第2回DIA総合ワークショップ
The Second Multitrack Workshop in Japan

医薬品評価の新時代に向けて
DIA Congress on Moving towards a New Era in New Drug Evaluation

ファーマコゲノミクス：個別化医療への挑戦と将来
Pharmacogenomics: Challenges and future for individualized medicine

医薬品開発戦略
Drug Development Strategy

臨床試験マネージメントの進歩と課題
Progress and Issues in Clinical Study Management

東京コンファレンスセンター・品川
Tokyo Conference Center·Shinagawa

2006年4月13日（木）、14日（金）
April 13-14, 2006

Program chairperson
TAKATOSHI SATO
HyCLIPS, K.K.

Program vice-chairperson
HIRONOBU SAITO
Sankyo Co., Ltd.

Endorsement by MHLW, PMDA and JPMA

REGISTER ONLINE! www.diahome.org
Dear Colleagues and Friends,

On behalf of the program committee, it is my pleasure and honor to welcome you to the second multitrack workshop in Japan, the “DIA Congress on Moving towards a New Era in New Drug Evaluation.” The first DIA multitrack workshop in Japan, “Development and Utilization of Pharmaceuticals,” was held in September 2005. Following the success of this workshop, planning for the second multitrack got underway.

The meeting will begin with two keynote presentations from the PMDA and JPMA. Discussions of clinical study circumstances at medical sites, the importance of project management worldwide, and the “critical path” led by the US FDA will follow. This session will conclude with a panel discussion involving all of these speakers.

The process of new product development is made up of three steps: research, planning, and execution. Track A is titled “Pharmacogenomics: Challenges and Future of Individualized Medicine,” Track B is “Drug Development Strategy,” and Track C is “Progress and Issues in Clinical Study Management” to examine various stages of the process and discuss key issues. Each track will deal with issues that occur within various phases of each of these activities and will specifically target problem-solving activities. All meeting participants will be able to attend sessions in any of these tracks.

The “Ask the Regulators” session, featuring open discussion between attendees and representatives from regulatory agencies, will take place during the afternoon of the second day of our workshop. A similar session presented at the DIA 5th Workshop in Japan for Progress in Clinical Trials, held in Tokyo in February 2005, was well attended and received positive evaluations. The discussion will encompass two different themes, Pharmacogenomics and Biologics, and R&D Regulation. All questions will be considered in this open forum.

Tabletop exhibits will be open throughout the meeting, and a wine and cheese reception will be held on the evening of the first day. A visit to the exhibits will afford participants the opportunity to network with colleagues and exhibitors.

Program Chairperson:
Takatoshi Sato
HyCLIPS K.K., Japan

Program Vice-Chairperson:
Hironobu Saito
Sankyo Co., Ltd., Japan

Program Advisors:
Hiroshi Betsui, Pharmaceuticals and Medical Devices Agency, Japan
Hiroshi Maeda, HyCLIPS K.K., Japan
Yasuo Ohashi, PhD, The University of Tokyo, Japan
Hideki Okuda, PhD, Shionogi & Co. Ltd., Japan
Katsutoshi Tanaka, Pharmaceuticals and Medical Devices Agency, Japan
Atsushi Tomaru, PhD, Kyowa Hakko Kogyo Co., Ltd., Japan
Motoko Watanabe, MD, Pfizer Japan Inc., Japan

Program Committee:
Yasuhiro Fujiwara, MD, PhD, National Cancer Center Hospital, Japan
Hiroshi Gushima, PhD, National Institute of Biomedical Innovation, Japan
Yasuhiro Hashimoto, MD, MediBIC, Japan
Shigeru Kageyama, MD, PhD, Jikei University School of Medicine, Japan
Atsunori Kaibara, PhD, Astellas Pharma Inc., Japan
Ryosei Kawai, PhD, Novartis Pharma K.K., Japan
Fumiaki Kobayashi, PhD, Japan Medical Association Center for Clinical Trials, Japan
Masaaki Kuwahara, PhD, Takeda Pharmaceutical Company Limited, Japan
Yoshitaka Nagasawa, (retired), Pfizer Japan Inc., Japan
Tetsuto Nagata, Pfizer Japan Inc., Japan
Keiko Oishi, CMIC Co., Ltd., Japan
Shunsuke Ono, PhD, Pharmaceuticals and Medical Devices Agency, Japan
Ichiro Oshiba, Site Support Institute Co., Ltd., Japan
Kazuhiro Sase, MD, PhD, National Cardiovascular Center Hospital, Japan
Takeyuki Shibabayashi, AstraZeneca K.K., Japan
Yoshikazu Shibata, Artemis Business Consulting Limited, Japan
Makoto Shiragami, PhD, Nihon University, Japan
Mieko Tamaoki, Astellas Pharma Inc., Japan
Koiti Todaka, MD, PhD, Kyushu University Faculty of Medicine, Japan
Atsushi Tsuji, Amgen Limited, Japan
Kichiro Tsutani, MD, PhD, The University of Tokyo, Japan
Tohru Uwii, PhD, Bellsystem24, Inc., Japan
Toshihiko Watanabe, Bellsystem24, Inc., Japan
Sanae Yasuda, PhD, Eisai Co., Ltd., Japan
PART 1: DIA WELCOME
Chair: Hiroyuki Usuki, Japan Representative, DIA Japan Office, Japan
Speakers: David M. Maola, Esq., Executive Director, Drug Information Association, USA; Theresa Kane Musser, President, Drug Information Association, and Rigal Pharmaceuticals, USA; Takatoshi Sato, Chair, DIA Advisory Council of Japan and HyCLIPS K.K., Japan

PART 2: KEYNOTE PRESENTATIONS AND PANEL DISCUSSION ON MOVING TOWARDS A NEW ERA IN DRUG DEVELOPMENT
Chairs: Takatoshi Sato, Chair, DIA Advisory Council of Japan and HyCLIPS K.K., Japan; Hironobu Saito, Senior Vice Director, Clinical Development Department, Sankyo Co., Ltd., Japan
Panelists include Keynote Presenters and: Suminobu Ito, MD, PhD, Director, Clinical Research Division, Department of Medical Service, NHO Headquarters, Japan; Theresa Kane Musser, President, Drug Information Association, and Rigal Pharmaceuticals, USA; Nancy D. Smith, PhD, Director, Office of Training and Communications, FDA, USA

Keynote #1: Satoshi Toyoshima, PhD, Executive Director, Director, Center for Product Evaluation, PMDA, Japan
Keynote #2: Hatsuo Aoki, PhD, President, Japan Pharmaceutical Manufacturers Association (JPMA); Chairman, Astellas Pharma Inc., Japan

Two keynote speakers, Dr. Satoshi Toyoshima, Director of Center for Product Evaluation, PMDA, and Dr. Hatsuo Aoki, President of the Japan Pharmaceutical Manufacturers Association, will present their perspectives on “Dreams and Expectations of New Product Development.” After these two keynote presentations, opening panel discussion will follow with additional panelists: Dr. Suminobu Ito (National Hospital Organization), Ms. Theresa Kane Musser (DIA President) and Dr. Nancy Smith (CDER, FDA, USA). Dr. Ito will present the organization's efforts to improve clinical study circumstances at medical sites. Ms. Musser will discuss the importance of project management in global development, and Dr. Smith will introduce the new US FDA critical path initiative and provide some examples from this initiative. Drug development costs have increased and the length of the development process has prolonged drastically over recent years. Moreover, despite our big expectation of new compound development after genomics (studies of gene structure analysis), proteomics and nanotechnology, the number of new registrations in these fields does not seem to have increased enough. Our task is to move the drug development process forward by developing an innovative approach to meeting these challenges.

GENERAL INFORMATION
Registration
Registration will start at 8:30 on the 5th floor

Exhibition
Thursday, April 13, 10:30-19:30 at the Foyer on the 5th floor
Friday, April 14, 9:00-17:15 at the Foyer on the 5th floor

Reception
Thursday, April 13, 17:30-19:30 in the Exhibition Area on the 5th floor.
A mini-session, “What is the DIA World?” will be held during the reception from 18:30-20:00 in Room 406. This session is open to the newcomers/freshmen to DIA.

Travel and Hotel
Please make your airline reservations as early as possible to ensure availability. The most convenient airport to this hotel is Narita Airport. There are a limited number of rooms at the Le Meridien Pacific Tokyo (Hotel Pacific Tokyo) at the reduced rates shown below (includes taxes and breakfast). Please make your room reservations as soon as possible.

- Single ¥19,950/night
- Twin/Single Use ¥22,260/night
- Twin ¥23,215/night

To reserve your room, please contact the Le Meridien Pacific Tokyo by telephone at +81-3-3445-6711, or by fax at +81-3-3445-5137 and mention the DIA Workshop. The Le Meridien Pacific Tokyo is located at 3-13-3, Takanawa, Minato-ku, Tokyo 108-8567.

WHAT TO SEE IN JAPAN
Recommended traditional local package tours are shown below.

Please note that a tour desk will not be available on site at this workshop. You can make reservations at http://www.jtbgmt.com/sunrisetour/te5/

- **Tokyo Afternoon Tour**
  (Daily 3.6 Hours) ¥5,000 (child 6-11 yrs. ¥3,800)
  (Seaside Top, Sumida River Cruise, Asakusa Kannon Temple, Nakamise Shopping Street, Imperial Palace Plaza)

- **Dynamic Tokyo**
  (Daily 8.2 Hours) ¥12,000 (child 6-11 yrs. ¥9,800)
  (Tokyo Tower, Tea Ceremony and Bonsai Trees, Barbecue Lunch, National Diet Building (drive by), Imperial Palace Plaza, Ginza Shopping District (drive through), Sumida River Cruise, Asakusa Kannon Temple, Nakamise Shopping Street)

- **Shinkansen Tour**
  A. Mt. Fuji (¥10,000.- or up)
  B. Hakone (¥10,000.- or up)
  C. Nikko World Heritage (¥11,500.- or up)
  D. Kamakura Walking Tour (¥11,000.- or up)
Congress at a Glance

Thursday, April 13, 2006

8:30-9:30 Registration

9:30-10:00 Plenary Session – Part 1: DIA Welcome

Chair: Hiroyuki Usuki, Japan Representative, DIA Japan Office, Japan

DIA Welcome Speech

David M. Maola, Esq., Executive Director, Drug Information Association, USA

Theresa Kane Musser, President, Drug Information Association, and Riget Pharmaceuticals, USA

Takatoshi Sato, Chair, DIA Advisory Council of Japan and HyCLIPS K.K., Japan

10:00-11:00 Plenary Session – Part 2: Keynote Presentations and Panel Discussion: Moving towards a New Era in Drug Development

Chair: Takatoshi Sato, Chairman, HyCLIPS K.K., Japan

Hironobu Saito, Senior Vice Director, Clinical Development Department, Sankyo Co., Ltd., Japan

11:00-11:20 Refreshment Break

11:20-12:50 Plenary Session – Part 2 continued

11:20-11:40 The Organization Efforts to Improve Clinical Study Circumstances at Medical Sites

Suminobu Ito, MD, PhD, Director, Clinical Research Division, Department of Medical Service, NHO Headquarters, Japan

11:40-12:00 Value of PM in the Productivity of Drug Development

Theresa Kane Musser, President, Drug Information Association, and Riget Pharmaceuticals, USA

12:00-12:20 FDA Critical Path Initiative for More Efficient Drug Development in the Future

Nancy D. Smith, PhD, Director, Office of Training and Communications, FDA, USA

12:20-12:50 Panel Discussion

Satoshi Toyoshima, PhD, Hatsuho Aoki, PhD, Suminobu Ito, MD, PhD, Theresa Kane Musser, and Nancy D. Smith, PhD

12:50-14:00 Lunch Break

14:00-15:30 Concurrent Sessions

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<td>Pharmacogenomics: Challenges and Future for Individualized Medicine</td>
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<td>Track Chair: Masaki Kuwahara, PhD</td>
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<td>Group Manager, Regulatory Affairs Department, Takeda Pharmaceutical Company Limited, Japan</td>
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SESSION 1 – BT/PP

Guideline for Pharmacogenomics

Chair: Mieko Tamaoki, Planning and Administration, Drug Discovery Research, Astellas Pharma Inc., Japan; Yoshikazu Uyama, PhD, Deputy Review Director, Office of New Drug III, PMDA, Japan

14:00-14:30 Industrial Guideline for Pharmacogenomics

Tomoko Ichihara, Manager, Clinical Pharmacology Department, Chugai Clinical Research Center, Chugai Pharmaceutical Co., Ltd., Japan

14:30-14:50 Guideline for Pharmacogenomics in Japan

Tetsunari Kihira, PhD, Deputy Director, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, Japan

14:50-15:10 Guideline for Pharmacogenomics in the USA

Lois Himan, PhD, Director of Regulatory Affairs, Pharma Development, Hoffmann-La Roche, Inc., USA

15:10-15:30 Pharmacogenomics in the EU

Prof. Marc Vasseur, PhD, Chairman and CEO, Serono France Holding, France

14:00-14:15 Track Overview: Global Drug Development Strategy and Clinical Trials in Japan

Shigeru Kageyama, MD, PhD, Professor, Division of Clinical Pharmacology and Therapeutics, Jikei University School of Medicine, Japan

SESSION 1 – CR/RD

Late Stage of Drug Development Strategy

Chair: Kazushiro Sase, MD, PhD, Professor, Clinical Pharmacology and Pharmacy, Juntendo University Medical School, Japan; Hironobu Saito, Senior Vice Director, Clinical Development Department, Sankyo Co., Ltd., Japan

14:15-14:40 The Experience of Multinational Study (Japan/US)

John H. Alexander, MD, MS, FACC, Assistant Professor of Medicine, Division of Cardiology, Duke University Medical Center, Duke Clinical Research Institute, USA

14:40-15:05 The Experience of Multinational Study (Japan/Asia)

Hironobu Saito, Senior Vice Director, Clinical Development Department, Sankyo Co., Ltd., Japan

15:05-15:30 The Opinion from the Regulatory Point of View

Kazuhiro Mori, Director, Office of New Drug I, PMDA, Japan

14:00-14:15 Track Overview: Global Drug Development Strategy and Clinical Trials in Japan

Shigeru Kageyama, MD, PhD, Professor, Division of Clinical Pharmacology and Therapeutics, Jikei University School of Medicine, Japan

SESSION 1-2 – PM/OS/CR

Multinational and Local Resource Management for Effective Clinical Study Operation

Chair: Takayuki Shibayashi, Senior Advisor, Clinical Science, Clinical Division, R&D, AstraZeneca K.K., Japan

14:00-14:25 Challenges of Resource Management in a Global Context: A CRO Perspective

Wendy Buckland, Executive Director, Clinical Operations, Latin America and Asia, PPD, USA

14:25-14:45 Project Risk Management in Clinical Development: Practical Applications of a Project Risk List

Yasuhiro Katsuura, PhD, Senior Manager, Pharmaceutical Development Coordination Department, Teijin Pharma Limited, Japan


Allen C. Sarapu, PhD, President, Value-Added Drug Development, LLC, USA

15:05-15:30 Operation of International Clinical Teams: From Cross-cultural Learning to Study Delivery

Mike Hardman, MD, MRCP, FFPM, Senior Director, Head of Clinical Development, R&D, AstraZeneca K.K., Japan

15:30-15:50 Refreshment Break
Thursday, April 13, 2006 continued

15:50-17:20 Concurrent Sessions

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<tr>
<td><strong>Pharmacogenomics: Challenges and Future for Individualized Medicine</strong>&lt;br&gt;<strong>SESSION 2 – BT/RA</strong>&lt;br&gt;<strong>Ethics in Pharmacogenetics</strong>&lt;br&gt;Chair: Kichiho Tsuchi, MD, PhD, Professor, Department of Pharmacogenomics, Graduate School of Pharmaceutical Sciences, The University of Tokyo, Japan</td>
<td><strong>Drug Development Strategy</strong>&lt;br&gt;<strong>SESSION 2 – CR/RD/CP</strong>&lt;br&gt;<strong>Postmarketing Stage of Drug Development Strategy</strong>&lt;br&gt;Chairs: Koji Todaka, MD, PhD, Department of Cardiovascular Medicine, Kyushu University Faculty of Medicine, Japan; E. Stewart Greary, MD, Director, Medical Regulatory Affairs and Pharmacovigilance Department, Eisai Co., Ltd., Japan</td>
<td><strong>Progress and Issues in Clinical Study Management</strong>&lt;br&gt;<strong>SESSION 1-2 continued</strong>&lt;br&gt;<strong>Multinational and Local Resource Management for Effective Clinical Study Operation</strong>&lt;br&gt;Chairs: Takayuki Shibayabashi, Senior Advisor, Clinical Science, Clinical Division, R&amp;D, AstraZeneca K.K., Japan; Yosshaiki Shibao, CEO and President, Artemis Consulting Limited, Japan</td>
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<td><strong>What Is Needed to Deliver the Promise of Pharmacogenomics? Discussing the Challenges in Japan</strong>&lt;br&gt;Shy-Fuh Liu, Prof, Head of Pharmacogenetics Asia Pacific Section, Clinical Genetics Office, Tsukuba Research Labs, GlaxoSmithKline K.K., Japan</td>
<td><strong>The Concept of ICH-E2E Guideline</strong>&lt;br&gt;Yusuke Tanigawara, PhD, Professor and Director, Department of Hospital Pharmacy, School of Medicine, Keio University, Japan</td>
<td><strong>15:50-16:10 Conducting Clinical Trials in Southeast Asia:</strong>&lt;br&gt;<strong>Delivering Results with Best Resource Management</strong>&lt;br&gt;Elikc Wong, PhD, Adjunct Professor, Department of Pharmacy, National University of Singapore, Principal Consultant, PharmaWork Consultants, Singapore</td>
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<td><strong>16:20-16:50 What Is Needed to Deliver the Promise of Pharmacogenomics? Discussing the Challenges in Japan</strong>&lt;br&gt;Shy-Fuh Liu, Prof, Head of Pharmacogenetics Asia Pacific Section, Clinical Genetics Office, Tsukuba Research Labs, GlaxoSmithKline K.K., Japan</td>
<td><strong>16:20-16:50 The Implementation for New Pharmacovigilance Strategy</strong>&lt;br&gt;Kazuhiko Sase, MD, PhD, Professor, Clinical Pharmacology and Pharmacy, Juntendo University Medical School, Japan</td>
<td><strong>16:10-16:30 Resource Management in Clinical Study from the Viewpoint of CRO</strong>&lt;br&gt;Shinichi Keino, Deputy Director, President Office, CMIC Co., Ltd., Japan</td>
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<td><strong>16:50-17:20 Genetic Exceptionalism</strong>&lt;br&gt;Yashiro Kukeka, PhD, Center for Biomedical Ethics and Law, School of Health Sciences and Nursing, The University of Tokyo, Japan; Tohru Masui, PhD, ICRB Cell Bank, Division of Bioresources, National Institute of Biomedical Innovation, Japan</td>
<td><strong>Panel Discussion</strong>&lt;br&gt;John H. Alexander, MD, MS, FACC, Yusuke Tanigawara, PhD, Kazuhiko Sase, MD, PhD, Hiroonobu Satoo, Koji Todaka, MD, PhD, E. Stewart Greary, MD, Kazuhiko Mori Junko Sato, PhD, Deputy Review Director, Office of New Drug I, PMDA, Japan</td>
<td><strong>16:30-16:50 The Experience of Handling Clinical Trials in Asian Countries, Including Japan, from Industry Point of View</strong>&lt;br&gt;Kensuke Morimoto, Team Leader, Asia Regulatory and Development Section, Sankyo Co., Ltd., Japan</td>
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<td><strong>17:30-19:30 Reception in the Exhibition Area</strong></td>
<td><strong>16:50-17:20 Panel Discussion</strong>&lt;br&gt;Wendy Buckland, Yashiro Katsurau, Allen C. Sarapu, Mike Hardman, Elikc Wong, Shinichi Keino and Kensuke Morimoto</td>
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<td><strong>18:30-20:00 Mini-session, “What is the DIA World?” Chair: Shunsuke Ono, PhD, Reviewer, PMDA, Japan Room 501</strong></td>
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| 9:00-10:30 Concurrent Sessions

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<td><strong>Pharmacogenomics: Challenges and Future for Individualized Medicine</strong>&lt;br&gt;<strong>SESSION 3 – BT/CR/RA</strong>&lt;br&gt;<strong>Pharmacogenomics in Clinical Development and Practice – Part 1</strong>&lt;br&gt;Chairs: Yashiro Fujivara, MD, PhD, Chief, Breast and Medical Oncology Division, National Cancer Center Hospital, Japan; Yashiro Hashimoto, MD, President and CEO, MediciB, Japan</td>
<td><strong>Drug Development Strategy</strong>&lt;br&gt;<strong>SESSION 3 – CR/RD</strong>&lt;br&gt;<strong>Early Stage of Drug Development Strategy</strong>&lt;br&gt;Chairs: Byssei Kawai, PhD, Director, Drug Metabolism and Pharmacokinetics, Novartis Pharma K.K., Japan; Atsunori Kaibara, PhD, Senior Manager, Clinical Pharmacology, Astellas Pharma Inc., Japan</td>
<td><strong>SESSION 3-4 – PM/OS/CR</strong>&lt;br&gt;<strong>Striving for Efficiency in Clinical Trials</strong>&lt;br&gt;Chairs: Ichiro Oshiba, President and CEO, Site Support Institute Co., Ltd., Japan; Tetsuto Nagata, Chair, Clinical Evaluation Subcommittee, JPM, Japan</td>
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<td><strong>9:00-9:30 Use of Pharmacogenomics in Pharmacotherapy</strong>&lt;br&gt;Akihiro Hisaka, PhD, Assistant Professor, Department of Pharmacy, University of Tokyo Hospital, Japan</td>
<td><strong>9:00-9:30 Trend in Designing and Conducting Early Stage Clinical Studies in Japan: How They May Change Based on Clinical Experiences Obtained in Other Countries</strong>&lt;br&gt;Atsunori Kaibara, PhD, Japan Pharmaceutical Manufacturers Association, Japan</td>
<td><strong>9:00-9:05 Overview:</strong>&lt;br&gt;<strong>Controlling the Cost of Clinical Trials</strong>&lt;br&gt;Kenshiro Inami, Head of Clinical Trial Office, NHO, Japan</td>
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<td><strong>9:30-10:00 Pharmacogenic Activities in Japanese Pharmaceutical Industries</strong>&lt;br&gt;Yashiro Hashimoto, MD, President and CEO, MediciB, Japan</td>
<td><strong>9:30-10:30 Panel Discussion</strong>&lt;br&gt;Atsunori Kaibara, PhD</td>
<td><strong>9:05-9:25 Reduce Plans of Investigational Fees on National Hospital Organization</strong>&lt;br&gt;Kenshiro Inami, Head of Clinical Trial Office, NHO, Japan</td>
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<td><strong>10:00-10:30 The Present Situation of PGx in Japan and a PGx Study of Irimotecan</strong>&lt;br&gt;Osamu Sato, PhD, Deputy General Manager, Scientific Advisory Office, Daiichi Pharmaceutical Co., Ltd., Japan</td>
<td><strong>10:00-10:30 Panel Discussion</strong>&lt;br&gt;Akiko Urushidani, Toru Sumiyoshi, Executive Officer, Business Development Department, Site Support Institute Co., Ltd., Japan</td>
<td><strong>9:25-9:45 Analysis of Investigational Fees in Japan</strong>&lt;br&gt;Akiko Urushidani, Manager, R&amp;D Finance, GlaxoSmithKline, JPM, Japan</td>
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<td><strong>10:30-11:00 Refreshment Break</strong></td>
<td><strong>10:05-10:30 Panel Discussion</strong>&lt;br&gt;Kenshiro Inami, Akiko Urushidani and Toru Sumiyoshi</td>
<td><strong>9:45-10:05 Current SMO Cost Structure and Attempts for SMO Cost Reduction</strong>&lt;br&gt;Toru Sumiyoshi, Executive Officer, Business Development Department, Site Support Institute Co., Ltd., Japan</td>
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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.
Friday, April 14, 2006

11:00-12:30  Concurrent Sessions

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<td>Progress and Issues in Clinical Study Management</td>
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SESSION 4 – BT/CR/RA
Pharmacogenomics in Clinical Development and Practice – Part 2
Chairs: Masaaki Kuwahara, PhD, Group Manager, Regulatory Affairs Department, Takeda Pharmaceutical Company Limited, Japan; Sanee Yasuda, PhD, Manager, Clinical Pharmacology, Data Management Department, Clinical Research Center, Eisai Co., Ltd., Japan

11:00-11:30
Current Guidance on RxDx Co-development: Development, Hoffmann-La Roche, Inc., USA
Lois Hinman, PhD, Ellen Bech Christensen, MSc, Yasuhiro Fujiwara, MD, PhD, Chairs: and Practice – Part 2
Pharmacogenomics in Clinical Development

11:30-12:00
Declarations in Neuropsychiatric Disorders: Challenges and Lessons Learned
Ellen Bech Christensen, MSC, Specialist, Clinical Pharmacology and Pharmacokinetics, H. Lundbeck A/S, Denmark

12:00-12:30
Current Guidance on RxDx Co-development: Industry Perspectives on Key Issues and Next Steps
Lois Hinman, PhD, Director of Regulatory Affairs, Pharma Development, Hoffmann-La Roche, Inc., USA

12:30-13:45  Lunch Break


Chair:
Pharmacogenomics and Biologics
Kikicho Tsutani, MD, PhD, Professor, Department of Pharmacoeconomics, Graduate School of Pharmaceutical Sciences, The University of Tokyo, Japan; Masaaki Kuwahara, PhD, Group Manager, Regulatory Affairs Department, Takeda Pharmaceutical Company Limited, Japan

R&D Regulation
Shunsuke Ono, PhD, Reviewer, PMDA, Japan; Yoichi Ishii, Department Manager, Regulatory Affairs Department, Development Headquarters, Tanabe Seiyaku Co., Ltd., Japan

Panelists:
Yoshihiko Ono, PhD, Senior Manager, Regulatory Policy and Intelligence Group, Regulatory Policy and Intelligence, Pfizer Japan, Japan; Masahiro Miyazaki, Manager, Pharmaceutical Development Division, Takeda Pharmaceutical Company Limited, Japan; Makoto Shimoaraiso, PhD, Deputy Director, Evaluation and Management, Division, Pharmaceutical and Food Safety Bureau, MHLW, Japan

15:15-15:45  Refreshment Break

15:45-17:15  Ask the Regulators continued

17:15  MEETING ADJOURNED

Upcoming DIA Japan Meeting 2006
October 5-6, 2006  |  Tokyo Conference Center – Shinagawa, Tokyo, Japan

The Third Multitrack Workshop in Japan: How could companies, regulators and academia better collaborate in pharmaceutical development?
Program Chair: Yasuo Ohashi, PhD, The University of Tokyo, Japan

TRACK A: Invitation to new era of data and documents
TRACK B: Collaboration to fulfill our joint mission of delivering to patients medications of greater efficacy and greater safety with greater speed
TRACK C: Value-added contribution of biostatistics to drug development

Other Events of Interest

June 18-22, 2006  |  Philadelphia, PA, USA
42nd Annual Meeting
Program Chair
Charles C. Depew, PharmD, GlaxoSmithKline, USA

March 26-28, 2007  |  Vienna, Austria
19th EuroMeeting
Program Chairs
Christa Wittmayer-Hoche, AGES PharmMed, Austria
Gerd Bode, Consultant, Germany

The 3 rd DIA 総合ワークショップ
薬剤品開発における資材学の役割分担とその協働に向けて
2006年 10月 9日（木）, 8日（金） 東京カンファレンスセンター/品川
[プログラム委員長：大橋 哲雄（東京大学）]

☆Track A：データ・デジタル化社会への接続
☆Track B：どのように有効でより安全な薬剤品をより早く患者の手に届けけるか
その共通するシナジーを果たすための協働
☆Track C：治療学的な発見開発にいかに貢献できるか
PLEASE CONSIDER THIS FORM AN INVOICE

Second Multitrack Workshop in Japan: DIA Congress on Moving Towards a New Era in New Drug Evaluation
Meeting I.D. # 06302 – April 13-14, 2006, Tokyo Conference Center-Shinagawa, AREA Shinagawa, Tokyo, Japan

REGISTRATION FEES Please check all applicable fees. If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks and reception. Registrations will be accepted by mail, fax, or email.

MEMBER EARLY-BIRD OPPORTUNITY
Available on nondiscount member fee only.

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<tr>
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<td>Meeting Fee</td>
<td>Total Amount Due with 5% Consumption Tax</td>
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<tr>
<td>Member Fee</td>
<td>¥ 59,000</td>
<td>¥ 61,950</td>
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<td>Government (Full-time)</td>
<td>¥ 39,000</td>
<td>¥ 40,950</td>
</tr>
<tr>
<td>Charitable Nonprofit/Academia (Full-Time)</td>
<td>¥ 51,200</td>
<td>¥ 53,760</td>
</tr>
</tbody>
</table>

Join DIA now to qualify for the early-bird member fee!

Please check all applicable fees. If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks and reception. Registrations will be accepted by mail, fax, or email.

CANCELLATION POLICY: On or before APRIL 7, 2006
Administrative fee that will be withheld from refund amount:
Member/Nonmember = ¥ 21,400
Government/Academia/Nonprofit (Member/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.
第2回DIA総合ワークショップ [医薬品評価の新時代に向けた
2006年4月13-14日 東京エコールセンター・品川（東京都港区港南1丁目9-36アトレ品川）]

【参加申込書】

参加申込方法
DIAホームページ（www.diehome.org）よりお申し込み頂けます。この申込書に必要事項をご記入の上、FAXにてお申し込み下さい。
＜DIA日本事務所＞ 〒105-0001 東京都港区虎ノ門1-18-1 虎ノ門第10高輪ビル2階 TEL: 03-5511-1131 FAX: 03-5511-0100

参加費用（該当する方でチェックしてください）

<table>
<thead>
<tr>
<th>会員登録費</th>
<th>参加登録費</th>
<th>合計</th>
</tr>
</thead>
<tbody>
<tr>
<td>一般</td>
<td>￥61,950（¥59,000）</td>
<td>￥67,200（¥64,000）</td>
</tr>
<tr>
<td>非会員</td>
<td>￥61,950（¥59,000）</td>
<td>￥76,650（¥73,000）</td>
</tr>
<tr>
<td>合計</td>
<td>￥61,950（¥59,000）</td>
<td>￥76,650（¥73,000）</td>
</tr>
</tbody>
</table>

追加申込（該当する方でチェックしてください）

アルファベットでご記入ください

Last Name  First Name  Middle Name  Degrees  □Dr.  □Mr.  □Ms.
Job Title  Affiliation (Company)
Address  City  State  Zip/Postal  Country
Email (必须)  Phone Number (必须)  Fax Number

主としてご参加予定のトラック1つにチェックしてください（必須）

Track A  Track B  Track C

出席案内に希望します

参加のキャンセルは、お申込み発表後、2006年4月7日まで受け付けとして会員、非会員とも21,400円を、政府/非営利団体/大学関係者については会員・非会員とも10,700円を申し受けます。それ以後のキャンセルについては参加費全額を申し受けますのでご注意下さい。同一会社からの参加者も可能ですが、その際はお早めにお知らせください（会員資格の確認はできませんので、非会員としての参加費を申し受ける場合があります）。参加のキャンセルは必ず事務局に事前連絡を、また、宿泊のキャンセルは直接ホテルまでご連絡願います。変更が変更される場合がありますのでご了承ください。