

# JCROA 15<sup>th</sup> Anniversary Commemorative Symposium

## "The new paradigm/stream of the clinical development"

\*\*How to adopt Japan clinical trials to international environment \*\*

(Simultaneous Interpretation Available)

Date: February 26, 2009

Venue: Concorde Ball Room, 5<sup>th</sup> Floor, Keio Plaza Hotel (Shinjuku-Ku, Tokyo)

(15:00 to 15:03)

Opening Greetings Kazuo Nakamura, Chairman of JCROA

(15:03 to 15:21)

Greetings by the Guests

- Shuichi Kishida, Ph.D., Director, Minister's Secretariat, Ministry of Health, Labor & Welfare (MHLW)
- Tatsuya Kondo, M.D., Ph.D, Chief Executive Pharmaceuticals and Medical Devices Agency (PMDA)
- Derek Winstanly, MBChB (3min)  
Chairman, Association of Clinical Research Organizations
- Antoine Cournot (5min)  
President, CRO European Federation (EUCROF)

(15:21 to 15:51)

Plenary Lecture "Basic Principles on Global Clinical Trials"  
Haruo Akagawa, Associate Center Director  
Pharmaceuticals and Medical Devices Agency  
(PMDA)

Invited Lectures

Chairperson: Tatsuo Kurokawa, Ph.D., (EX. MHLW Director)

Professor, Graduate School of Pharmaceutical Sciences, Chiba University

(15:52 to 16:22)

Lecture 1 "Conducting Clinical Trials in the EU – 5 Years of Experience with the New Directive"  
Dagmar Chase, Ph. D., Vice President, EUCROF

Break

(16:37 to 17:22)

Lecture 2 "Representing A Global Industry"  
Douglas Peddicord, Ph.D., Executive Director, ACRO  
"The Modern Day CRO – Expectations"  
Derek Winstanly, MBChB, Chair, ACRO

(17:22 to 17:52)

Lecture 3 “Positioning of Japan in Global Clinical Trials“  
-From the View Point of Japanese Pharmaceutical  
Manufacturer-

Hidetoshi Shuto, Corporate Executive, Vice  
President□  
Clinical Development Administration, Development  
Astellas Pharma Inc.

(17:52 to 18:22)

Lecture 4 “Transition and Prospects for Clinical Development in Japan”  
Kazuo Nakamura, Chairman of JCROA

(18:22 to 18:32)

Closing Remarks including JCROA Business Report for 2008 and Press Release  
Kyoro Sakai, Executive Vice Chairman of JCROA

(18:45 □□Reception