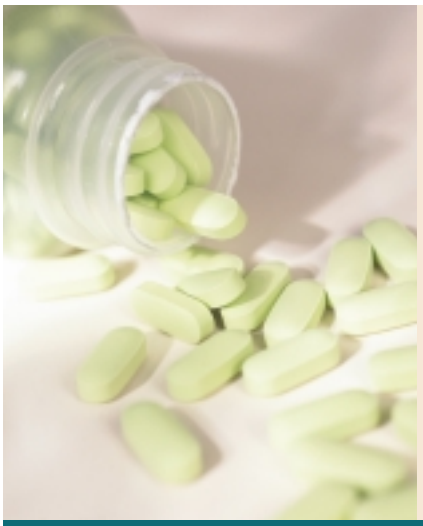


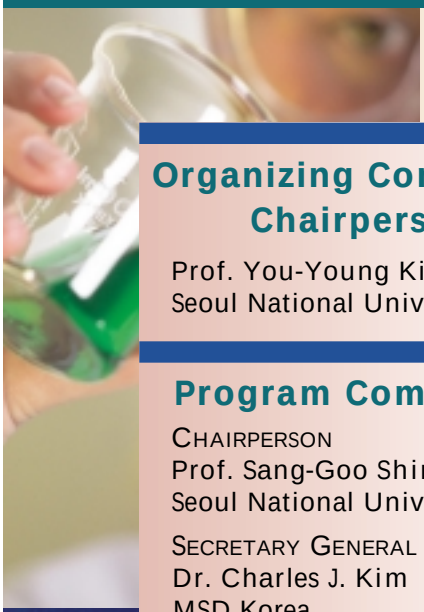
Drug Information Association
The leading member-driven, multi-disciplinary non-profit association

The Drug Information Association announces a workshop on

Evolution of Drug Regulatory Process in Asia

SEPTEMBER 28-29, 2000

The Hotel Lotte World
40-1 Chamshil-Dong, Songpa-Ku, Seoul, Korea



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Seoul National University

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Overview

Since the successful completion of major parts of the ICH process in 1997, many Asian countries have been implementing ICH guidelines and recommendations in their regulations. During this implementation process, two areas have become a real challenge for most of the countries: accepting foreign clinical data as full or partial support for approval of an application and generating local clinical data that meet a global standard.

This conference provides a forum for industry, academia, and regulatory agency to discuss relevant issues on Good Review Practice and Good Clinical Practice in Asia and the possibilities for greater harmonization of standards, polices, and procedures on these areas.

Session Topics Include

- Evolution of Good Review Practice in US FDA
- Recent Evolution of New Drug Review & Approval System in Asia and Pacific
- Recent Experiences and Future Perspectives of Accepting Foreign Clinical Data in Asia
- Evolution of Good Clinical Practice
- Issues in Conducting Clinical Trials in Asia
- Modeling and Simulation in Clinical Drug Development
- Emerging Issues in High Quality Clinical Trial

Who Should Attend?

■ This conference is essential for all those who are involved in clinical development and approval of new drugs, be they within pharmaceutical companies, contract research organizations, academia, and regulatory authorities: personnel from clinical research, clinical supply, quality assurance, regulatory affairs, medical writing, and project management, investigators, study coordinators, IRB members, reviewers, and regulators.

Committee Members

Prof. Yoon-Ok Ahn, Seoul National University
Prof. Yung-Jue Bang, Seoul National University
Prof. In-Joon Cha, Inje University
Prof. Young-Nam Cha, Inha University
Dr. Deborah Chee, Bayer Korea
Dr. Dae-Kee Kim, SK Chemical
Prof. Hoon-Kyo Kim, Catholic University
Dr. Hyun-Soo Kim, Cheil Jedang Corp
Dr. Jin Kim, Pharmacia & Upjohn Korea
Prof. Kyung-Hwan Kim, Yonsei University
Dr. Dong-Soo Lee, Pfizer Korea
Dr. Howard Lee, Georgetown University
Mr. Jae-Won Lee, LG Chemical
Dr. Jong-Wook Lee, Yuhan Corp
Prof. Myoung-Mook Lee, Seoul National University
Dr. Yil-Seob Lee, Handok Pharmaceuticals Co., Ltd.
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Singapore	Ms. Tan Shook Fong, Ministry of Health
Taiwan	Dr. Herng-Der Chern, Center for Drug Evaluation
Thailand	Dr. Vichai Chokervivian, Ministry of Public Health

Dates and Times

Thursday, September 28, 2000

08:00-14:00 REGISTRATION

Opening Ceremony

09:00-09:40 Moderator
Dr. Youn-Sung Choo
LG Chemical, Korea

WELCOME REMARKS
Prof. You-Young Kim
Chairperson of DIA 2000 Seoul Conference Organizing Committee
Dr. Elizabeth D'Angelo
Past-President of Drug Information Association
Astra Zeneca, USA
Dr. Keun Huh
Commissioner of Korea Food and Drug Administration
Dr. Jeung-Soo Kim
President of Korea Pharmaceutical Manufacturers Association
Mr. Laurence Smith
President of Korea Research Based Pharmaceutical Industry Association

Plenary Session:

09:40-10:30 Session Chairperson
Prof. You-Young Kim
Seoul National University, Korea

Evolution of Good Review Practice in U.S. Food and Drug Administration
Prof. Carl C. Peck
Director, Center for Drug Development Science
Georgetown University, USA

Topics to be presented
- *Why and how the concept of Good Review Practice (GRP) has been introduced in drug regulatory field?*
- *Historical background of GRP in US FDA*
- *Barriers to overcome when implementing GRP in US FDA*
- *Lessons learned*
- *Future perspectives of GRP*

10:30-11:00 REFRESHMENT BREAK

Drug Regulatory Session I:

11:00-12:30 RECENT EVOLUTION OF NEW DRUG REVIEW AND APPROVAL SYSTEM IN ASIA AND PACIFIC (PART I)
Session Co-Chairpersons
Prof. Yoon-Ok Ahn
Seoul National University, Korea
Prof. Kiichiro Tsutani
Tokyo Medical and Dental University, Japan

Korea — *Dr. Soo-Young Choi*
Director, Pharmaceutical Safety Bureau
Korea Food and Drug Administration, Korea

Japan — *Mr. Daisaku Sato*
Deputy Director, Evaluation and Licensing Division
Ministry of Health and Welfare, Japan

China — *Dr. Liya Cao*
Deputy Director
Center for Drug Evaluation
State Drug Administration, China

Taiwan — *Dr. Oliver Hu*
Director General, Bureau of Pharmaceutical Affairs
Department of Health, Taiwan

12:30-14:00 LUNCHEON

Drug Regulatory Session II:

14:00-15:30 RECENT EVOLUTION OF NEW DRUG REVIEW AND APPROVAL SYSTEM IN ASIA AND PACIFIC (PART II)
Session Co-Chairpersons
Dr. Jong-Wook Lee
Yuhan Corporation, Korea
Dr. Ellick Wong
Pharmacia Corp., Singapore

Australia — *Dr. Leonie Hunt*
Director
Drug Safety and Evaluation Branch, Australia

Singapore — *Ms. Tan Shook Fong*
Director and Chief Pharmacist
Ministry of Health, Singapore

Indonesia — *Prof. Iwan Darmansjah*
PUKO, Clinical Trial Center
University of Indonesia, Indonesia

Malaysia — *Dr. Hj Mohd Ismail Merican*
Deputy Director of the Ministry of Health
Institute of Medical Research, Malaysia

Topics to be presented
- *Changing environment of drug regulatory field; past experience in each country*
- *Implementation of GCP in each country*
- *Challenge from internal and external forces*
- *Recent noticeable changes and their impacts in drug development*
- *Future perspectives*

15:30-16:00 **Panel Discussion and Q&A**
Speakers of Drug Regulatory Session I and II will be invited as panelists, and interactive discussions between panel and floor are encouraged.

16:00-16:30 REFRESHMENT BREAK

ICH E5 Session:

16:30-17:50 RECENT EXPERIENCES AND FUTURE PERSPECTIVES OF ACCEPTING FOREIGN CLINICAL DATA IN ASIA
Session Co-Chairpersons
Prof. Young-Nam Cha
Inha University, Korea
Dr. Stephen Spielberg
Janssen Research Foundation, USA

Experiences in Japan
Dr. Chikayuki Naito
Senior Technical Advisor
The Organization for Pharmaceutical Safety and Research, Japan

Perspectives from Regulatory Agency
Dr. Herng-Der Chern
Deputy Executive Director
Center for Drug Evaluation, Taiwan

Perspectives from Industry
Dr. Yil-Seob Lee
Handok Pharmaceuticals Co., Ltd., Korea

Perspectives from Academia
Prof. Sang-Goo Shin
Director, Clinical Trial Center
Seoul National University, Korea

Topics to be presented
- *Experiences in accepting foreign clinical data as a main supporting evidence of drug's safety and efficacy*
- *How could ethnic issues be incorporated into each country's regulation in a balanced and scientific manner?*
- *Single guideline or regulation applicable to all Asian regulatory agencies; Reality or Fantasy?*
- *Future perspectives*

17:50-18:20 **Panel Discussion and Q&A**
Speakers of this session will be invited as panelists, and interactive discussions between panel and floor are encouraged.

19:00-20:30 CONFERENCE DINNER (All Registrants)

Friday, September 29, 2000

08:00-14:00 REGISTRATION

Plenary Session:

09:00-10:00 Session Chairperson
Prof. Kyung-Hwan Kim
Yonsei University, Korea

Evolution of Good Clinical Practice
Dr. Elizabeth D'Angelo
Past-President of Drug Information Association
Astra Zeneca, USA

Topics to be presented
- *Behind story; ICH GCP*
- *Main changes and challenges expected in introducing new ICH GCP*
- *How does multinational pharmaceutical company see the current GCP statues in Asia?*
- *Future perspectives*

10:00-10:30 REFRESHMENT BREAK

Clinical Trial Session:

10:30-12:00 ISSUES IN CONDUCTING CLINICAL TRIALS IN ASIA
Session Co-Chairpersons
Prof. Hoon-Kyo Kim
Catholic University, Korea
Dr. Anthony Rebuck
SmithKline Beecham, Singapore

Clinical Trial Authorization in Korea
Dr. Deborah Chee
Bayer Korea, Ltd., Korea

Topics to be presented
- *Current regulations regarding clinical study authorization in Korea*
- *Things a pharmaceutical company should consider when planning to include Korea as amember country of a multinational IND-type study*
- *Ways to reduce time to commence a study in Korea; practical viewpoints*

Barriers of Multinational Trials in Asia

Dr. Joanne Andrews
MSD, Australia

Topics to be presented
- *Asia, the Untouched Continent in clinical drug development*
- *Regulation; is it an only reason?*
- *Social and psychological barriers to make multinational trials in Asia difficult*
- *Future perspectives*

Ethical Considerations in Clinical Trials in Asia

Prof. Noritoshi Tanida
Internal Medicine
Hyogo College of Medicine, Japan

Topics to be presented
- *Clinical trial ethics in Asia*
- *Can the same guidelines ensure 'the same' ethical quality in different countries?*

Present and Future Role of CRO in Asia

Mr. Kazuo Nakamura
CMIC Co., Ltd., Japan

Topics to be presented
- *History of CRO development in Asia*
- *How can CRO contribute the quality of clinical drug development in Asia?*
- *Local or regional CRO vs multinational CRO*

12:00-12:30 **Panel Discussion and Q&A**

Speakers of this session will be invited as panelists, and interactive discussions between panel and floor are encouraged.

12:30-14:00 LUNCHEON

Concurrent Session I:

14:00-16:00 MODELING AND SIMULATION IN CLINICAL DRUG DEVELOPMENT

Session Co-Chairpersons

Prof. Sang-Goo Shin
Seoul National University, Korea

Prof. Jun-Hee Woo
University of Ulsan, Korea

Conceptual Basis and Need of Modeling and Simulation

Prof. Carl C. Peck
Director, Center for Drug Development Science
Georgetown University, USA

Technical Issues of Modeling and Simulation

Prof. Hui C. Kimko
Center for Drug Development Science
Georgetown University, USA

Clinical Trial Simulation: Case Study I

Prof. Nick Holford
Pharmacology and Clinical Pharmacology
University of Auckland, New Zealand

Clinical Trial Simulation: Case Study II

Prof. In-Jin Jang
Clinical Pharmacology/Pharmacology
Seoul National University, Korea

Concurrent Session II:

14:00-15:30 EMERGING ISSUES IN HIGH QUALITY CLINICAL TRIAL I

Session Co-Chairpersons

Ms. Hye-Yeon Park
Janssen Korea Ltd., Korea

Dr. Ling Su
MSD, China

How to Manage Clinical Trials: Regulatory Perspectives

Representative
Korea Food and Drug Administration, Korea

How to Achieve Quality by QA and Audit

Dr. Elizabeth D'Angelo
AstraZeneca, USA

How to Optimize Clinical Supplies Management

Mr. Frank Reale
Merck Research Laboratory, USA

15:30-16:00 REFRESHMENT BREAK

16:00-17:30 EMERGING ISSUES IN HIGH QUALITY CLINICAL TRIAL II

Session Co-Chairpersons

Dr. Dae-Kee Kim
SK Chemical, Korea

Dr. Pol Vandenbroucke
Pfizer, Hong Kong

How to Select CRO, SMO or Academic Sites for High Quality Clinical Trials

Dr. Tai Akera
Banyu, Japan

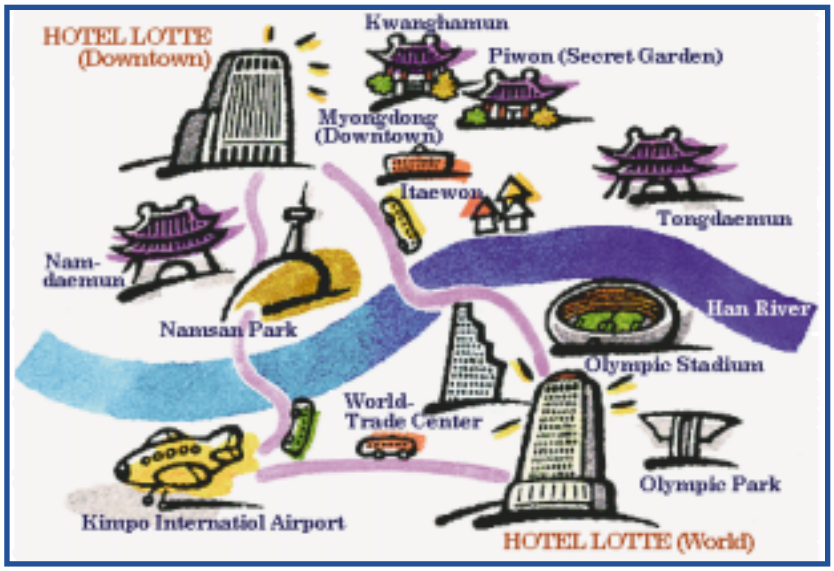
How to Assess Clinical Trial's Performance

Dr. Woo-Ick Jang
SmithKline Beecham Korea, Korea

How to Efficiently Coordinate Multi-center Trials

Prof. Byung-Joo Park
Preventive Medicine
Seoul National University, Korea

17:30 Adjourn



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Evolution of Drug Regulatory Process in Asia

Meeting I.D. # 00027

September 28-29, 2000

Hotel Lotte World, Seoul, Korea

REGISTRATION FEES:

Registration Fee includes Refreshment Breaks, Luncheons and Reception.

Industry	US $250 ❑
Government & Academia	US $150 ❑

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Exhibits will be available at the meeting site. Meeting attendees are welcome to visit the exhibits during the conference. For those interested in exhibiting, please contact Ms. Eunok Koh at the DIA Seoul Conference Organizing Committee Office in Seoul, Korea by telephone: +82 2 6363 0082, fax: +82 2 6389 0107 or e-mail: eunok_koh@merck.com

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email: diaeurope@stepnet.de
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Tel: +81 3 5322 1336 Fax: +81 3 5322 2872
email: diajapan@gol.com

CANCELLATION POLICY: ***On or before* SEPTEMBER 20, 2000**

Administrative fee that will be deducted from registration fee:

Industry = **$100** Gov't/Academia = **$50**

Registrants who do not cancel by the date above and do not attend will be responsible for the full registration fee. *Registrants are responsible for cancelling their own hotel reservations.* **Cancellations must be in writing**. You may transfer your registration to a colleague at any time. Please notify DIA of any such substitutions as soon as possible.

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Degrees ❑ Dr. ❑ Mr. ❑ Ms.

Job Title

Affiliation (Company)

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Statements made by speakers are their own opinion and notnecessarily that of the organization they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice.

Audio/Visual taping of any DIA Workshop is prohibited without prior written consent from DIA.

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Evolution of Drug Regulatory Process in Asia
Meeting #00027
September 28-29, 2000, Hotel Lotte World, Seoul, Korea

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Tel :+82 2 419 7000 Fax :+82 2 417 3655

For more information, please visit a Hotel Lotte website http://hotel.lotte.co.kr

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We recommend that you make your airline reservations as early as possible to ensure availability. The most convenient airport to this hotel is Kimpo International Airport. The KAL Limousine bus runs every 15 minutes between Kimpo International Airport and the Hotel Lotte World (takes about 1-1/2 hours).

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