

# 5th Annual Clinical Trials Summit 2008

## Project Management in Pan-Asian Clinical Trials

29–30 October 2008 | Sheraton Towers Hotel Singapore

**FIRST IN ASIA! – A PROJECT MANAGEMENT CONFERENCE TAILORED FOR CLINICAL TRIALS!**

### Line-Up of Distinguished Speakers Include:



**Dr. Ming Tong**, *Medical Director, Medical Division, Worldwide Pharmaceutical Operation, Pfizer Inc, USA*



**Dr. Nelleman Lars**, *Regional Medical Director, AS Lundbeck Overseas Far East (Rep. Office), Singapore*



**Dr. Hironobu Saito**, *Director, Clinical Development Group, Asian Development Department, Daiichi Sankyo Co Ltd, Japan*



**Dr. Kyung-Mee Yang**, *Regional Head, Clinical Director, Boehringer Ingelheim, Korea*



**Dr. Ling Su**, *Vice President, Clinical R&D, Asia Pacific, Wyeth Research, China*



**Dr. Victoria Elegant**, *Vice President, Asia-Pacific, Regulatory Affairs / Pharmacovigilance, Baxter Healthcare Corporation Inc (Shanghai), China*



**Mr. Manish Narang**, *Clinical Manager, Asia Pacific, Abbott Vascular, International Clinical Operations, India*



**Dr. Kanokwan Pornprasit**, *SEA Medical Director, Eli Lilly Asia Inc, Thailand*



**Dr. Suzanne Gagnon**, *Snr Global Vice President, Medical Affairs, ICON Clinical Research, USA*

### New in 2008

- Over 25 presentations by industry experts from across and beyond Asia!
- 4 days of valuable insight into Asian clinical trials
- 1 day pre-conference symposium on Clinical Trials Regulatory Affairs in Asia
- 1 day post-conference workshop on Effective Risk Management in Clinical Trials

### Key Benefits of Attending

- Be updated with clinical trials regulatory affairs in developed and emerging Asian countries
- Avoid budget losses by identifying potential unanticipated costs
- Know how to prepare your site for a FDA inspection
- Breeze through internal audits
- Overcome potential pitfalls and challenges in your trial management
- Discover how you can capitalise on your human resources
- Be equipped with essential contracting and negotiation skills to devise a profitable strategy with your sponsor or vendor
- Understand Risk Management

### PLUS! SEPERATELY BOOKABLE

**PRE-CONFERENCE SYMPOSIUM** Tuesday 28th October 2008  
**CLINICAL TRIALS REGULATORY AFFAIRS IN ASIA**

**POST-CONFERENCE WORKSHOP** Friday 31st October 2008  
**EFFECTIVE RISK MANAGEMENT IN CLINICAL TRIALS**

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# Clinical Trials Summit 2008

## PRE-CONFERENCE SYMPOSIUM

28 OCTOBER 2008

### CLINICAL TRIALS REGULATORY AFFAIRS IN ASIA

- 09:00 **Update of Japanese Regulatory Status of Clinical Trials**  
From recently-held government symposiums, it was concluded that more cooperation among regulatory agencies is necessary to promote and protect public health. To make global drug development successful, it will be very important to understand current regulatory situations in Asia, and the strategies in which Asian regulatory agencies plan to adopt in order to achieve this objective. At the same time, be updated of the regulatory status of clinical trials in Japan.



Dr. Hironobu Saito, *Director, Clinical Development Group, Asia Development Department, R&D Division, Daiichi Sankyo Co Ltd.*

- 09:45 **Recent Updates of Regulations and Tips for Conducting Clinical Research in Korea**

Since the establishment of the Korea FDA's (KFDA) Clinical Management Division in 2006, there have been many changes to regulations on clinical trials in Korea. In this presentation, get an overall of guidelines on timelines, the basic and minimum requirements for conducting international studies, as well as important pointers when approaching the KFDA for these studies. At the same time, gain useful tips on conducting trials in the Korea.



Dr. Kyung-Mee Yang, *Regional Head, Clinical Director, Boehringer Ingelheim, Asia*

- 10:30 Morning Refreshments Break

- 11:00 **An Insight into the Indian Regulations for Conduct of Clinical Trials**

This presentation will cover the details of Amended Schedule Y/recent advances in the regulations and its impact on clinical research in India, regulatory authorities, procedures & timelines, critical documentations and improving regulatory compliance – industry perspective, and current trends for clinical trials for devices, biosimilar products and stem cell based therapies.



Dr. Jayasheel B. G., *Manager – Medical Writing & Monitoring, Manipal AcuNova Ltd*

- 11:45 **An Outline of the Regulatory Requirements for Clinical Research in Thailand**

In this presentation, learn about the ethics committee application approval process in Thailand as well as be acquainted with the Thai FDA's regulatory requirements for clinical trial supplies as well as specimen export restriction.



Dr. Kanokwan Pornprasit, *SEA Medical Director, Eli Lilly Asia Inc*

- 12:30 Networking Luncheon

- 14:00 **Current Regulatory Affairs Status of Clinical Trials in Malaysia**

This presentation focuses on both new and experienced perspectives, particularly on the challenges and opportunities of the application for clinical trial import license (CTIL) for global study, potential regulatory issues pertaining to conducting clinical study in Malaysia and as CTIL holder.



Dr. Alvin Tan, *Associate Director, Access to Patients, Quintiles East Asia Pte Ltd*

- 14:45 **PANEL DISCUSSION: Overcoming Regulatory Challenges in Asian Clinical Trials**

In this session, country representatives will gather to share various challenges experienced when conducting clinical trials in their respective countries. The audience will be given an opportunity to address pressing concerns they have with their existing and/or prospective trials in these countries.



**MODERATOR:**  
Dr. Jayasheel B. G., *Manager – Medical Writing & Monitoring, Manipal AcuNova Ltd*

**PANELISTS:** All speakers of the day

- 15:30 Afternoon Refreshments Break

- 16:00 **Current Update of Regulations for Conducting Clinical Trials in Taiwan**

In this presentation, explore the regulatory environment for clinical trials in Taiwan and be updated the current status of regulatory processing by the Department of Health (DOH). Potential challenges will be identified and effective solutions to overcome them. We will also be looking into the benefits of Taiwan as a choice for global studies.



Mr. Albert Liou, *Corporate Vice President and General Manager, Asia-Pacific Region, PAREXEL APEX International Co Ltd*

- 16:45 **Understanding SFDA's Regulatory System for Clinical Research in China**

China is known to have certain regulatory requirements that differ from the other Asian countries. Be acquainted with State Food and Drug Administration's (SFDA) regulatory system and recent updates to maximise compliance of your trials.



Dr. Yun Zhang, *Medical Director, Medical Affairs and Clinical Operations, Sino-American Tianjin SmithKline & French Labs Ltd*

- 17:30 End of Symposium

## DAY 1 | 29 OCTOBER 2008

- 08:00 Registration and Coffee

- 09:00 Chairperson's Welcome and Opening Remarks

### Triumph Over Potential Challenges in Clinical Trial Management

- 09:10 **KEYNOTE ADDRESS: Key Challenges in Clinical Trials Project Management in Asia**

- Overview of clinical trials in Asia
- Key difficulties in conducting clinical trials in the region eg. ethnic concerns
- Partnership and collaboration as a strategy for effective project management
- Case study: Daiichi Sankyo's Tokyo with several Asian subsidiaries



Dr. Hironobu Saito, *Director, Clinical Development Group, Asia Development Department, R&D Division, Daiichi-Sankyo Co Ltd, Japan*

- 09:45 **Overcoming Challenges of a First-in-Man Study**

- Selecting the best study design for your Phase 1 trial
- Determining the appropriate endpoints to meet the objectives of your trial
- Case study: First-in-Man studies with:
  - i. Singapore's first Oncology Drug SB939 (HDAC Inhibitor) and
  - ii. Tyrosine Kinase Inhibitor



Dr. Wei Peng Yong, *Consultant, Department of Haematology-Oncology, The Cancer Institute@National University Hospital (TCI@NUH), Singapore*

### Ensuring Your Organisation is Making the Right Investments

- 10:20 **Regulatory Framework for Clinical Trials in Asia – Now and Future**

- History of Asian clinical trials
- Overview of the current regulatory requirements
- Understanding and making use of the advantages of Asia-Pacific for clinical research
- Development and future trends of Pan-Asian trials



Dr. Victoria Elegant, *Vice President, Asia-Pacific, Regulatory Affairs/Pharmacovigilance, Baxter Healthcare Corporation Inc (Shanghai), China*

- 10:55 Speed Networking and Morning Refreshments Break

# Project Management in Pan-Asian Clinical Trials

## Avoid Costly Delays by Accelerating Application Approvals

### 11:35 Maximise Compliance With Your Ethics Committee To Reduce Application Approval Time!

- Identify what your IRB want and why they do things the way they do, for mutually satisfactory outcomes
- Common causes of delays in application approval
- Foster a collaborative relationship with your IRB to ensure efficient, safe and compliant study initiation and conduct



Dr. Kok Wei Yap, *CEO*, GleneaglesCRC Pte Ltd and *Group Vice President (Research)*, Parkway Health Group of Companies, Singapore

## Managing Your Human Capital for Maximum Productivity

### 12:10 Enhancing Staff Performance in Multinational/Multi-Centered Trials

- Structure of existing system for training and monitoring staff performance
- What are the common problems of staff monitoring and effective solutions



• Strategies to cope with high staff turnover rate to minimise cost  
Mr. Manish Narang, *Clinical Manager, Asia Pacific*, Abbott Vascular, International Clinical Operations, India

12:45 Networking Luncheon

### 14:00 Win the Race for Talent with the Rapid Growth of Clinical Trials Industry in Asia

- Need for talents to meet the demand of growth and expansion
- Strategies to develop and retain your talents
- Win-win: Collaboration in training and education to support the competitiveness of clinical trials in Asia



Dr. Ling Su, *Vice President, Clinical R&D, Asia Pacific*, Wyeth Research, China

## Capitalise on Project Budget by Identifying the Key Sources of Losses

### 14:35 Rising Cost of Clinical Trials in Asia

- Diverse socio-economic situation in Asia
- Drivers of cost competitiveness in Asia
- Challenges linked to the increase of clinical research activity in Asia and consequences on cost



Dr. Christophe Tournerie, *Vice President, Clinical Research-Asia Pacific*, PharmaNet Pte Ltd, Singapore

15:10 Speed Networking and Afternoon Refreshments Break

### 15:50 PANEL DISCUSSION:

#### Effective Planning and Negotiating your Budgets with Partners

In this session, learn from industry experts and your counterparts on their strategies on how to effectively plan your trial budgets, negotiate with sponsors and CROs/SMOs to attain a win-win strategy and cope with increasing investigator fees & engagement charges.



#### MODERATOR:

Mr. Manish Narang, *Clinical Manager, Asia Pacific*, Abbott Vascular, International Clinical Operations, India

#### PANELISTS:

Dr. Jing Ping Yeo, *Director, Clinical Operations*, Novo Nordisk International Operations, China

Dr. Christophe Tournerie, *Vice President, Clinical Research – Asia Pacific*, PharmaNet Pte Ltd, Singapore

Dr. Suzanne Gagnon, *Snr Vice President and Chief Medical Officer*, ICON Clinical Research, USA

Mr. Albert Liou, *Corporate Vice President and General Manager, Asia-Pacific Region*, PAREXEL APEX International Co Ltd, Taiwan

### 16:30 Needs of Investigators in Partnerships from Sponsors and CROs

- Overview of clinical trials in Asia by type of trial and therapeutic area
- Views of clinical trial professionals in terms of working with sponsors and CROs



- Needs and unmet needs of clinical trial professionals in terms of running trials in Asia

Ms. Rhenu Bhuller, *Vice President, Pharmaceuticals*, Frost & Sullivan (S) Pte Ltd, Singapore

17:05 Chairperson's Closing Remarks

17:20 End of Day One

## DAY 2 | 30 OCTOBER 2008

08:00 Registration and Coffee

09:00 Chairperson's Welcome and Opening Remarks

## Project Quality Control and Assurance – Is Yours Reaping The Desired Quality Returns?

09:10 KEYNOTE ADDRESS:

### Is Your Inspection Site FDA-Ready?

- Understanding audits and inspections
- How to prepare for an FDA inspection



• What practices can Asian clinical trials adopt from those in USA  
Dr. Suzanne Gagnon, *Snr Vice President and Chief Medical Officer*, ICON Clinical Research, USA

09:45 Preparing for an Internal Audit – Experience-Sharing by a Leading Pharmaceutical

- Types of audit: systematic vs. for-cause audit; in-house vs. on-site audit
- Understanding the audit requirements
- Common loopholes and challenges, and the effective solutions to overcome them



- The importance of teamwork in a successful audit

Dr. Yun Zhang, *Medical Director, Medical Affairs and Clinical Operations*, Sino-American Tianjin SmithKline & French Labs Ltd, China

10:20 CASE STUDY:

### A Global CRO's Effective Strategies on Dealing With Audits and Inspections

- Understanding the difference between audits and inspections
- Meeting the different requirements
- Sharing of potential loopholes and challenges



Mr. Albert Liou, *Corporate Vice President and General Manager, Asia-Pacific Region*, PAREXEL APEX International Co Ltd, Taiwan

10:55 Morning Refreshments Break

## Be Rid of Contract and Negotiation Woes by Understanding Your Collaborator

11:35 Overview of Clinical Outsourcing Landscape in Japan

- General tendencies of outsourcing in Japan
- Support of multinational studies by CROs in Japan
- Emerging dilemma and complexity in conducting global studies in Japan



Ms. Keiko Oishi, *Snr Managing Director*, CMIC Co Ltd, Japan

12:10 Tackling Increased Complexity in Clinical Trial Agreements (CTA)

- Understanding the important elements and what to pay attention to in preparing a CTA
- Avoiding pitfalls in contracts pertaining to subject injury and insurance
- Addressing concerns of professional liability/indemnification for Principal Investigators



• Learn how to maintain your IP/Patent rights when you outsource  
Dr. Nelleman Lars, *Regional Medical Director*, AS Lundbeck Overseas Far East (Rep. Office), Singapore

# Clinical Trials Summit 2008

12:45 Networking Luncheon

14:00 **CASE STUDY:**

## A SMO's Collaborations with Sponsors and CROs in Taiwan

- Regulatory updates on clinical trials in Taiwan
- Role and responsibility of CRO and SMO in Taiwan
- Collaboration or competition between CRO and SMO?
- SMO: efficient and reliable partner to both Sponsor and CRO

Ms. Jade Liu, *Chief Operation Officer*, Taiwan Total Management Consulting Ltd, Taiwan

14:35 **Minimise Conflict and Achieve a Profitable Sponsor-Vendor Partnership**

- Case study of a successful partnership with a Sponsor
- What do CRO look for in a good sponsor?
- Importance of billing terms in contracts
- Learn how to work with your sponsor for a profitable study
- Find out how trial site costs/RFPs are prepared



Dr. Ganesh Babu, *Manager, Clinical Information & Medical Writing*, Manipal AcuNova Ltd, India

15:10 Afternoon Refreshments Break

15:50 **PANEL DISCUSSION:**

## Gaining a Mutual Understanding Of The Expectations To Minimise Conflict with Your Collaborator

In this session, we will be exploring the common hurdles in collaborative work, and learn how to avoid them by identifying important issues such as contract and billing terms. Hear from both sides of the story (sponsor vs. vendor).

**MODERATOR:**

Dr. Ming Tong, *Medical Director, Medical Division, Worldwide Pharmaceutical Operation*, Pfizer Inc, USA

**PANELISTS:**

Dr. Nelleman Lars, *Regional Medical Director, AS Lundbeck Overseas Far East (Rep. Office)*, Singapore

Dr. Ganesh Babu, *Manager, Clinical Information & Medical Writing*, Manipal AcuNova Ltd, India

Ms. Keiko Oishi, *Snr Managing Director*, CMIC Co Ltd, Japan

16:30 **Exploring Collaborative Opportunities and Clinical Trial Partnership**

- Identifying the anticipated advantages of a collaborative clinical trial alliance for greater efficiency and cost reduction
- Developing programs for successful partnership
- Utilising thought leader networking



Dr. Kanokwan Pornprasit, *SEA Medical Director*, Eli Lilly Asia Inc, Thailand

17:00 Chairperson's Closing Remarks

17:10 End of Conference

## POST-CONFERENCE WORKSHOP

31 OCTOBER 2008 | 09:00–16:00

### EFFECTIVE RISK MANAGEMENT IN CLINICAL TRIALS

#### OVERVIEW:

This workshop will provide an overview of pharmacovigilance for pharmaceutical and clinical research professionals. There will be discussions on global pharmacovigilance and regulations, and a detailed explanation of quality medical assessments of safety reports as well as the concepts of "seriousness" and "expectedness". The process of generating high-quality case narratives and case processing for the safety data base, the organisational structure and function of Data Safety Monitoring Boards will be reviewed. In addition, the usage of MedDRA® and CIOMS, how to perform SUSAR reporting, and safety-related topics including IRBs and the unblinding process for clinical trial safety will be covered. Finally, we will examine the current status of safety reporting requirements in Asia.

#### TOPICS COVERED IN THIS WORKSHOP INCLUDE:

1. What is Risk Management?
2. Importance of Pharmacovigilance and Risk Management in clinical research
3. Risk Management – Implementation of effective system and planning
4. The Risk Management review and current status in Asia
5. Case Study: Risk Management – Lessons learned

#### WORKSHOP LEADER:



Dr. James Fan, *Associate Medical Director, Medical Affairs and Drug Safety/Asia Pacific Region*, ICON Clinical Research Pte Ltd

Dr. Fan currently leads a drug safety group in Singapore that monitors and studies the safety of investigational drug in Asia-Pacific for the global clinical trials. His working experience includes 11 years of clinical practice as a physician in the university hospitals and Medical Director in Taiwan-based CRO and American biotech company Optimer Pharmaceuticals Inc (USA). Dr. Fan is also a member of the Academy of Pharmaceutical Physicians and Investigators (APPI).



## SPONSORSHIP & EXHIBITION OPPORTUNITIES

Enhance your corporate profile and promote your products and services to your potential market and key decision-makers!

This focused event presents an excellent opportunity to showcase your expertise, products and solutions for clinical trials project management to an exclusive audience of clinical trials sponsors, investigators, and key decision-makers. Various sponsorship and exhibition packages are available.

For further discussion, please contact Ms Catherine Wong, Tel: +65- 6732 1970, Email: [catherine.wong@ibcasia.com.sg](mailto:catherine.wong@ibcasia.com.sg)

Register Today! Tel: (65) 6514 3180 Fax back to (65) 6733 5087 / 6736 4312

# Clinical Trials Summit 2008

## EVENT OVERVIEW

With the rapid increase in number of Pan-Asian Clinical Trials and increasing complexity of protocols, successful Clinical Project Management has become an escalating challenge for project managers and key decision-makers in the region. It is no longer about simply managing your resources to meet all project and research objectives, but the ability to optimise them to attain results of international standards. The rising participation in collaborations and outsourcing has also brought about new challenges.

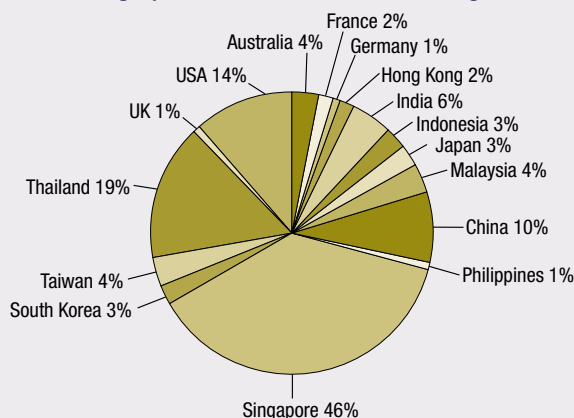
Being informed of the potential challenges ahead will equip project managers and key decision-makers with the essential skills and knowledge to tackle hurdles encountered in cost, time, people and quality management.

In its 5th year running, IBC Life Science's *5th Annual Clinical Trials Summit 2008* returns this year with key focus on *Project Management in Pan-Asian Clinical Trials* to help key decision-makers discover how to save time, cut cost and capitalise on their resources by accelerating application approval, identifying critical factor and effective solutions. These include the key sources of project losses such as unanticipated increasing investigator and vendor charges. Hear from industry experts on what to expect in order to better prepare for your audit and site inspections. Know what the FDA is looking for in their inspection to make sure your investigation site is ready for it at all times!

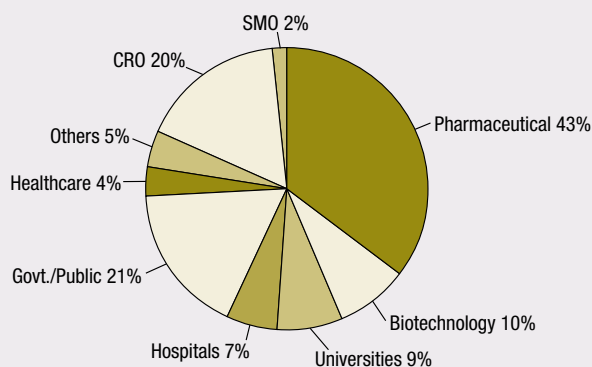
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## PAST DELEGATES PROFILE

Geographical Breakdown of Past Delegates



Industry Breakdown of Past Delegates



## WHO SHOULD ATTEND?

### Title:

- Project Managers/Directors/Leaders
- Principal Investigators
- CRAs/CROs/Monitors/Associates
- Physicians and Medical Liaisons
- Regulatory Affairs Professionals
- Research Scientists

### With Responsibilities In:

- Clinical Trials Management
- Clinical R&D
- Clinical Operations
- Clinical Outsourcing and Partnership
- Regulatory and Safety Affairs
- Business Development
- Contracts Management
- Quality Assurance/Control

### Industry:

- Bio/Pharmaceutical
- Contract Research Organisations
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- Research Institutes
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## 5th Annual Clinical Trials Summit 2008

### HOTEL INFORMATION

**Sheraton Towers Hotel Singapore**  
39 Scotts Road  
Singapore 228230  
Tel: +65 6837 6888  
Fax: +65 6733 4366  
Contact Person: Joanne Leong  
Email:  
Joanne.leong@sheraton.com

### 5 EASY WAYS TO REGISTER

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All payments should be made in US or Singapore dollars

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Ph: +65 6835 5141 or Fax: +65 6734 4053.

### GROUP BONUS:

Register 3 delegates and the 4th delegate can attend for FREE  
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If you have already received a copy of this brochure, we apologise. For reasons of confidentiality, your full particulars were not available to IBC Asia (S) Pte Ltd for deduplication prior to mail drop.

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Yes! I/We will attend the **5TH ANNUAL CLINICAL TRIALS SUMMIT 2008** • 29-30 October 2008, Sheraton Towers Hotel Singapore

Ist delegate	2nd delegate
Name: Dr/Mr/Ms _____	Name: Dr/Mr/Ms _____
E-Mail _____	E-Mail _____
Job Title _____	Job Title _____
Mobile no _____	Mobile no _____
Department _____	Department _____
Company _____	
Address _____	
Post Code _____	Country _____
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Options	Price	Saving	Price	Saving	Price	Saving
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Fee includes luncheons, refreshments and complete set of documentation. It does not include the cost of accommodation and travel.

**CANCELLATIONS SUBSTITUTION** If you are unable to attend, a substitute delegate will be very welcome in your place. If this is not suitable, a 10% service charge will be payable. Registrations cancelled less than seven days before the event must be paid in full

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