

# Managing R&D Outsourcing & Partnerships 2009

Enhancing R&D outsourcing effectiveness and management to improve drug discovery and clinical trial outcomes

Grand Copthorne Waterfront  
Hotel, Singapore

16th & 17th November 2009

"By mutual confidence and mutual aid – *great deeds* are done, and *great discoveries* made."

Homer, Greek Poet

Capitalising on innovative technologies and strategic alliances with outsourcing partners to deliver drug discovery and development breakthroughs



## Attend this informative event and gain practical insights into:

- **Analysing** the impact of the economic crisis on R&D outsourcing in Asia
- **Examining** CRO industry performance in Asia to identify the right partner
- **Developing** successful relationship management with pharmaceutical suppliers
- **Overcoming** challenges in running clinical trials in frontier markets
- **Re-negotiating** contracts to improve project success and reduce costs
- **Moving** from Full Service Providers (FSPs) to Niche Providers to boost efficiency

## Some testimonials of past marcus evans' Life Sciences conferences and trainings:

"I enjoyed the conference and networking opportunity that marcus evans provided."

Regional Operations Director  
**US, Pfizer Inc (USA)**

"Opening new horizon and keep you updated with well-selected topics and panel of speakers."

Medical & Regulatory Director  
**Sanofi-Aventis Group (Indonesia)**

"A good combination of project management and clinical research training."

Head of Clinical Research  
**Boehringer Ingelheim (China)**

**\*Early Bird & Group Discounts**  
Ask about our savings

## Your eminent panel of speakers:

**Dr Angela Rodrigues** Regional Medical Director, Global Scientific Support, International Medical Development  
**Abbott Laboratories, India**

**Richard Wang** Director - Strategic Alliance & Collaboration  
**AstraZeneca Innovation Centre China**

**Dr Hideaki Nakaya** Centre for Clinical Research  
**Keio University School of Medicine, Japan**

**Dr Michael Schroter** COO & Director of Business Development / Alliance Management  
**Lilly Singapore Centre for Drug Discovery, Singapore**

**Swaminathan Subramaniam** Director - Worldwide Licensing & External Research, India  
**Merck & Co, Inc., India**

**Dr Gerard Wong** Deputy Director, Investigational Medicine Unit (IMU)  
**National University Health System, Singapore**

**Dr Stella Xu** Executive Director  
**Roche Pharma Partnering, Roche China**

**Dr Timothy Low** Regional Medical Director  
**Schering-Plough, Singapore**

**Dr Sven Ohlman** Regional Director, Clinical Study Operations Asia  
**AstraZeneca Research & Development, Singapore**

**Dr Teoh Yee Leong** Director, Clinical R&D and Medical Affairs  
**GlaxoSmithKline Biologicals, Singapore, Malaysia & Brunei**

**Dr Rajesh Karan** Regional Head of Translational Medicine & Scientific Operations  
**Novartis India**

**Monique Jackson** Global Clinical Development – Asia Pacific  
**Kendle**

**Kristian Robinson** Director, Head of Chemical & Life Sciences Patent Department  
**Ella Cheong Spruson & Ferguson**

**Dr Nirav Gandhi** Director - Clinical Services  
**Accutest Research Laboratories**

Official Supporting Organisation



Official Media Partner



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# Monday 16th November 2009

## 0830 Registration & coffee

## 0855 Welcome remarks by Chairperson

**Dr Stella Xu** Executive Director  
Roche Pharma Partnering, Roche China

## 0900 Contact Initiation Session (CIS)

In this 15-minute session, delegates will get to know their peers and be able to share, among others:

- Name, job title and company represented
- 1 key accomplishment in regards to Outsourcing or Partnerships

## 0915 Session One

### Roche Pharma Partnering in Asia – Pursuing innovation and sharing opportunities

- Driving innovative personalised healthcare through partnerships
- Building win-win alliances with external innovation leaders
- Transforming scientific collaborations into differentiated medicines
- Strengthening existing collaborations and R&D presence through our Asian partnering network

**Dr Stella Xu** Executive Director  
Roche Pharma Partnering, Roche China

## 1000 Session Two

### Optimising the management of decentralised R&D through effective organisational structures

- Overcoming inherent complexity of multiple external relationships that exist as part of a network
- Managing time zone, geographic and cultural transitions in discovery processes
- Creating effective coupling between internal knowledge and external resources
- Permitting innovation without losing control
- Examining ideas for organisational structures and governance processes that support these objectives

**Swaminathan Subramaniam** Director – Worldwide Licensing & External Research, India  
**Merck & Co, Inc., India**

## 1045 Morning refreshments and networking

## 1115 Session Three

### Developing a new generation of progressive blockbusters by drawing on R&D restructuring

- Proposing innovative solutions that respond to the unmet needs of patients
- Channelling and synergising R&D activities focussing on new innovative products and getting them to market faster
- Narrowing the focus of development efforts to fix research problems
- Targeting chronic disease segments such as cancer, specialised care and biotech with lesser emphasis on primary care medicines

**Dr Michael Schroter** Chief Operating Officer & Director of Business Development / Alliance Management  
**Lilly Singapore Centre for Drug Discovery, Singapore**

## 1200 Session Four

### Unravelling the complex options available in the outsourced clinical research market today to complement your core competencies

- Diving into differences in service provider offerings based on price, patient recruitment times and timeliness
- Scrutinising total research cost involved in outsourcing to a particular CRO
- Discovering potential hidden costs early to pre-empt delays to the successful completion of a trial
- Performing post-contract evaluations to rate the effectiveness of the service provider

**Dr Angela Rodrigues** Regional Medical Director – Global Scientific Support, International Medical Development  
**Abbott Laboratories, India**

## 1245 Networking luncheon

## 1345 Session Five

### Developing successful partnerships with CROs

- Aligning objectives between sponsor and service providers throughout the chain of responsibility
- Encouraging transparency to quickly resolve teething issues in meeting deadlines
- Establishing robust, interactive channels of communication to quickly manage challenges during the project life
- Moving contingency planning to the forefront of your operations in the early stages of the partnership

**Monique Jackson** Global Clinical Development – Asia Pacific  
**Kendle**

## 1430 Session Six

### CRO outsourcing in Japan: An investigators' perspective

- Detailing the present status of clinical research outsourcing in Japan
- Focusing on the challenges and opportunities in multinational trials and CRO outsourcing
- Developing capacity to support investigator-initiated trials: infrastructure, manpower and expertise
- Future perspective for CRO in Japan

**Dr Hideaki Nakaya** Centre for Clinical Research  
**Keio University School of Medicine, Japan**

## 1515 Afternoon refreshments and networking

## 1545 Session Seven – Panel Discussion

### Reducing risk with the right CRO partner – Evaluating CROs with confidence

- Comparing CRO performance in Asia particularly India & China
- Diving into differences in service provider offerings based on price, patient recruitment times and timeliness
- Examining the role of site management expertise in the selection of a service provider
- Tackling the mechanics of issue identification and resolution to promote informed decisions

Panellists:

**Swaminathan Subramaniam** Director – Worldwide Licensing & External Research, India  
**Merck & Co, Inc., India**

**Dr Timothy Low** Regional Medical Director – Asia Pacific  
**Schering-Plough, Singapore**

## 1630 Session Eight

### Overcoming challenges in managing outsourced clinical trials in frontier markets

- Investing in training of CROs and Investigators for customised and long term projects
- Streamlining turnaround times for key project management tasks to facilitate agile decision-making
- Managing deviations from pre-established trial timelines to minimise costs
- Drawing on cultural considerations in dealing with staff and patients

**Dr Timothy Low** Regional Medical Director – Asia Pacific  
**Schering-Plough, Singapore**

## 1715 Closing remarks from the Chair and end of Day One

## Who should attend

**Presidents, Vice Presidents, Chief Scientific Officers, Managing Directors, Directors, General Managers, Medical Directors and Heads of:**

- Research & Development
- Regulatory/Medical/Scientific Affairs
- Corporate/Strategic Planning
- Contract & Outsourcing
- Business Operations
- Medical Services
- Central Laboratory Services
- Clinical Trials/Clinical Research/Clinical Development/Clinical Operations
- Clinical Study Monitoring/Project Management/Quality Assurance/Compliance

**From:**

- Pharmaceuticals
- Biotechnology
- Biopharmaceutical
- Clinical Research Centres/Laboratories
- Research/Discovery & Development
- Medical Technology

## About the Supporting Organisation

The **Malaysian Organisation of Pharmaceutical Industries (MOPI)** was incorporated on March 6th 1981, as a company limited by guarantee, by eight local, foreign and joint venture companies involved in the manufacturer of pharmaceutical products. Raja Zainal Abidin bin Raja Haji Tachik of Raza Manufacturing Sdn Bhd was elected as MOPI's first president. MOPI membership is open to all manufacturers of pharmaceutical products whose manufacturing facilities in Malaysia are licensed by the Drug Control Authority Ministry of Health. MOPI main activities are promoting and developing the pharmaceutical industry, foster closer co-operation among members of the industry, facilitate and encourage the development, exchange and transfer of information and technology, domestically and internationally. MOPI in co-operation with the government and other bodies, also represents the interests of the pharmaceutical industry.

## Why you cannot miss this event

The pharmaceuticals industry faces tremendous challenges in the coming years. The patents for their profitable block-buster drugs are expiring, competition from generics is rising, increasing volume of globalised trials, lack of capacity and their efforts in R&D are not resulting in the approval of new drugs to replace the outgoing ones in their pipelines. This combined with the present economic situation forces players in the industry to effect cost reduction measures to ensure the profitability of their company as well as meet their shareholders' expectations.

This event is specifically designed to meet market participant's demands to understand the R&D outsourcing situation in Asia. This conference will equip you with the latest updates on the current R&D outsourcing environment, identify best practices in management of CROs and help you determine the most practical approach to the selection of a partner to drive your research efforts forward. You will gain insights of how award-winning companies have benefited from outsourcing their R&D in the region, and also how they have succeeded in doing so.

**This event will provide you with strategic information to leverage R&D outsourcing to enhance your ROI in drug discovery and development.**

## Tuesday 17th November 2009

0830 Morning coffee

0900 Opening and welcome remarks by Chairperson

**Dr Nirav Gandhi** Director - Clinical Services  
Accutest Research Laboratories

0915 Session One

**Implementing performance-based incentives in research contracts to improve project efficiency**

- Building the right team for outsourcing success
- Determining metrics for project manager/CRA performance
- Optimising the cost, speed and quality of delivery of service providers
- Training and incentivising staff to ensure compliance and time-keeping

**Dr Nirav Gandhi** Director - Clinical Services  
Accutest Research Laboratories

1000 Session Two – Case Study

**Outsourcing Translational Medicine (TM) (Phase 1 and 2A including PharmaKinetic studies/TQT studies) studies to India**

- Examining the patient recruitment opportunities that India provides for TM studies in completing a study on time
- Exploring the regulatory, infrastructural and manpower challenges in outsourcing TM studies to India to determine feasibility of outsourcing
- Analysing the acceptability of data from India by USFDA as a critical factor in deciding to run trials
- Sharing three years of experience in running outsourced TM studies in India

**Dr Rajesh Karan** Regional Head of Translational Medicine & Scientific Operations  
Novartis India

1045 Morning refreshments and networking

1115 Session Three

**Examining the Intellectual Property (IP) challenges of outsourcing R&D in Asia**

- Tracking the changing climate in cross-border intellectual property protection
- Protecting trade secrets in cross-border transactions
- IP Rights issues and challenges relating to drug discovery in emerging markets
- Implementing IP management software to manage and reduce risks

**Kristian Robinson** Director, Head of Chemical & Life Sciences Patent Department  
**Ella Cheong Spruson & Ferguson**

1200 Session Four

**Optimising the external provider partnership model to drive efficiencies**

- Creation of a Clinical Outsourcing Strategy
- Decision making and optimal internal resource management
- Creating a true joint partnership operating model
- Aligning external providers with demand

**Dr Sven Ohlman** Regional Director Clinical Study Operations Asia  
AstraZeneca Research & Development, Singapore

1245 Networking luncheon

1345 Session Five

**Moving from full service CROs to niche providers to gain a greater success rate in R&D**

- Distinguishing between full service model and niche providers – which adds value when?
- Assessing the options available for biopharma in outsourcing to niche providers and the development of parallel clinical development portfolios
- Tackling the increased resource burden in managing multiple niche providers
- Coordinating with multiple niche providers - challenges and benefits

**Richard Wang** Director – Strategic Alliance & Collaboration  
AstraZeneca Innovation Centre China

1430 Session Six

**Forming strategic clinical alliances to boost R&D efforts in the search for new therapies**

- Developing partnership models to improve research productivity and success rates
- Tapping on expertise in therapeutic areas without the need for additional headcount
- Establishing a basis for stronger working partnerships through the sharing of lessons learnt

**Dr Gerard Wong** Deputy Director, Investigational Medicine Unit (IMU)  
National University Health System, Singapore

1515 Afternoon refreshments and networking

1545 Session Seven – Panel Discussion

**Predicting the future of outsourcing – Moving from a zero-sum game to deriving true value**

- Determining the true value of strategic partnerships in R&D
- Examining how the pharmaceutical services community has responded to industry challenges
- Moving from the low cost differential to value-added services
- Examining avenues which the CRO can add value to research organisations

Panellists:

**Dr Teoh Yee Leong** Director, Clinical R&D and Medical Affairs  
GlaxoSmithKline Biologicals, Singapore, Malaysia & Brunei

**Dr Sven Ohlman** Regional Director Clinical Study Operations Asia  
AstraZeneca Research & Development, Singapore

1645 Closing remarks and close of conference

### About the Official Supporting Organisations

The **Pharmaceutical Society of Singapore (PSS)** is the only professional, non-profit organisation representing pharmacists in Singapore. Originally founded in 1905 as the Straits Pharmaceutical Society, our membership comprises pharmacists practicing in the community, hospital, marketing and sales, distribution, research, regulatory, and academic sectors. Today it is steered by an elected council comprising a president and 11 council members. PSS aims to improve the public's understanding of medication and its use, promote responsible self-care and promote safe and appropriate use of medicines.

**ACRP** and Bilcare consolidated its presence in Asia by opening its third ACRP Chapter in Singapore on 19th December, 2007. The Chapter inauguration took place on the premises of Bilcare Singapore Pte Ltd. All these factors have prompted many global leading pharmaceutical players to set up their regional clinical trial centres in Singapore to engage the region, including: AstraZeneca, Aventis, Eli Lilly, GlaxoSmithKline, Merck & Co, Novartis, Novo Nordisk, Sanofi-Synthelabo and Schering-Plough. Setting up a Chapter of ACRP is important in view of the extensive involvement of these companies in clinical research. Additionally a large number of employees from these organizations have revealed an interest in joining ACRP as members as well as taking the certification examination. The Chapter is also looking forward to the establishment of the Bilcare Research Academy in Singapore. The faculty of the academy will strengthen the Chapter to develop more programs for co-operation among clinical research professionals. The Chapter will also find ready resource persons from the academy and will also provide expertise to the academy from the industry to further clinical research education in Singapore. For more membership details, please contact ACRP Singapore Chapter Head, Mr. Ramnarayan Venkit at [ramnarayan.venkit@bilcare.com](mailto:ramnarayan.venkit@bilcare.com)

### About the Official Supporting Media

**Asia Pacific Biotech News (APBN)**, the first and only fortnightly report on pharmaceutical, medical, agricultural and environmental sciences in Asia Pacific. APBN is a premium magazine providing industry professionals and experts with breaking news and updates on biotechnology in Asia Pacific. With its rich contents accompanied by insightful and in-depth reports, APBN is widely read by professionals and researchers in the biotechnology sector around the world. Our magazine has a wide reach to the life sciences and biotech community and is present in major conferences in the region.

### About the Official Media Partner

**Pharma Asia** is the leading source of information for scientists in Asia looking to stay abreast of innovative technologies and trends impacting the pharmaceutical industry. Launched in February 2006, the publication provides timely and useful insights into cutting-edge techniques and practices for improving the pace of pharmaceutical research and development in the region. It features in-depth articles on technologies and research relevant to the industry, news and market trends, new product offerings, listings of regional events and profiles of relevant companies and service providers.

Pharma Asia is published bi-monthly in English, with a target of 10,000\* qualified readers. PharmaAsia Digital reaches 8,000 qualified subscribers in the region, mainly to the Lab Management, Staff Scientists, Corporate Management, Faculties, Post-Doctoral Fellows, Associates, Production/QC/QA Management, Consultants and Vendors in the Pharmaceutical Companies, Biotechnology Companies, Academia, Universities, Hospitals, Medical Centers, Government Laboratories and Instrument/Equipment/Manufacturers. For more information, please visit us at [www.PharmaAsia.com](http://www.PharmaAsia.com).

### In-House Training Solutions

If you have a number of delegates with similar training needs, then you may wish to consider having an In-House Training solution delivered locally on-site. Course can be tailored to specific requirements.

Please contact **Sarah Faradilla** on +603 2723 6600 or email [sarahf@marcusevanskl.com](mailto:sarahf@marcusevanskl.com) to discuss further possibilities.

**marcus evans** would like to thank everyone who has helped with the research and organisation of this event, particularly the speakers and their staff for their support and commitment.