

**Health and Labor Sciences Research Grant 2014 “Developing and
standardizing experimental protocols using human iPS-derived cells to
predict adverse drug reactions in pre-clinical safety studies” Study Group /
2nd Think Tank Meeting on Cardiac Safety 2015 Joint International Open
Symposium**

**New Wave on Integrated Cardiac Safety
— A Revolution in Clinical Trials and Novel Approach in Nonclinical Test
Using Human iPS-derived Cells —**

Date & Time: Thursday, February 19th, 2015, 12:15~18:00 (11:30 Hall Open)

Venue: YAYOI AUDITORIUM, ICHIJO HALL, Faculty of Agriculture, The University of
Tokyo, 1-1-1 Yayoi, Bunkyo-ku, Tokyo, 113-8657, Japan

<http://www.a.u-tokyo.ac.jp/yayoi/map.html>

Attendance fee: Free

Registration: No Pre-Registration, Onsite Registration Only

The Organizer:

“Developing and standardizing experimental protocols using human iPS-derived cells to
predict adverse drug reactions in pre-clinical safety studies” Study Group

Japan iPS Cardiac Safety Assessment (JiCSA)

Management committee of Kirishima conference

In Association:

The Japanese Safety Pharmacology Society

Congress Secretariat:

Division of Pharmacology, Biological Safety Research Center, National Institute of
Health Sciences

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Yuko Sekino and Seiichi Ishida

Meeting Agenda

Leading a meeting: Daiju Yamazaki (National Institute of Health Sciences)

12:15 ~ Opening Remarks

Yuko Sekino (National Institute of Health Sciences)

Session 1: New wave on clinical trials

Moderators: Yuko Sekino (National Institute of Health Sciences)

Atsushi Sugiyama (Toho University)

12:30 ~ Can the thorough QT study be replaced by ECG assessment in early phase clinical development?

Borje Darpo (iCardiac Technologies) (Lecture on WEB)

13:05 ~ A Brief Sketch of Integrated Prediction System for Proarrhythmia with New Drugs: Their Present Conditions and Future Prospects - Focusing on CIPA Update Workshop CSRC-HESI-SPS-FDA Meeting / IQ-CSRC Meeting, December, 11,12 2014-

Hiroyuki Fukase (CPC Clinical Trial Hospital, Medipolis Medical Research Institute)

13:40 ~ Utility of UT-Heart on evaluation of multiple channel effects

Jun-ichi Okada (The University of Tokyo)

14:15 ~ Does ER-analysis Obviate the Need for Thorough QT Study? -From Statistical Point of View-

Tadashi Koga (CPC Clinical Trial Hospital, Medipolis Medical Research Institute)

14:50 ~ Coffee Break (15 min)

Session 2: Novel Approach in Nonclinical Test Using Human iPS-derived Cells

Moderators: Seiichi Ishida (National Institute of Health Sciences)

Yasunari Kanda (National Institute of Health Sciences)

15:05 ~ Cardiac safety evaluation assessment using human iPS-derived cardiomyocytes: Next generation

Yuko Sekino (National Institute of Health Sciences)

15:25 ~ Successes and Evolving Challenges Posed by the Comprehensive In Vitro Proarrhythmia Assay (CiPA)

Gary Gintant (AbbVie Inc)

16:15 ~ Refinement of experimental conditions and interim analysis of the results for proarrhythmia risk assessment with iPS cell derived cardiomyocytes in J-iCSA study

Kohei Sawada (Eisai Co.Ltd.)

17:05 ~ **Panel Discussion**

17:50 ~ Closing Remarks

Akiyoshi Nishikawa (Director of Biological Safety Research Center, National Institute of Health Sciences)