the applicable category:

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Last Name

First Name M.I.

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Company

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email **Required for confirmation**

Phone Number **Required** Fax Number

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
email: toru-ishikawa@grandpalace.co.jp
URL: http://www.grandpalace.co.jp/english/index.htmll

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**
email **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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Drug Information Association Ordinary Account Number:
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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.

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Please include BANK TRANSFER REFERENCE #

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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

プログラム委員長

CoreLab Partners Inc.
Boaz Mendzelevski

プログラム副委員長

塩野義製薬株式会社
伊藤　眞紀

プログラム委員

ブリストル・マイヤーズ株式会社
今井　康彦

北里大学東病院
北里大学
熊谷　雄治

武田薬品工業株式会社
中村　浩己

独立行政法人 医薬品医療機器総合機構
品川　香

東邦大学
杉山　篤

プログラムアドバイザー

独立行政法人 医薬品医療機器総合機構
宇山　佳明

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られています。このガイドラインの特徴は、ThoroughQT(TQT)試験、もしくはTQT試験の実施がそぐわない薬剤(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試験に関わ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
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email: **diajapan@diajapan.org**

日本語・英語間の同時通訳あり

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Mumbai, India　Beijing, China

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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における動向

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. レギュラトリーラウンドテーブル – 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

アブストラクト・セッション

座長
武田薬品工業株式会社
中村　浩己
東邦大学
杉山　篤

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

14:00-15:30　セッション 4　2階　桃源

THOROUGH QT 試験とINTENSIVE PHASE 1 QT 試験

座長

塩野義製薬株式会社
伊藤　眞紀

独立行政法人 医薬品医療機器総合機構
品川　香

14:00-14:15
The Future of the TQT Study — Are we there yet?
Karolinska Institute
Börje Darpö

14:15-14:30
The Intensive Phase 1 QT Study: A Sponsor Point of View
武田薬品工業株式会社
中村　浩己

14:30-14:45
The Risk of Failing a TQT Study and Risk Mitigation Strategies
eRT
Robert Kleiman

14:45-15:00
False Positive and False Negative Results of QT Effects, Based on Non-clinical Data
東邦大学
杉山　篤

15:00-15:30
ディベート “Assay sensitivityは、まだ全てのTQT試験に必要か”

15:00-15:10
賛成の立場から: Assay sensitivity is required and can take many forms
北里大学東病院
北里大学
熊谷　雄治

15:10-15:20
反対の立場から: Assay sensitivity is obsolete and should be replaced with alternative approaches
Eli Lilly
Charles Benson

15:20-15:30
規制当局からのコメント
FDA　（録画ビデオによる講演）
Nitin Mehrotra

15:30-16:00　コーヒーブレイク　2階　平安

16:00-17:30　セッション 5　2階　桃源

民族間差と海外QTデータの評価

座長

ブリストル・マイヤーズ株式会社
今井　康彦

独立行政法人 医薬品医療機器総合機構
品川　香

16:00-16:20
Moxifloxacin Cardiac Safety Study in Japanese Subjects
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
深瀬　広幸

16:20-16:40
What is the Evidence to Support Ethnic Differences in Drug Induced QT Prolongation
Richmond Pharmacology Ltd.
Jörg Täubel

16:40-17:00
Is Extrapolation of Foreign QT Data Required? — A Regulatory Perspective
独立行政法人 医薬品医療機器総合機構
安藤　友紀

17:00-17:30
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

Medicines and Healthcare products Regulatory Agency
Krishna Prasad

Health Canada
Colette Strnadova

17:30-19:00　レセプション　2階　平安

2日目｜2012年 5月29日（火）

8:30-8:45　受付　2階　ロビー

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　雄治

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

独立行政法人 医薬品医療機器総合機構

品川　香

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

甘粕　晃平

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　2階　桃源

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
堀　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

15:10-15:20

INTRODUCTION TO THE CARDIAC SAFETY RESEARCH CONSORTIUM

Quintiles
Rick Turner

15:20-15:25

閉会の挨拶

CoreLab Partners
Boaz Mendzelevski

15:25　閉会

ご案内

登録受付
開始時間：1日目 9:00、2日目 8:30
場　　所：2階ロビー

企業展示
展示時間：1日目 12:00 – 19:00、2日目8:45 – 13:40
場　　所：展示会場 （2階「平安」）

レセプション
展示時間：1日目 17:30 – 19:00
場　　所：展示会場 （2階「平安」）

DIA会議 今後の開催予定

第1回CMCフォーラム
6月11日（月） 中野サンプラザ

第1回FDA IND/NDAトレーニングコース
6月14日－15日　山のホテル（箱根）

第9回DIA日本年会
11月19日－21日　都市センターホテル

Private Social Function Policy

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5月27日（日）	終日
5月28日（月）	8:00以前、20:00以降
5月29日（火）	8:00以前、16:30以降

会議参加申込書

一般社団法人ディー・アイ・エー・ジャパン Fax: 03-3583-1200 〒106-0041 東京都港区麻布台1-11-10 日総第22ビル7F Tel: 03-5575-2130

第3回DIAカーディアック・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

◆ 参加申込方法

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会 員

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一般	2012年5月11日までのお申込み	¥61,950	❑ ¥61,950
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政府関係		¥26,250	❑ ¥26,250
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❑ 請求書を希望します

非 会 員

会員登録する 登録費 ¥15,750	一般	早期割引 2012年5月11日までのお申込み	¥61,950	❑ ¥77,700
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会員登録しない	一般		¥82,950	❑ ¥82,950
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Last Name (姓) First name (名) Middle Initial Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title Company

Address City State Zip/Postal Country

email (必須) Phone Number (必須) Fax Number

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