

VIEW FULL AGENDA INSIDE!

Presented by  Lychee Group



# CHINATRIALS 2009

GLOBAL CLINICAL DEVELOPMENT SUMMIT

## Your Gateway to Conducting Clinical Trials in China

### WHY YOU SHOULD ATTEND

- Industry-Focused on the Business AND Science of Clinical Trials in China
- Learn How to Dramatically Reduce Time and Cost for Your Global Trials
- Create New Global Clinical Development Partnerships
- Featuring Over 75 Speakers from Over 40 Leading Companies
- Network With Hundreds of Global Clinical Development Executives
- In-Depth Coverage on Oncology, Vaccine, and Medical Device Trials in China

NOVEMBER 8 - 10, 2009

Softel Wanda Hotel | Beijing, China



Register today at [www.chinatrialsevent.com](http://www.chinatrialsevent.com)

# welcome to chinatrials 2009

Dear Colleague:

Last year's CHINATRIALS Summit in Shanghai was the first major China-focused clinical development event to take place in China. The meeting was a great success, convening over 225 global executives to discuss the opportunities of conducting clinical trials in China.

This year's event will be even larger and feature many new topics and speakers based on hundreds of hours of research. Take a look at this year's agenda and you will find the latest topics covered by over 75 speakers of the world's top speakers, marking the largest gathering of China clinical speakers ever.

No other event provides an unbiased platform to discuss the business AND science of clinical trials in China.

Network with hundreds of your colleagues in Beijing this November 8-10 as we gather to discuss new ideas and strategies to harness China's newfound clinical development prowess to help bring innovative new medicines to market faster.

See you in Beijing!

Sincerely,



Jon E. Liong  
Managing Partner, LYCHEE GROUP

## advisoryboard



**Ole Molskov Bech, M.D.**  
*Vice President, Clinical & Medical Director*  
NOVO NORDISK



**Simon Li, M.D.**  
*Vice President, Medical Research*  
NEUROMED  
PHARMACEUTICALS



**Bin Peng, M.D., Ph.D.**  
*Director, Clinical Pharmacology*  
GLAXOSMITHKLINE



**James Cai, Ph.D.**  
*Vice President, Clinical Development*  
ATYR PHARMA



**Zili Li, M.D., MPH**  
*Head of Asia Pacific Regulatory Policy*  
MERCK & CO.



**Robert Pollard**  
*Director, Healthcare China*  
SYNOVATE



**Ruiping Dong, M.D., Ph.D.**  
*Vice President, Global Development & Medical Affairs*  
BRISTOL MYERS-SQUIBB



**Bradley Marchant, M.D.**  
*Executive Director, Head of Clinical Medicine Asia*  
PFIZER CHINA R&D CENTER



**Cezary Statuch, M.D.**  
*Executive Medical Director, Global Medical Affairs*  
BRISTOL-MYERS SQUIBB



**Frank Fan, M.D.**  
*Medical Director*  
WYETH



**Jay Mei, M.D., Ph.D.**  
*Executive Director, Clinical Development*  
CELGENE



**Claire Tan**  
*Director, Biostatistics*  
QUINTILES



**Min Irwin, M.D., Ph.D.**  
*Medical Director of BSP*  
BAYER HEALTHCARE



**Ding Ming, Ph.D.**  
*Senior Director, CHC Medicine*  
BOEHRINGER-INGELHEIM



**Jingsong Wang, M.D.**  
*Director, Discovery Medicine & Clinical Pharmacology*  
BRISTOL-MYERS SQUIBB



**Frank Jiang, M.D., Ph.D.**  
*Vice President, Global R&D/Head, China R&D*  
SANOFI-AVENTIS



**Fidela Li Moreno, M.D.**  
*Vice President, Global Development Operations*  
ALLERGAN



**William Wang, Ph.D.**  
*Head, Asia Pacific Operation-Biostats & Research Decision Sciences*  
MERCK & CO.



# pre-conference workshops

**SUNDAY — NOVEMBER 8, 2009**

3:00PM-4:00PM

## Workshop Registration & Early Conference Registration

4:00PM-7:00PM

## 2 Concurrent Workshops: Choose 1

7:00PM-8:30PM

## Welcome to Beijing Reception

See page 17 for details.

SPONSORED BY:



4:00PM-7:00PM

## WORKSHOP #1

### From Intention to Execution: A Step-by-Step Case Study Taking an International Company to Its First Clinical Operation in China

- Overview of Chinese healthcare and clinical trial system
- Development Strategy Design – expert panel evaluates the available development options for the case product based on in-depth analysis of its relevant regulatory, clinical and market considerations, and recommend a course of action.
- Starting Your China Operations – an overview of China CRO industry and CRO selection options, plus expert panel discussing the pros and cons of using the CRO resources and building a China operation from scratch.

WORKSHOP LEADERS:

**Chloe Liu, Ph.D.**, *Managing Partner*

MODULAR R&D

**James Cai, Ph.D.**, *Vice President, Clinical Development*

ATYR PHARMA

Led By:  **Modular R&D**  
Drug & Device Development in China

4:00PM-7:00PM

## WORKSHOP #2

### Strategies for Regional Drug Development in North Asia

- Regulatory differences by region
- GCP-compliance for physicians & clinical trials experience
- Patient/disease patterns for the Asia-Pacific region
- How can intergrating China, Taiwan, Japan, and Korea speed drug development?

WORKSHOP LEADERS:

**Albert Liou, Ph.D.**, *Corporate Vice President & General Manager*

PAREXEL APEX

**William Wang, Ph.D.**, *Head, Asia Pacific Operation, Biostatistics & Research Decision Sciences*

MERCK & CO.

Led By: 

# programagenda

MONDAY, NOVEMBER 9, 2009

7:00AM - 8:00AM

## Registration, Breakfast & Exhibits

8:00AM - 8:10AM

## Chairpersons' Opening Remarks

8:30AM - 9:40AM

## What Will China Healthcare Look Like in 5-10 Years?

- Likely impact of changing disease epidemiology & urbanization
- What are the current drugs available to treat these diseases?
- What will the impact of smoking be?
- An aging population & screening/earlier detection
- How will all the bio-clusters evolve?
- What will China's healthcare infrastructure look like in 5-10 years?

MODERATOR:

**Robert Pollard, Director, Healthcare China**  
SYNOVATE

PANELISTS:

**Ronghui Gao, Manager of Business Development**  
Dept.

BIOBAY

**James Li, M.D., Partner**

KLEINER PERKINS CAUFIELD & BYERS

**Jonathan Wang, Ph.D., Managing Director**  
ORBIMED ASIA

9:40AM - 10:30AM

## Mid-Morning Networking Break & Exhibits

10:30AM - 11:45AM

## Regulatory Review at the SFDA: Science, Quality, and Speed

- What is hidden behind discussion of CTA review time?
- The SFDA's move to being more "science-based"

- What SFDA and the industry can and should do to enhance the application review process
- China's role in global drug development: a regulatory agency's perspective
- How the FDA and SFDA can enhance collaboration

MODERATOR:

**Zili Li, M.D., MPH., Head of Asia Pacific Regulatory**  
MERCK & CO.

11:45AM - 12:45PM

## How Can We Ensure Quality in Clinical Trials in China from the Beginning?

- Building quality measures into clinical trial design
- Setting up proper Key Performance Indicators (KPIs) to track quality metrics in trials
- How to maintain quality control and quality assurance in fast growing trials
- How to handle quality issues when running multinational trials

MODERATOR:

**Bradley Marchant, M.D., Executive Director, Head of Clinical Medicine- Asia**  
PFIZER CHINA R&D CENTER

PANELISTS:

**Yan Wu, M.D., Medical & Clinical Development Director**

BIOGEN IDEC CHINA

**QingAn Jiao, M.D., Ph.D., Clinical Research Unit Director**

SANOFI-AVENTIS

12:45PM - 1:45PM

## Expert Luncheon

See page 17 for details.

SPONSORED BY:

**PAREXEL**



## TRACK A: EARLY-PHASE TRIALS IN CHINA, SAFETY ASSESSMENT & POST-MARKETING STUDIES IN CHINA

1:45PM - 2:10PM

### Mutual Acceptability of Clinical PK Studies in China, US & Europe

The ICH E5 guideline describes factors that could lead to different responses in different ethnic groups, including differences in pharmacokinetics (PK) and pharmacodynamics (PD). The satisfactory foreign clinical data can be used to support approval in a new region if there is an additional bridging study. A bridging study will often provide a comparison of dose-response relationships between the two regions. Therefore, a bridging strategy in the new drug application between China and Western countries will be critical. The bridging strategy will be summarized and discussed.

**Bin Peng, M.D., Ph.D., Director, Clinical Pharmacology**  
GLAXOSMITHKLINE

2:10PM - 2:35PM

### Phase I Studies in China: Industry Outlook

- What is possible today?
- What is the current status of conducting first-in-human studies in China?
- A look from the industry perspective

**Qi Yin, Ph.D., Regional Manager, Exploratory Development**  
NOVARTIS

2:35PM - 3:00PM

### Phase I Studies in China: Investigator Outlook

- What is the current capabilities of the hospitals in China?
- What is the current status of conducting first-in-human studies in China?
- A look from the investigator's perspective

**Hu Pei, M.D., Professor**  
PEKING UNION HOSPITAL

3:00PM - 4:00PM

### Post-Marketing Surveillance & Life Cycle Management in China

- Post-marketing program (investigator initiated studies, nonintervention trials, surveys & registry, etc.)

- Risk management for safety monitoring
- New indications
- Marketing collaboration

MODERATOR:

**Min Irwin, M.D., Ph.D., Medical Director of BSP**  
BAYER HEALTHCARE

PANELISTS:

**Frank Fan, M.D., Medical Director-HK**  
WYETH

**Chengming Gu, Medical Affairs Director of Asia-Pacific**  
BAXTER BIOSCIENCE

4:00PM - 4:30PM

### Mid-Afternoon Networking Break & Exhibits

4:30PM - 5:30PM

### Clinical Safety Assessment & Risk Management During New Drug Development in China

- Appropriate trial design to maximize the learning of safety risks
- Targeted and sensible collection of clinical safety data
- Effective monitoring and analysis of safety data
- Prompt decisions to protect subjects and to protect the development program
- Use of Data Safety Monitoring Board (DSMB) to enhance safety assessment and decision making
- Optimal risk management plan as a critical part of new drug applications

MODERATOR:

**Songlin Xue, M.D., Ph.D., Vice President & Global Head of Clinical Epidemiology**  
NOVARTIS

PANELISTS:

**Ming Tong, M.D., MBE, Wall Street Advisory**  
STANDARD & POOR'S (Former Medical Director, PFIZER)

**Dan Zhang, M.D., MPH, Chief Executive Officer**  
FOUNTAIN MEDICAL DEVELOPMENT

5:30PM

### End of Track A & Day One

# programagenda

## TRACK B: INNOVATIONS IN CLINICAL TRIALS

1:45PM - 1:55PM

### Session Chairperson's Opening Remarks

**Jingsong Wang, M.D.**, *Director, Discovery Medicine & Clinical Pharmacology*  
BRISTOL-MYERS SQUIBB

1:55PM - 2:20PM

### Personalized Medicine: From Concept to Reality

Personalized medicine is now moving from concept to reality. As the practice becomes more widespread, many new applications are currently in development. Comprehensive genetic and clinical information on the individual level could result in more effective and efficient diagnosis and treatment for diseases. Government initiatives could also assist in stimulating progress through key policy initiatives. International harmonization benefits multiple parties including patients, physicians, test and drug developers, regulatory bodies, trade and commerce. This presentation will discuss the opportunities this may present for the industry.

**Frank Jiang, M.D., Ph.D.**, *Vice President, Global R&D & Head, China R&D*  
SANOFI-AVENTIS

2:20PM - 3:45PM

### Biomarker Discovery & Development & Translational Medicine in China

- What is currently available and what are the challenges in China for biomarker discovery/development and translational medicine collaboration?
- Advantages in linking translation medicine collaborations with clinical trials
- Local providers vs. International CROs for biomarker analysis
- Patient sample collection and exportation challenges
- Effectively managing collaborations with local MD's and scientists
- The role of intellectual property in clinical discovery & development in China

MODERATOR:

**Jingsong Wang, M.D.**, *Director, Discovery Medicine & Clinical Pharmacology*  
BRISTOL-MYERS SQUIBB

PANELISTS:

**Thomas G. Evans, M.D.**, *Head of Translational Science*  
CHINA NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH

**Giora Feuerstein, M.D.**, *Assistant Vice President & Head, Discovery Translational Medicine*  
WYETH RESEARCH LABORATORIES

**Pearl Huang, Ph.D.**, *Vice President, Franchise Integration*  
MERCK & CO.

**Frank Jiang, M.D., Ph.D.**, *Vice President, Global R&D & Head, China R&D*  
SANOFI-AVENTIS

**Kenneth Fang, M.D.**, *Senior Director*  
XDX, INC.

3:45PM - 4:15PM

### Mid-Afternoon Networking Break & Exhibits

4:15PM - 5:30PM

### New Developments in Modeling & Simulation & Adaptive Trial Design

- Drug Development: A Learning-Confirming Paradigm
- Hype and Hope of Adaptive Trial Designs
- Application of Modeling and Simulation in Oncology Drug Development

MODERATOR:

**Liping Zhang, Ph.D.**, *Associate Director*  
BRISTOL-MYERS SQUIBB

PANELISTS:

**Feng Guo, Ph.D.**, *Director, Head of Clinical Pharmacology & Pharmacometrics-Asia*  
PFIZER CHINA R&D CENTER

**Frank Shen, Ph.D.**, *Head, Biometrics & Clinical Management*  
ROCHE PHARMA DEVELOPMENT CENTER

5:30PM

### End of Track B & Day One

**TUESDAY, NOVEMBER 10, 2009**

**TRACK A: GLOBAL CLINICAL DEVELOPMENT IN CHINA & NORTH ASIA**

7:00AM - 8:00AM

**Registration, Breakfast & Exhibits**

8:00AM - 8:10AM

**Chairpersons' Opening Remarks**

**Ruiping Dong, M.D., Ph.D.,** *Vice President, Global Development & Medical Affairs*  
BRISTOL-MYERS SQUIBB

8:10AM - 8:40AM

**New Strategies for Japanese-Chinese Bridging Studies in Drug Development**

- Concept and expectations
- Regulatory requirements from Japanese regulatory agency
- Ethnical considerations
- Practical clinical development plans covering drugs approved in Western countries, not yet approved in Western countries and simultaneous development in Asian & Western countries

**Yoshihiro Arai, M.D.,** *Executive Vice President, Development*  
SOLASIA PHARMA KK

8:40AM - 9:10AM

**How Japanese Companies View and Perform in Asian Drug Development**

- Ethnic similarity and difference between Japanese, Chinese and other Asians
- GCP similarity and difference between Japan and China
- Linkage of GCP inspection and clinical operation: direction for improvement

**Kensuke Morimoto,** *Project Leader- Asia Development Department*  
DAIICHI-SANKYO

9:10AM - 9:40AM

**The Regulatory Infrastructure for Clinical Trials in Taiwan**

- Evolving concept for IND assessment
- The evolution of bridging evaluation

**Li-Jiuan Hsu, M.D.,** *Division Director of Clinical Medicine*  
CENTER FOR DRUG EVALUATION- TAIWAN

9:40AM - 10:10AM

**Mid-Morning Networking Break & Exhibits**

10:10AM - 11:10AM

**East Asia Simultaneous Drug Development Strategies**

- Chinese-Japanese partnerships
- Acceptibility of clinical trials data between Japan, China, Korea & Taiwan
- Navigating the regulatory affairs differences between Asia-Pacific trials

MODERATOR:

**Albert Liou, Ph.D.,** *Corporate Vice President & General Manager*  
PAREXEL APEX

PANELISTS:

**Yoshihiro Arai, M.D.,** *Executive Vice President, Development*  
SOLASIA PHARMA KK

**Ruiping Dong, M.D., Ph.D.,** *Vice President, Global Development & Medical Affairs*  
BRISTOL-MYERS SQUIBB

**Victoria Elegant, Ph.D.,** *Vice President, Regulatory Affairs & Pharmacovigilance*  
BAXTER

**Ming-Chu Hsu, Ph.D.,** *Chief Executive Officer*  
TAIGEN BIOTECHNOLOGY

11:10AM - 12:10PM

**Developing the Best Clinical Strategy in China & East Asia: Local vs. Multinational CROs**

- CRO identification and selection criteria
- Governance structures and relationship management
- Negotiating and contracting with CROs
- Creating a CRO Oversight Plan
- Establishing appropriate performance metrics

MODERATOR:

**Fidela Moreno, M.D., Ph.D.,** *Vice President, Global Development Operations*  
ALLERGAN

12:10PM - 1:10PM

**Networking Lunch**

# programagenda

1:10PM - 1:35PM

## Conducting Large Scale Trials in China: Lessons Learned

- Fundamentals: China trials not just about medical
- Challenges of large scale trials such as turnover, management, government oversight, vaccine trials
- Lessons learned: practical guidelines to improve outcome performance

**Mark Engel, Chairman**  
EXCEL PHARMASTUDIES

1:35PM - 2:00PM

## A New Era of Biopharmaceuticals in the Global Financial Crisis

This presentation will address the trend of pharmaceutical R&D development comparing small vs. large molecules in established and emerging markets, particularly sharing an interesting and unique view from Asia/China in the ongoing challenges of the financial crisis. What lessons could the pharmaceutical and biopharmaceutical companies learn? What opportunities can Asian/Chinese pharmaceuticals leverage to catch another wave of strong development?

**James Cai, Ph.D., Vice President, Clinical Development**  
ATYR PHARMA

2:00PM-2:25PM

## How Does the Clinical Trials Environment in China Compare to Other Key Asian Territories?

- Demographic and epidemiological features of the Chinese landscape
- Regulatory aspects of conducting clinical trials in China
- Working with investigators and sites in China

**James Garner, M.D., Ph.D., Regional Medical Director (Asia)**  
QUINTILES

2:25PM - 2:45PM

## Chinese Academic Clinical Research Organization (CACRO): The Government's Key Role in New Drug Development

SCRC is an Academic Clinical Research Organization. It will be allying with the top clinical institutions in China – called Chinese Academic Clinical Research Organization (CACRO). CACRO will be one-of-a-kind partnership that represents an innovative academic collaboration in clinical research to expedite the clinical trial process in China. Through CACRO, industry sponsors have access to investigators at leading academic centers with a reciprocal IRB approval process. SCRC can help manage Phase I, Phase II, III and IV studies, with national science authorities and industry-sponsored clinical trials.

**Jack Xu, M.D., Senior Vice President**  
SHANGHAI CLINICAL RESEARCH CENTER

2:45PM - 3:00PM

## Mid-Afternoon Short Break

3:00PM - 3:30PM

## Implementation of Chinese Clinical Trials with Digital Pathology

**David Yang, Ph.D., Principal Scientist, Oncology Biomarker Imaging**  
NOVARTIS

4:00PM

## Track A & Conference Concludes



## TRACK B: THERAPEUTIC CLINICAL TRIALS

SPONSORED BY US CHINESE ANTI-CANCER ASSOCIATION (USCACA)



7:00AM - 8:00AM

### Registration & Breakfast

8:00AM - 8:10AM

### Chairpersons' Opening Remarks

**Li Yan, M.D., Ph.D.**, *Director, Clinical Oncology*  
MERCK & CO.

*Managing Director, US CHINESE ANTI-CANCER ASSOCIATION (USCACA)*

8:10AM - 8:40AM

### SFDA Presentation on Oncology Development in China

**Jian Peng, Ph.D.**, *Director of Division Oncology Drug, Center for Drug Evaluation*

STATE FOOD AND DRUG ADMINISTRATION (SFDA)

8:40AM - 9:10AM

### Chinese Society for Clinical Oncology (CSCO) Presentation

**Prof. Li Zhang**, *Vice-Chair of Department of Medical Oncology*

SUN YAT-SEN HOSPITAL

*Chair of International Collaboration, CHINESE SOCIETY FOR CLINICAL ONCOLOGY (CSCO)*

9:10AM - 9:40AM

### Personalized Therapy – The Future of Oncology Drug Development: How Does China Position Itself To Be A Leader in 2010 and Beyond

**Li Xu, M.D., MSD, MBA**, *Senior Director, Head, Oncology Operations*

PFIZER ONCOLOGY

9:40AM - 10:10AM

### Mid-Morning Networking Break & Exhibits

10:10AM - 10:30AM

### Western Multinational Perspective on Oncology Development in China

**Xiaoxiang Chen, M.D.**, *Director, Medical Research- Global Clinical R&D*

WYETH RESEARCH

10:30AM - 10:45AM

### The Role of Sponsor in Building a High-Quality and Highly Informed Oncology Trial in the Current Chinese Environment

**Xian-Ping Lu, Ph.D.**, *Chief Scientific Officer*  
CHIPSCREEN BIOSCIENCES

10:45AM - 11:00AM

### CRO Perspective on Oncology Development in China

**Wenchi Lin**, *Associate Director, Clinical Operations*  
PAREXEL APEX

11:00AM - 12:10PM

### Conducting Oncology Trials in China

- How can China transform from a service provider in global oncology development into an innovative anti-cancer drug R&D hub?
- How can China transform cancer hospitals and cancer centers from global trial participants to leaders & initiators?
- How can China transform from merely a global trial patient recruitment center to a strategically critical country for oncology compound development?
- Global development and regulatory strategies to develop anti-cancer drugs in China for prevalent cancer types to expedite global compound development

MODERATOR:

**Joy Zhu, Ph.D.**, *Senior Vice President, Global Clinical Development*

S\*<sup>2</sup>BIO

PANELISTS:

**Ying Ma, M.D.**, *Assistant Clinical Research Director- Oncology*

SANOFI-AVENTIS

**Jay Mei, M.D., Ph.D.**, *Executive Director, Clinical R&D*

CELGENE

**Jerry Xu, M.D.**, *Deputy General Manager*  
TIGERMED



# programagenda

12:10PM - 1:10PM

## Networking Lunch

1:10PM - 1:55PM

### Is China A Destination to Conduct Biologics Clinical Trials?

- What are the SFDA's major concerns vs. industry's concerns?
- How can drug companies work with the SFDA to reduce the review timeline for biologics?
- What is the current and future landscape on regulation of biosimilar products in China (patents, pricing & manufacturing)?
- What is the future outlook for Chinese companies enter the US market?

MODERATOR:

**Frank Fan, M.D.**, *Medical Director- HK WYETH*

PANELISTS:

**James Cai, Ph.D.**, *Vice President, Clinical Development*  
ATYR PHARMA

**Simon Li, M.D., Ph.D.**, *Vice President, Medical Research*  
NEUROMED PHARMACEUTICALS

1:55PM - 2:20PM

### The Design of Vaccine Clinical Trials in China

The research aim should be defined, the registration classification needs to be clarified, and phases required at the very beginning of the design. Safety and Ethics should be paid special attention as well. The subjects recruitment,

control vaccine, immunization schedule, evaluation criteria, and sample size are critical. This presentation will include three parts: the characteristics of vaccine clinical trials, the vaccine clinical trials concerned regulations, and the critical control points of the vaccine trials.

**Jianzhong (Jack) Liu**, *Director, Scientific Affairs*  
SANOFI-PASTEUR

2:20PM - 2:45PM

### The Profile of Demyelinating Disease in Asia: Trends in Global Clinical Trials for Multiple Sclerosis

**Leslie Shinobu, M.D., Ph.D.**, *Head, Clinical Development*

GLAXOSMITHKLINE R&D CHINA

**Maria V. Lopez-Bresnahan, M.D., MBA**, *Vice President and Global Head, Medical and Scientific Affairs*

i3 GLOBAL

2:45PM - 3:00PM

### Mid-Afternoon Short Break

3:30PM - 4:00PM

### Medical Device Trials in China

- An update and overview of the current status for medical device trials in China
- SFDA requirements for medical device trials

**Dalvin Ni, M.D.**, *VP, Operations*  
FOUNTAIN MEDICAL DEVELOPMENT

4:00PM

### Track B & Conference Concludes

## TRACK C: IMPROVING CLINICAL OPERATIONS IN CHINA & SPECIAL TOPICS

7:00AM - 8:00AM

### Registration & Breakfast

8:00AM - 8:10AM

### Chairpersons' Opening Remarks

8:10AM - 9:10AM

### Biostatistics Practices: Are You Doing Something Outdated?

- Comparison between biostats principle and practice, including frequently used stats methods for common data between the Chinese/Western medical/pharmaceutical industry

- Comparison of roles of biostatisticians and understanding of GSP (Good Statistical Practices)
- Perspectives on how biostatisticians practicing in China can meet international standards
- Developing the 3 inter-dependent biometrics professions (biostatisticians, scientific programmers and database managers)

MODERATOR:

**William Wang, Ph.D.**, *Head, Asia Pacific Operation, Biostatistics & Research Decision Sciences*  
MERCK & CO.



PANELISTS:

**Yao Chen**, *Vice Director*  
PEKING UNIVERSITY

*Clinical Research Institute, Professor and Head of  
Department of Biostatistics*

PEKING UNIVERSITY FIRST HOSPITAL

**Frank Shen, Ph.D.**, *Head, Biometrics & Clinical  
Management*  
ROCHE PHARMA DEVELOPMENT CENTER

**Minzhi Liu, Ph.D.**, *Deputy Managing Director &  
VP, Statistics*  
MACROSTAT

9:10AM - 9:40AM

## Patient Recruitment & Retention in China & East Asia Clinical Trials

- Impact of clinical trial globalization on patient recruitment
- Competition for study participants, availability of experienced investigators, GCP-focused training and other challenges
- Changing regulatory requirements that increase trial complexity and accessibility
- Recruitment enhancement tactics
- Creating and implementing a Patient Recruitment, Retention and Contingency Plan

**Fidela Moreno, M.D., Ph.D.**, *Vice President,  
Global Development Operations*  
ALLERGAN

9:40AM - 10:10AM

## Mid-Morning Networking Break & Exhibits

10:10AM - 11:10AM

## Electronic Data Capture & Clinical Data Management in China

- Growth in China of sites and patient recruitment for global & regional studies
- China, the new Data Management hub
- Practical experience with EDC implementation in China, comparison with USA, Europe and rest of Asia
- Technology advances for conducting clinical trials across all phases
- Adoption of Data Standards for clinical trials

MODERATOR:

**Jon Carrano, Ph.D.**, *Regional Director & General  
Manager*  
PHASE FORWARD

PANELISTS:

**Suresh Ramu**, *Vice President & Regional Head –  
Asia Global Data Management*  
QUINTILES TECHNOLOGIES

**Dan Zhang, M.D., MPH**, *Chief Executive Officer*,  
FOUNTAIN MEDICAL DEVELOPMENT

11:45AM - 12:10PM

## Clinical Trial Logistics: When Logistics is More Than Just “Logistics”

- Logistics in the value chain of a clinical trial
- Applying GCP in clinical trial logistics
- Potential regulatory compliance risk within clinical trial logistics
- Critical component of a clinical trial logistics solution

**James Lee**, *General Manager*  
ZUELLIG PHARMA CHINA

12:10PM - 1:10PM

## Networking Lunch

1:10PM - 1:40PM

## Regulation of Nonprescription Medicines – An Essential Part of the Health Care System

**William R. Soller, Ph.D.**, *Executive Director,  
Center for Consumer Self Care*  
UNIVERSITY OF CALIFORNIA AT SAN FRANCISCO

1:40PM - 2:40PM

## Over-the-Counter (OTC) Pharmaceu- tical Development & Opportunities in China

As the Chinese pharmaceutical market has experienced strong growth in the last decade, the sales of OTC healthcare in China have grown 11 to 12 percent annually during the past eight years. The Chinese OTC market has been ranked fourth after the US, Germany and Japan. In the near future, this market is expected to increase even more as estimates predict that China might have the second largest OTC market worldwide by 2011. This panel discussion will address:

- Healthcare evolution demands for more OTC pharmaceutical products
- Key drivers for a successful Rx-OTC switch
- Defining the OTC claims—creating a brand that sells

# programagenda

- The role of healthcare/clinical research professionals in OTC development
- Clinical data specific to OTC development: Testing of label, consumer judgment & consumer behavior

## MODERATOR:

**Qing Li, M.D., Ph.D.**, *Director, Global Medical Affairs & Clinical Research*

**J&J CONSUMER & PERSONAL PRODUCTS WORLDWIDE**

## PANELISTS:

**James Fan, Ph.D.**, *Senior Consultant/Founder*  
**NICHOLAS HALL & COMPANY/JOWIN COMMUNICATIONS**

**William R. Soller, Ph.D.**, *Executive Director, Center for Consumer Self Care*  
**UNIVERSITY OF CALIFORNIA AT SAN FRANCISCO**

**David C. Spangler**, *Senior Vice President, Policy & International Affairs*  
**CONSUMER HEALTHCARE PRODUCTS ASSOCIATION**

**Paul Starkey, M.D.**, *Worldwide Head, Medical Affairs*  
**SCHERING-PLOUGH CONSUMER HEALTHCARE**

**Yan Yan Starkey, M.D., MBA**, *Director, Medical Affairs*  
**GLAXOSMITHKLINE CONSUMER HEALTH**

2:40PM - 3:00PM

## Mid-Afternoon Short Break

3:00PM - 3:30PM

## Clinical Trials Training in China for Principal Investigators, CRA & CRC Staff

In China, the history of clinical research is less than 10 years. China is not one of the ICH countries. So it's very essential to collaborate with global authoritative training organization to certify and train local clinical professionals, which will improve the level of domestic clinical research profession. The training center of SCRC aims to establish a platform of local, regional and international clinical trial training activities and works as a bridge between pharmaceutical industry, academy and government.

**Sally Sha**, *Senior Training Director*  
**SHANGHAI CLINICAL RESEARCH CENTER (SCRC)**

4:00 PM

## Track C & Conference Concludes

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## GOLD

**PAREXEL International Corporation** is a leading global bio/pharmaceutical services organization, providing a broad range of knowledge-based contract research, medical communications and consulting services to the worldwide pharmaceutical, biotechnology and medical device industries. Committed to providing solutions that expedite time-to-market and peak-market penetration, PAREXEL has developed significant expertise across the development and commercialization continuum, from drug development and regulatory consulting to clinical pharmacology, clinical trials management, medical education and reimbursement. Perceptive Informatics, Inc., a subsidiary of PAREXEL, provides advanced technology solutions, including medical imaging, to facilitate the clinical development process. Headquartered near Boston, Massachusetts, PAREXEL operates in 63 locations throughout 52 countries around the world, and has more than 8,050 employees. For more information about PAREXEL International visit [www.PAREXEL.com](http://www.PAREXEL.com).



**Pfizer** has been operating in China since the early 1980's committed to improving the health of the Chinese people and contributing to China's overall prosperity. Pfizer

has built on this legacy by introducing innovative, relevant medicines and investing in doctor and patient educational programs. Furthermore, Pfizer contributes to China's scientific and medical development by including China in our global R&D projects. In recognition of the highly-skilled and talented scientists in China, Pfizer established its China Research and Development Center in Shanghai in 2005. The center is staffed with more than 200 Pfizer colleagues supporting various aspects of Pfizer's global R&D efforts.

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## GOLD



**RPS**, a next generation CRO, provides comprehensive global Phase 1-4 clinical development solutions to

the pharmaceutical, biotechnology and medical device industries. By combining an experienced clinical research operations infrastructure with the industry's largest resourcing engines, RPS is uniquely positioned to offer our Clients both integrated and full service global outsourcing solutions. These solutions are powered by highly experienced and seasoned study teams providing innovative, cost-effective and high quality services.



## SILVER

**Fisher Clinical Services** is a leading provider of global

clinical supply solutions. We offer our customers access to the capacity, state-of-the art equipment and processes of the industry's largest packaging and distribution supplier for clinical trials with locations strategically placed across the world to support clinical research.. Our services include labeling, comparator sourcing, clinical manufacturing, overencapsulation, logistics, ancillary supply management and return drug destruction and accountability.



**BioBay** is located in Dushu Lake Higher Education Town of Suzhou Industrial Park. BioBay is building total 1 million square meter facility with 36% green

ratio on the land of 86.3 hectares. Under visionary and professional planning and construction monitoring by world-class architectural and pharmaceutical industry design firm, BioBay has built 70,000 m2 of incubation buildings and 24,000 m2 total of four individual R&D buildings, another 160,000 m2 area of facilities will be completed by end of 2008 catering for research and development, pilot-manufacturing, nanotech commercialization, commercial and living amenities. BioBay has more than 80 high-tech companies focusing on biotech, pharmaceutical, diagnostics, medical device, CRO, nanotech, and is committed to building a dynamic and interactive innovation cluster for talents and experts.

## BRONZE



**Covance**—one of the world's largest and most comprehensive drug

development services companies - has the people, global resources and problem-solving culture to respond to pharmaceutical and biotechnology clients' toughest drug development challenges. We provide a portfolio of preclinical and clinical development and commercial service offerings - delivered through industry-leading nonclinical testing services, the world's largest central laboratory network, and a global team of clinical trial professionals and cardiac safety experts. With headquarters in Princeton, New Jersey, Covance Inc (NYSE: CVD) has annual revenues greater than \$1.5 billion, global operations in 20 countries, and approximately 8,900 employees worldwide. Strategic partnerships built on decades of success Covance is dedicated to helping bring your miracles to market sooner.



**Excel PharmaStudies** is a

full service provider of clinical research, registration, biometrics, and training and consultation services. Founded in Beijing in 1999, Excel has grown quickly to become the leading CRO in China. Working with more than 120 of the industry's top global companies, Excel has conducted over 160 clinical trials (phase I~IV) and obtained over 200 regulatory approvals. Additionally, Excel's 13 offices, located strategically throughout China, allow access to a broad range of subjects. Through this far-reaching network, Excel has managed sites in over 40 cities, worked with over 150 hospitals, and enrolled over 150,000 subjects.



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**Quintiles** is the global leader in pharmaceutical services, improving healthcare worldwide by providing innovative, quality professional expertise, market intelligence and partnering solutions to meet the dynamic needs of the pharmaceutical, biotechnology and healthcare industries. Quintiles Asia Pacific has clinical development offices in 13 countries. Since 1993, the Quintiles clinical team in Asia Pacific has completed over 600 clinical trials involving about 3,500 sites and more than 80,000 patients. It offers the full spectrum of clinical development services, including clinical research, laboratory services, regulatory affairs and consulting to pharmaceutical and biotechnology firms. In short, Quintiles has the resources and the right approach to deliver excellent results for small and large projects every step of the way, in Asia and virtually anywhere in the world, bringing true value to clinical development investments.



**Tigermed Consulting Co., Ltd** is the leading full service Contract Research Organization (CRO) in China, providing regulatory service, Phase I-IV clinical research, biometrics, medical translation and R&D consulting services for drugs, medical devices, diagnostic reagents and functional food products. Headquartered in Shanghai, Tigermed operates 15 offices in China and one subsidiary in the USA. Tigermed has set up its own phase I study unit and established strategic alliances with Microstat based in Shanghai to provide R&D solutions to worldwide pharmaceuticals and biotech industries. Since our inception in 2002, Tigermed has successfully conducted 147 clinical trials with more than 13,000 subjects enrolled in 351 centers. Our biometrics services comply with US FDA 21 CFR Part 11 requirements and our clinical services comply with ICH GCP. Visit [www.tigermed.net](http://www.tigermed.net).

EXHIBITOR



**Aperio** is digitizing pathology. We provide systems and services for digital pathology, a digital environment for the management and interpretation of pathology information that originates with the digitization of a glass slide. Our award-winning ScanScope® slide scanning systems and Spectrum™ digital pathology information management software improve the efficiency and quality of pathology services. Our scanners create a digital image of an entire microscope slide at giga-

pixel resolution in minutes, with inherently superior image quality. Our Spectrum software provides a consolidated view of relevant case information—anywhere, anytime—across international borders in a secure GLP environment. Aperio is utilized in discovery, preclinical, and clinical trials in 10 of the top 15 largest pharmaceutical companies, the two largest preclinical pathology and some of the largest clinical trials pathology providers. In discovery, pharmaceutical researchers can monitor efficacy with whole tumor measurements like angiogenesis, apoptosis, and localized protein expression. In pre-clinical pathology, pathologists can better measure morphological changes, work across international boundaries, and better communicate tissue toxicology results to their clients. In clinical trials, Aperio is being used for protein expression and phosphorylation measurements, and to reduce shipping times for glass slides or travel costs and delays for pathologists. [www.aperio.com](http://www.aperio.com)

**GEORGE CLINICAL** **George Clinical** is the contract research arm of The George Institute, an independent, global scientific research institute with headquarters in Australia and offices in China, India and UK. George Clinical conducts global, multi-centre clinical trials in its areas of expertise, including cardiovascular disease & diabetes, neurology, renal disease, musculoskeletal conditions and critical care medicine. With investigator contacts in 40 countries and over 300 sites under management, George Clinical couples large-scale global patient recruitment with scientific credibility. George Clinical offers full service clinical trial management, including protocol development, clinical monitoring, project management, data management, statistical services and endpoint management, delivering the essential elements of high quality clinical research.

**MARKEN** **Marken** is professional logistic company offering global time sensitive delivery solutions to its customers worldwide who are the world's leading pharmaceutical, biotechnology and prestigious CROs and central laboratories. We handle diagnostic and infectious biological samples during all phases of clinical trials and across all temperature ranges. A number of the services we provide for the pharmaceutical industry include clinical supply and investigational drug transportation, clinical trial co-ordination, recommendation and furnishing of packaging materials, ongoing site support, site training and provision and replenishment of dry ice on a global basis. Marken Time Critical Express (Beijing) Co., Ltd. is a legal entity in China with more than six years

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professional business experience and gained reliability from our customers through efforts in pharmaceutical and biotechnology industries in China. Our service scope can reach most major cities in China.



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clinical trial solutions that enable the world's most advanced life science organizations to maximize the value of their clinical research investments. A pioneer since 1999 in innovative technologies to optimize clinical research processes - protocol design; clinical data capture, management and reporting; and trial planning and negotiation - Medidata Solutions helps clinical researchers reduce trial cycle times, achieve early visibility to reliable clinical data, and maintain strict fiscal responsibility, while safely accelerating the process of bringing life-enhancing treatments to market.

### PHASE•FORWARD. **Phase Forward**

is a leading provider of integrated data management solutions for clinical trials and drug safety. The company offers proven solutions for electronic data capture (InForm™), phase I clinic automation (LabPas™), clinical data management (Clintrial™), clinical trials signal detection (CTSD™), strategic pharmacovigilance (Empirica Signal™) and Signal Management, adverse event reporting (Empirica Trace™), applied data standards (WebSDM™) and Web-integrated interactive response technology (Clarix™). In addition, the company provides services in the areas of application implementation, hosting and validation, data integration, business process optimization, safety data management and industry standards. Additional information about Phase Forward is available at [www.phaseforward.com](http://www.phaseforward.com).



**Promasys®** – Data and Workflow System for Clinical Trials is a cost-effective solution for clinical research. It combines ease of use with extensive security and QA functionality. It supports organizations to comply with regulations (GCP, FDA CFR 21 part 11). Use is simple, intuitive and timesaving. Researchers control workflow, eCRF design and data analysis (SAS) without

programmers or external consultants. Promasys provides extensive logistical support (e.g. automatic generation of CRF's). Promasys has been used over 20 years in demanding clinical research environments in over 400 trials resulting in more than 300 articles. Our customer base includes some of the leading clinical trial centers in China, Korea and Japan as well as the WHO. More information on our product is available at [www.promasys-software.com](http://www.promasys-software.com).



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**TransPerfect** is the world's leading provider of multilingual communications services to life sciences organizations. We offer an ISO 9001:2000-certified quality management system, rigorously-tested medical linguists, and 24/7 production capabilities in over 50 locations globally. This certified quality assurance process enables us to provide expert translation services in over 100 languages and meet the most demanding deadlines. Each translation is created by a team of professional translators, editors, and proofreaders who are selected for their target expertise and native-speaking skills only after they pass our rigorous testing process. Not only do our technology products reduce costs and improve consistency, but we now offer an on-line collaboration platform known as "Trial Interactive™". This platform is an easy-to-use portal that manages the submission, tracking and organization of global clinical study documentation in a highly secure environment and is available in 20 languages. TransPerfect: The ideal choice for clinical research, pharmaceutical, and biotechnology companies.



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**Zuellig Pharma** is a leading logistics and distribution provider of multinational pharmaceuticals in Asia for over 60 years. Since established in 1993, Zuellig Pharma China has been able to build a formidable reputation for the highest standards in modern pharmaceutical logistics & distribution services. We offer an unparalleled range of clinical trial logistics services, full transparency on supply chain visibility that cover the entire project life of study protocol through an extensive distribution network operations in China and innovative information platform.

# registration & general info

## REGISTRATION & PRICING

- Conference Only \$1,495 (\$1,595 after Oct. 9)
- Conference + Workshop \$1,595 (\$1,795 after Oct. 9)
- Academic, Government, and Hospital \$895 (\$995 after Oct. 9) Workshop included

Registration includes breakfasts, lunches, refreshments, receptions, off-site visits, and the conference documentation. It does not include hotel accommodations or travel costs for the event.

To register online, please visit [www.chinatrialsevent.com](http://www.chinatrialsevent.com).

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To inquire about group discounts for 3 or more people, please contact **Jon E. Liong** at [jon.liong@lycheegroup.com](mailto:jon.liong@lycheegroup.com).

## HOTEL INFORMATION

Sofitel Wanda Hotel  
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Phone: +86-10-85996666

## TRAVEL VISA REQUIREMENT

If you are not a Chinese Citizen, YOU WILL NEED A VISA TO ENTER CHINA. All registrants are responsible for obtaining the appropriate visa from their local Chinese consular authorities required to enter China.

## BOOK YOUR HOTEL

All conference delegates are required to book their own accommodations directly with the hotel. We have reserved a special limited room block at a discounted rate. Reserve your room by October 9, 2009 to take advantage of this special rate and be sure to mention that you are with China Trials 2009 when booking your room.

Space is limited and expected to go fast so book early to ensure availability. All hotel room cancellations must be handled directly with the hotel at least 48 hours prior to check-in. To reserve your hotel room at the official conference hotel, please contact Monica Chen at the Sofitel by email at [groupsales@sofitelwandabj.com](mailto:groupsales@sofitelwandabj.com) or by phone at +86-10-8599-6666-6837.

## CANCELLATION POLICY

All cancellations are subject to a \$250 processing fee. In order to receive a prompt refund, please fax or email your notice to cancel to us by October 16, 2009. Refunds will not be issued after this date.

Your registration may be transferred to another member of your organization or you may use the credit towards a future Lychee Group event. If you would like to send a replacement, please let us know as soon as possible so we can update the registration information in our system to ensure a smooth check-in on-site.

In the event that the conference is cancelled, your registration fee will be fully refunded. Lychee Group, LLC assumes no liability for non-refundable transportation costs, hotel accommodations or additional costs incurred by registrants if the conference is cancelled.

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## supporting organizations



**ChinaBio® Accelerator** is a non-profit organization created to accelerate the globalization of China's biotechnology industry by providing funding, mentoring and connecting early stage China life science companies to investors and partners in the U.S. If you are an early stage China biotech seeking funding or U.S. partnerships, or a U.S.-based organization looking to establish partnerships or operations in China, please contact us to find out how we can help. [www.ChinaBioLLC.com](http://www.ChinaBioLLC.com)



In Shanghai, to China, for the World", **SCRC** endeavors to be the link between pharmaceutical companies and clinical hospitals, a 3rd party organization with research services, assessment functions and public service platforms. SCRC endeavors to be a pioneer for the globalization of drug development in China, growing from a member towards an organizer in the multi-central drug clinical trials, to be a practitioner of the national development strategy in clinical research, joining and practicing the State Key project of novel drug development, and to be the driving force of the healthcare industry, creating the top-end service industry relevant to drug clinical research. See [www.scrctnet.org](http://www.scrctnet.org).



Founded in 1993, the **Sino-American Pharmaceutical Professionals Association (SAPA)** grew rapidly and has become one of the most active and well-recognized Chinese-heritage enduring professional organizations in the United States. SAPA is an independent, nonprofit and professional organization with over 4,000 members. Its headquarters is based in the tri-state area (NY-NJ-CT) with three regional chapters in New England, Greater Philadelphia and California, and one club in Shanghai, China. For more info, please go to SAPA website [www.sapaweb.org](http://www.sapaweb.org).



**US Chinese Anti-Cancer Association (USCACA)** is a not-for-profit organization initiated by cancer researchers and clinicians in US and China.

USCACA collaborates with Chinese Anti-Cancer Association (CACA) to (a) facilitate collaborations in the field of cancer research, treatment, prevention and novel cancer drug R&D; (b) promote knowledge and information exchange between US and China; (c) provide educational information for cancer patients, their families and the community. To join us, please visit [www.uscaca.org](http://www.uscaca.org).

## special events

### WELCOME RECEPTION- SUNDAY, NOVEMBER 8 — 7:00pm-8:30pm

Meet your fellow attendees, speakers, and sponsors over served drinks and food! Taking place immediately after the pre-conference workshops, this special reception will allow you to setup meetings and visits with prospective partners for the coming week.

### EXPERT LUNCHEON- MONDAY, NOVEMBER 9 — 12:45pm-1:45pm

Join a table discussion led by speakers and other experts in global clinical development. Each table at lunch will have a specific theme for discussion, covering all aspects of clinical development. The expert lunch will give you the opportunity to more personally interact with our speakers and experts and extends the learning beyond the conference room sessions.

### SPEAKERS' DINNER- MONDAY, NOVEMBER 9 — 6:00pm-7:30pm

In this closed-door session, speakers and advisory board members are invited to partake in an informal roundtable discussion over served dinner and drinks. Some of the biggest names in China clinical development will be in attendance. The informal setup will allow our speakers to exchange best practices and chart the course for clinical development advancement in China.

### OFF-SITE VISIT TO LOCAL HOSPITAL — MONDAY, NOVEMBER 9

You've come all the way to China- make the most of your trip! By attending our pre-arranged off-site visit, you will see firsthand the state-of-the-art and GCP/ICH compliant facilities in Shanghai. Participating in the off-site visit is free for all registered attendees and will be limited to 30 people. Transportation is provided.

For more information or to sign up for the off-site visit, please contact

**Jon E. Liong** at [jon.liong@lycheegroup.com](mailto:jon.liong@lycheegroup.com).

[www.chinatrialsevent.com](http://www.chinatrialsevent.com)

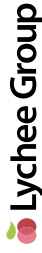
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