CLINICAL TRIALS OUTSOURCING & DEVELOPMENT

2-3rd December
Singapore

A clinical partnering event for outsourcing and development professionals and service providers in late phase clinical trials

DRAFT AGENDA

Subject to change

With the increase of clinical trial outsourcing to reduce costs, this event will serve as a collaboration forum to save money on the testing of clinical trials, meet regulatory requirements, and strategically outsource late phase (phase III) clinical development. This conference will bring together the leading Pharma& Biotech companies as well as the Contract Research Organisations (CRO's) responsible for decision making in Asia. Examining the latest technologies in clinical testing, driving patient recruitment, and identifying how to outsource clinical trial data, this event will delve into the challenges and opportunities of the evolving Asian Clinical Trials Industry.

Who you will meet at Clinical Trials Development & Outsourcing 2015

- Head of Clinical Procurement
- Head of Clinical Outsourcing
- Head of Clinical Development
- Head of Clinical Operations
- Head of Clinical Compliance
- Head of Regulatory Affairs

Early Confirmed Speakers:

Jin-San Yoo, CEO & President, **PharmAbcine Inc South Korea**
Fung Faith, Vice President, Clinical Development, Asia, **SFJ Pharmaceuticals Singapore**
Archana Subramanya, Director and Head, Global Data Management and Head CDOC, **GSK India**
Maggie Lim, Regional Clinical Quality Development Assurance Director, **GSK Asia- Pacific Singapore**
Tapankumar Shah, Country Head- SM & M (Clinical Operations), **AstraZeneca, India**

Speakers Invited:

Joanne Palmisano, Vice-President, Regulatory Affairs, **Boehringer Ingelheim**
Bernhardt Zeiher, President, Global Development, **Astellas Pharma USA**
Veronique Ollivier-Guillon, Director, Clinical Program Leader Asia Pacific, **Johnson and Johnson**

Yoichi Sato, VP, Head of Global Regulatory Affairs, **Shionogi & Co**
Darren Ji, VP and Global Head of Roche Partnering, **Asia and Emerging Markets**
Dr. Victoria Elegant, Vice-President, Medical and Regulatory Affairs, Asia Pacific, **Baxter Healthcare Shanghai**
Yuri Martina PhD, MBA, PMP, Vice President Clinical Operations, **SHIONOGI**
Koichi Miyazaki, Senior Director, Regulatory Affairs Group, Asia Development Department, **Daiichi-Sankyo, Japan**
Pauric McGinty, Global Head, Clinical Outsourcing & Provider Management, **EMD Serono, INC. / Merck Serono**
Patrecia Flynn- Valone, Senior Director, **Takeda Global Research & Development**
Lars Nelleman, Vice President, **Lundbeck**
Carlos Linn, Director, Clinical Program Lead (CPL) - Oncology, Pfizer China, **Pfizer**
Dilip Pawar, Director and head Emerging Market APAC, **MSD**
Bhaskar Chakraborty, Head R&D and Clinical Outsourcing, **Dainippon Sumitomo Pharma**
Dr. Pratik Shah, Head Clinical, Medical & Regulatory Affairs, PV and QA, **Astellas Pharma India Private Limited**
Lynn Newbould, Head of Clinical Procurement and Outsourcing, **Merrimack Pharmaceuticals**
Genevieve Wan, Asia Pacific Pharmaceuticals Compliance Director, **GSK**
Ratan Ratnesh, Director and Head, Clinical Outsourcing, **Otsuka Pharmaceutical Companies (US)**
Michihiko Wada, Vice President, Head of R & D Tokyo, **Alexion Pharmaceuticals**
Rene Stephens, Executive Director, Global Head, Global Contracts & Outsourcing Management**, Astellas Pharma Global Development**
David Baugnies, Head of Strategic Resourcing, **GlaxoSmithKline Biologicals**
Juan Pablo, Global Head, Clinical Trial Planning & Operations, **GSK**
Herve Gieerot, SVP & General Manager, China/Hong Kong, **GSK**
Graham Belgrave, Senior Vice President, Head Global Clinical Development Operations, **Gruenthal GmbH**
Jez Moulding, President North America Pharmaceutical Operations, **Sanofi**
Edward Hanover, Head of Compliance, Emerging Markets, **Takeda Pharmaceuticals**
Ritika Bajaj, Associate Director Clinical Operations, Sr. Clinical Country Lead South East Asia, **Biogen Idec Biotech India Pvt. Ltd.**
Lisa Li, Director, Infectious Disease, Immune Inflammation & dermatology, Clinical Development**, GSK R&D China**
Aziza Ahmed, Head Regulatory Affairs, Emerging Asia & Korea, **Baxter International Inc.**
David Slade, MD, Vice President, Global Head of Clinical Development and Clinical Operations, **Therakos, Inc.**
Ciu Ling Khoe, Regional Director, Head Regulatory Affairs, Asia Pacific, **A. Menarini Asia-Pacific Holdings Pte. Ltd**
Rong Zhao, Head of DMPK (China), **Novartis**
Guotao Yang, Director of Clinical Development**, Astellas China**
Pasi Piitulainen, Senior Director, Development Finance, Portfolio Management & Outsourcing, **Actelion**
Yufeng Chen, Principal Clinical Data Manager, **Boehringer Ingelheim International Trading Shanghai Co.**
Hong Wan, Executive Director and Head of DMPK, **Shanghai Hengrui Pharmaceutical Co**
Sean Low, Regional Director, Therapeutics Integrity, Novartis Oncology Asia Pacific, **South Africa & China**
Yi (Gloria) Wang, Chief China Clinical Development & Clinical Research Physician APAC, **United Therapeutics Corporation**
Yong Chen, Director, China Roche Partnering, **Roche**
Aaron Tabensky, Associate Director Clinical Operations Regional Therapeutic Lead, General Medicine**, Takeda**
Tokiko Adachi, Process Lead, **AstraZeneca**
Ajay Gautam, Executive Director and Head, Asia Pacific & Emerging Markets BD, **AstraZeneca**
Steve Martindill, Director, Clinical Operations International, **Gilead Sciences**
Juliana Wang, On Site Monitoring and Resourcing Manager, **Boehringer Ingelheim**
Jingsong Wang, Head of China Research & Development, **Sanofi**
Dr. Pranab Kalita, Medical Director, South East Asia Cluster, **Lundbeck**
Dr. Josemund Menezes, Regional Director, Clinical Development (Asia-Pacific), **Sanofi-Pasteur**

Conference Day One

2 December 2015

8:00 **Registration and Welcome Coffee**

8:30 **Opening Remarks from the Conference Chair**

8:40 **Keynote Presentation: The Impact of Globalisation on Development and Outsourcing for Biotech and Local Pharma**

This session will examine the drug development scenario across the Asian Pacific and the implications they have on the pharma and biotechs. This session will give an overview of the clinical development pathway for regional pharma in Asia and shed light into how to bring products to markets and effectively outsource them.

- Addressing the future of drug development and outsourcing for pharma and biotechs
- Examining current issues and challenges for biotech and local pharma in outsourcing & drug development
- Understanding the clinical development pathway to approval

Jin-San Yoo, CEO & President, **PharmAbcine Inc South Korea**

9:10 **Expert Government Panel Discussion: Regional Clinical Regulations in Asia**

With different regulations in each country across Asia, finding the correct pathway for clinical trials can be quite challenging.

- Understanding the APAC regulatory convergence and the regional harmonization initiatives
- Preparing your industry for ASEAN harmonization and future trends
- Analysing the updates and key considerations in clinical and drug development
- Predicting the future developments and remaining challenges for regulatory compliance

Invited: Churn-Shiouh Gau, Executive Director/ Center for Drug Evaluation, **Taiwan**
Dr. Victoria Elegant, Vice-President, Medical and Regulatory Affairs, Asia Pacific, **Baxter Healthcare Shanghai**
Joanne Palmisano, Vice-President, Regulatory Affairs, **Boehringer Ingelheim**

9:40 **Expert Presentation: Running Overseas Trials with Local Service Providers**

With the growth of risk monitoring in trials run with third party organisations, this session will paint the picture for utilising local service provider's knowledge of the population and patient compliance within the targeted region.

- Benchmarking effective communication pathways to ensure smooth monitoring
- Evaluating the methods of monitoring providers performance to safeguard your trial
- Effectively communicating patient criteria to ensure appropriate patient recruitment
- Building trust with local service providers to ensure operational excellence

Invited: Darren Ji, VP and Global Head of Roche Partnering, Asia and Emerging Markets, **Roche**

10:20 **Challenges and Opportunities for Successful Patient Recruitment**

Getting more patients involved in trials is instrumental to improving the clinical trial process. Identify the correct methods and strategies to make your patents more informed and better equipped to make a decision about joining a clinical trial.

- Assessing the rise of social media and increasingly rigid trial protocols
- Highlighting the changing landscape of trial recruitment
- Discussing the best practices for efficiently enrolling trial participants
- Considering the complexity of protocols with emphasis on stringent inclusion, exclusion criteria, and the standard of care (SOC) changes in therapeutic indications

11:00 ***SPEED NETWORKING SESSION***

Hosted by the Conference Chair:

A structured interactive session designed to help you expand your network through one-on-one focused conversations.

11:30 ***MORNING TEA AND NETWORKING BREAK***

12:00 **Examining Site Activation Strategies to Speed up the Clinical Trial Process**

Site activation remains the key in successful clinical trial processes. Learn the best strategies for ensuring smooth operation for the site processing and the trial development.

- How do you set up effective communication to ensure there are no delays?
- What are the best methods to accommodate both the site and the trial's needs?
- What are the best strategies to be put in place in the each phase of development?

Invited: Joshi Venugopal, Managing Director, Singapore & Asian Emerging Markets, **Novartis**

12:40 **Partnering with the Right Contract Research Organisations for your Company**

As more biopharmaceutical companies emerge with the goal of developing new medicines, and each potential drug requires extensive clinical testing, there will continue to b e an increasing rate of outsourcing clinical trials. How can pharmaceutical and biotechnology sponsors deliberate to find the right balance and manage resources between in-house and outsourced projects?

- Clinical Data challenges when outsourcing trials to CROs
- Reducing R & D costs, handling pricing pressures, and managing regulatory developments
- Can CRO's help reduce the expenses associated with clinical trials?

Invited: Jez Moulding, Senior Vice President, Japan & Pacific Zone, **Sanofi**

13:20 ***NETWORKING LUNCH***

14:20 **Managing Clinical Trials: Outsourcing to Central Labs**

Central laboratories have become an important part of running global and large multi-regional clinical trials in Europe and the United States. With the rapid increase in the number of global clinical trials in China and the Asia Pacific region, trial sponsors should understand how to choose central labs in those regions, and the reasons for those choices.

- Understanding partnerships with third party global labs and regional labs
- Assessing central labs key features like testing, specimen management, logistics management, kit production, data management and project management
- Deciding what critical factors to assess in choosing a central lab
- Emphasizing the regulations associated with sample testing for each region of lab

Invited: Ratan Ratnesh, Director and Head, Clinical Outsourcing, **Otsuka Pharmaceutical Companies (US)**

15:00 **Quality Assurance in Clinical Trials**

Clinical Trials are conducted to collect the data necessary to provide information fro academics, industry, and the regulators. The decisions re then made on the safety and efficacy of the disease, medicine, or preventative medicine. Join Maggie Lim as she discusses the role that quality assurance plays in clinical trials development and oversight.

- Monitoring the clinical trial to ensure patient protection
- Managing on-site visits to ensure quality assurance in the clinical trial
- Understanding how to produce successful risk assessments and evaluations of the trial
- Identifying methods for upholding the standard operating procedures

Maggie Lim, Regional Clinical Quality Development Assurance Director, **GSK Asia- Pacific**

15:40 ***AFTERNOON TEA AND NETWORKING BREAK***

16:00 **Japan Country Updates & Regulatory Environment Overview**

This session will provide and update on the current regulations taking place in the clinical trials industry in Japan.

- Understanding the regulatory landscape of Japan for Clinical Trials
- Assessing methods and strategies for negotiating with authorities and regulatory bodies
- Examining the challenges faced with operating trials in Japan
- Clarifying the guidelines for carrying out clinical trails in Japan

Invited: **Koichi Miyazaki,** Senior Director, Regulatory Affairs Group, Asia Development Department, **Daiichi-Sankyo, Japan**

16:40 **Interactive Discussion: Champagne Roundtable**

**This champagne roundtable will encourage you to further identify, benchmark, and analyse the key issues and challenges facing women in the public sector. Delegates will choose a topic that they wish to discuss and one member of the roundtable will present back to the group with their findings. Grab a glass of bubbly and discuss the issues that inhibit you from advancing your career whilst forming reputable relationships with influential experts.*

Table 1: Exploring Outsourcing Strategies for Rare Disease Trials

- What are the precautions with rare disease trials?
- How does the outsourcing strategy change with these trials?
- What are the best methods for identifying the correct market with rare disease trials?

Table 2: Enhancing your CRO relationship through Negotiation and Management

- What needs to be said in a contract with CRO's?
- What are the best methods for negotiating with third parties?
- How can Pharma/Biotech ensure that their relationship with CRO's is successful?

Table 3: The Role of Big Data in Clinical Trials

- What are some of the challenges of managing the growing wealth of data in the clinical space?
- Does big data hold the keys to clinical trial innovation?
- How does big data affect partnerships?

Table 4: Using Social Media for Patient Recruitment

- What are the best methods for social media patient recruitment techniques?
- How can companies produce the most engaging social media?
- What are the projected impacts of using social media to recruit patients?

17:20 ***END OF DAY ONE & NETWORKING DRINKS***

Conference Day Two

3 December 2015

9:00 **Registration and Welcome Coffee**

9:30 **Opening Remarks from the Conference Chair**

9:40 **Keynote Presentation: Where are the Emerging Locations for Clinical Trials in Asia Pacific?**

There are various locations in Asia that prove more successful for trials then other locations. This session will be a collaboration of where Big Pharma and Biotech companies are currently looking to begin new clinical trials.

- Examining the newest locations across the Asia Pacific that could offer superb locations for trials
- Highlighting the key regions that are looking to start trials oversees
- Collaborating on perspectives and predictions of the best methods for implementation in foreign and virgin territory for clinical trial development

Dr. Victoria Elegant, Vice-President, Medical and Regulatory Affairs, Asia Pacific, **Baxter Healthcare Shanghai**

10:20 **Creating a Comprehensive Contract with Service Providers**

This session will discuss the relevant timelines and realistic forecasts to create a practical project plan with your service providers.

- Analysing the correct methods for drafting a practical project plan
- Addressing the challenges that occur with change orders in the plan
- Negotiating the expectations from the sponsor and service provider
- Understanding the penalties, rewards, achievements, and progress during the trial
- Managing your expectations and responsibilities during the trial

Fung Faith, Vice President, Clinical Development, Asia, **SFJ Pharmaceuticals**

11:00 **Ensuring Good Clinical Practice and Standards in Strategic Partnerships**

Good Clinical Practice (GCP) in strategic partnerships is essential in maintaining relationships and ensuring business runs smoothly.

- Understanding how to conduct routine qualification audits of third party vendors
- Enforcing the assessment of qualifications and training of all personnel within the company and within vendors
- Evaluating the organisational structures to ensure clarity on both sides of the partnership

Archana Subramanya, Director and Head, Global Data Management and Head of Clinical Development Operations Centre, **GSK India**

11:40 ***NETWORKING MORNING TEA***

12:20 **Interview CEO Session: Biotech/Pharma Company**

- What have been the most successful strategies in clinical trials outsourcing you have used?
- How do you select a CRO for outsourcing?
- Do you use central labs and how effective have they been?
- What are the newest technologies your company is utilizing to further develop your clinical trials?

13:00 ***NETWORKING LUNCH***

14:00 **Panel Discussion: Next Generation Partnerships**

Addressing what sets the current and futuristic partnerships apart from one another, this session will identify key tips for the sponsor-vendor relations.

- Identifying the key determinants of success
- Discussing how change management can be utilised effectively
- Examining the Sponsor/CRO relationship and benchmarking the success of current partnerships
- Collaborating ideas to move this relationship to new innovative partnerships

Moderator:
Panellists: Archana Subramanya, Director and Head, Global Data Management and Head CDOC, **GSK India**
Invited: Jennifer Wang, CRO Outsourcing and procurement Lead, **GSK Singapore**
Darren Ji, VP and Global Head of Roche Partnering, **Asia and Emerging Markets**

14:40 **Assessing Site Predictability to Improve Consistency**

This session will help you to master internal and external data and a create a more comprehensive view of investigative site capabilities.

- Highlighting consistent performance
- Uncovering new quality measures to increase efficiency
- Examining prescription volume data

Jennifer Wang, CRO Outsourcing and procurement Lead, **GSK Singapore**

15:20 ***AFTERNOON TEA AND NETWORKING BREAK***

15:40 **Clinical Development Oversight and Progression**

16:20 ***MAIN CONFERENCE CLOSE***

Workshops

4 December 2015

Workshop A:

Risk-based Monitoring for Vendor Oversight across Asia

What the workshop will cover:

- Implementing the best practices for vendor oversight
- Utilising risk based approaches to maximise return on investment
- Monitoring the vendor to ensure successful clinical trails of late phase trials

How you will benefit:

- Be able to approach vendors with pre-determined plan of attack
- Administer risk based approaches to staff training and client liaison
- Be able to correctly manage your vendors to ensure quality assurance

Workshop B:

Quality Assurance for Clinical Trials across Asia

What the workshop will cover:

- Understanding GCP and quality assurance in the conduction of clinical trials
- Assessing the guarantees of operating in emerging locations
- Highlighting the quality assurance agreements in patterning relationships

How you will benefit:

- Be able to implement the best quality assurance plan for your organisation
- Be able to assess the most successful methods of quality assurance in clinical trials

Workshop C:

Clinical Sites and Sponsors Creating Win-Win Relationships

What the workshop will cover:

- Site activation negotiations and opportunities
- Understanding the CRO and Pharma relationship
- Best practices for negotiation techniques

How you will benefit:

- Enable your organisation to create beneficial situations for both parties
- Benchmark your current situation against competitors
- Be able to implement best methods for liaising with CROs and service providers

Workshop D:

Understanding the new Regulatory Landscape in Japan

With the new regulatory changes occurring in Japan, this country boasts a spectacular region for clinical trials.

What the workshop will cover:

- Examining the newest regulatory updates in japan
- Assessing the opportunities that now lie in this emerging location and its implications
- Analysing the regulatory landscape and its benefits to the clinical trial's industry

How you will benefit:

- Be able to implement new measures to conduct trials in Japan
- Completely understand the data relevance in the new updated regulations
- Be able to consider trials in Japan and create a successful outsourcing plan to carry out these trials

Pricing and Discounts

	EXTRA EARLY BIRD *Register & pay before **23 September 2015**	**EARLY BIRD:** *Register & pay before **21 October 2015**	Standard Pricing
Conference + 4 workshops	$4,199 (Save $1,200)	$4,999 (Save $400)	$5,399
Conference + 3 workshops	$3,949 (Save $1,150)	$4,749 (Save $350)	$5,099
Conference + 2 workshops	$3,599 (Save $1,100)	$4,399 (Save $300)	$4,699
Conference + 1 workshops	$3,199 (Save $1,100)	$3,999 (Save $300)	$4,299
2 Day Conference	$2,499 (Save $1,100)	$3,299 (Save $300)	$3,599

Above pricing is exclusive of GST.

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IQPC recognises the value of learning in teams. Take advantage of one of these special rates:

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- Ask about multi-event discounts. Call **+ 61 2 9229 1000** for more details

Please note:

- Discounts are not available to vendors or solution providers.

To register:

To reserve your place at Clinical Trials Outsourcing & Development 2015 call IQPC on + 61 2 9229 1000 or email registration@iqpc.com.au

For more information email enquire@iqpc.com.au