



PROGRAM AGENDA

SUNDAY, NOVEMBER 7, 2010

1:00PM - 2:00PM **Workshop Registration & Early Conference Registration**

2:00PM - 5:00PM

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 an expert panel discussing the pros/cons of using the CRO resources vs. building a China operation from scratch

WORKSHOP MODERATOR:

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

MODULAR R&D

SPEAKERS:

Irene Deng, *Head of DRA, Oncology Business Unit*

BEIJING NOVARTIS PHARMA

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

BIOGEN IDEC CHINA

2:00PM - 5:00PM

WORKSHOP #2

What Can Be Learned For China GCP-Based Training From FDA Warning Letters?

- Introduction on FDA warning letters and when they may be issued
- What are the expectations from the FDA when you receive one?
- A close look and analysis of what GCP rules that were violated?
- Focus on investigator/physician responsibilities

WORKSHOP LEADERS:

Nadina Jose, M.D., *Director, Clinical Site Monitoring & Project Management*

ALLERGAN

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

ALLERGAN

5:00PM - 7:00PM

WORKSHOP #3

Development Considerations for Non-Inferiority Studies

- Regulatory & Biostatistical Considerations for Non-Inferiority Studies
- Protocol Development for Non-Inferiority Studies
- A Case Study Non-Inferiority Trial of an Anticoagulant Therapy

WORKSHOP LEADERS:

Ning Li, M.D., Ph.D., *Senior Group Director, Regulatory & Medical Policy*

SANOFI-AVENTIS CHINA



PROGRAM AGENDA

Simon Li, M.D., Ph.D., *Global Clinical Leader, PC*
BAYER HEALTHCARE

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

7:00PM - 8:30PM

Welcome to Beijing Reception

MONDAY, NOVEMBER 8, 2010

7:00AM - 8:00AM

Registration, Breakfast & Exhibits

8:00AM - 8:05AM

Chairpersons' Opening Remarks

8:05AM - 9:25AM

The Green Channel: How Can the Pharmaceutical Industry Partner with the SFDA to Speed Up Development Cycle Times?

In January 2009, the SFDA introduced the Green Channel, a process for expedited review of clinical trial applications and new drug applications. How does the Green Channel work and what makes a drug eligible? What has been the experience of SFDA to date? How does FDA see the future for this process? What has been the experience of the sponsor of this process? At this session, you will hear from senior management at SFDA of their experience and perspective of the Green Channel as well as sponsors, both MNC and local pharma.

SESSION LEADERS:

Ning Li, M.D., Ph.D., *Senior Group Director, Regulatory & Medical Policy*
SANOFI-AVENTIS CHINA

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

Laurence Huang, M.D., *Regulatory Affairs Director*
ASTRAZENECA

■ Keynote Presentation: Regulatory Perspective

STATE FOOD & DRUG ADMINISTRATION

■ Health Authority Perspective

■ Multinational Perspective

Laurence Huang, M.D., *Regulatory Affairs Director*
ASTRAZENECA

■ Local Pharma Perspective

■ Panel Discussion with Audience Q&A

9:25AM - 9:50AM KEYNOTE ADDRESS #1

The Future of Targeted Therapy in Oncology Drug Development

Mace Rothenberg, M.D., *Senior Vice President, Clinical Development & Medical Affairs*



PROGRAM AGENDA

PFIZER ONCOLOGY

9:50AM - 10:10AM KEYNOTE ADDRESS #2

Global Collaborations for Oncology Trials in China

Professor ShuKui Qin, President

CHINESE SOCIETY FOR CLINICAL ONCOLOGISTS (CSCO)

10:10AM - 10:15AM

USACA Scholar Award Presentation

10:15AM - 10:40AM

Networking Exhibition Break

10:40AM - 11:40AM

How Has Big Pharma's China/Asia Clinical Development Strategies Evolved from their Original Vision in the Past Few Years? What Has Been Learned?

At the inaugural ChinaTrials meeting in 2008, much of the discussion centered around opinions from big pharma's China development leaders on how the clinical industry in China would evolve in the coming years. Looking back, has China's clinical development industry evolved as expected? How has big pharma's strategy changed in the past few years based on a rapidly evolving industry in China? What lessons have been learned and do these lessons allow us to better predict how the industry will evolve in the next few years?

MODERATOR:

Frank Jiang, M.D., Ph.D., Vice President, Global R&D, Head, China R&D

SANOFI-AVENTIS CHINA

PANELISTS:

Ole Molskov Bech, Vice President, Clinical & Medical

NOVO NORDISK

Min Irwin, M.D., Ph.D., Medical Director of BSP

BAYER HEALTHCARE

Frank Shen, Ph.D., Asia Pacific Head of GPD Biometrics

ROCHE GLOBAL PRODUCTS DEVELOPMENT IN ASIA PACIFIC

Ling Su, Ph.D., Senior Vice President, Head of Development China

NOVARTIS

11:40AM - 12:40PM

Shape up or Ship Out in an Environment of Increasing Oversight and Scrutiny: Building Strong QC and QA Operating Models Within Your Strategic Collaborations

It is clear that there is an increasing level of scrutiny by regulatory agencies on sponsors, providers and investigative sites regarding obligations to ensure adequate oversight and compliance of clinical trials. Regardless of the outsourcing model utilized, the Sponsor retains the ultimate obligation to ensure effective oversight of all internal and external activities related to the conduct of their clinical trial programs. Without an effective quality management process, the potential for good clinical practice (GCP) breaches that impact new drug approvals will continue to exist. This keynote session will examine the complexities that exist in establishing shared quality systems across strategic partnerships and the organizational designs, systems and processes needed for building and sustaining quality operating models.

MODERATOR:

David Marks, Senior Director & Global Head, Quality Management



PROGRAM AGENDA

RPS

PANELISTS:

Menghis Bairu, M.D., *Executive Vice President, Chief Medical Officer & Head of Global Development*

ELAN PHARMACEUTICALS

Xun Chen, *Head of Clinical Sciences & Operations*

SANOFI-AVENTIS CHINA

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

ALLERGAN

12:40PM - 1:45PM

Expert Luncheon

CLINICAL SAFETY ASSESSMENT & PATIENT RECRUITMENT IN CHINA

1:45PM - 2:45PM

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

Clinical safety is essential for a successful new drug which is determined based on its favorable benefit-risk profile. Good clinical safety depends on appropriate clinical trial design and monitoring to learn the safety risks of a new drug, timely decision to address safety issues, and best strategy to manage the identified risks. In this session, some key aspects of clinical safety during new drug development, particularly pertinent to clinical research practices in China, will be discussed, such as:

- 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., *Senior Vice President & Global Head of Pharmacovigilance*

TAKEDA PHARMACEUTICALS

PANELISTS:

Ming Ji, M.D., *Senior Medical Director, Clinical Safety Evaluation/Global Pharmacovigilance*

ABBOTT LABORATORIES

Conny Mo, *Manager, Department of US Clinical Trial Safety Processing*

PFIZER

Yuan Meng, *Head of Country Pharmacovigilance (Greater China)*

BRISTOL-MYERS SQUIBB

3:30PM - 4:00PM

Mid-Afternoon Networking Break & Exhibits



PROGRAM AGENDA

CONDUCTING CLINICAL TRIALS IN THE USA

4:00PM - 4:15PM

Chairpersons' Opening Remarks

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

4:15PM - 4:35PM

Case Study: A Phase I Herbal Trial in US for Oncology

KANGLITE PHARMACEUTICALS (INVITED)

4:35PM - 4:55PM

TBA

JIANGSU HENGRUI PHARMACEUTICALS (INVITED)

4:55PM - 5:15PM

Case Study: A Phase II Herbal Trial in US for Cardiovascular Indication

He Sun, Ph.D., *Vice President, International Operations*
TIANJIN TIAN-SHI-LI PHARMA

5:15PM - 5:45PM

Case Study: Bioequivalence Study in USA to Support An ANDA Application in USA

Peng Wang, Ph.D., *Chief Scientific Officer*
SIMCERE PHARMACEUTICAL GROUP

5:45PM

End of Track A & Day One

TRACK B: "PEOPLE" IN CLINICAL RESEARCH IN CHINA

1:45PM - 1:50PM

Session Chair's Opening Remarks

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

1:50PM - 2:55PM

Hiring Quantitative Scientists in China: How Do The Different Characteristics of Quantitative Scientists in China Reflect The Unique Business Environment?

- What is the benchmark for salaries in China for quantitative scientists?
- Challenges in hiring the right people
- The increased interest of industry to hire epidemiologists, modeling/simulation experts, health economics specialists in addition to biostatisticians
- Developing the 3 inter-dependent biometrics professions (biostatisticians, scientific programmers and database managers)



PROGRAM AGENDA

MODERATOR:

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

MERCK & CO.

PANELISTS:

Raymond Bain, Ph.D., *Vice President, Biostatistics & Research Decision Sciences*

MERCK & CO.

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

ATYR PHARMA

Catherine Qin, *Consultant- Pharmaceutical Division*

THE MRI CHINA GROUP

Frank Shen, Ph.D., *Asia Pacific Head of GPD Biometrics*

ROCHE GLOBAL PRODUCTS DEVELOPMENT IN ASIA PACIFIC

2:55PM - 3:45PM

Hiring, Managing & Retaining Top Clinical Talent in China: From Management's Perspective

With regards to the challenges of clinical operations in China, much discussion is focused around the fast-changing regulatory environment. Shortage of talent, high turn over rate, high expectation of the salary increase: has your firm experienced these problems? Are you prepared to face this competitive talent market? Management teams are always asking, "What can we do to keep our people? It is already so hard to find any qualified talent." To answer this question, we should deeper into the motivations of know they are leaving. This panel will include panelists from top managers in China's life sciences industry to help us more fully understand these issues.

MODERATOR:

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

BAYER HEALTHCARE

PANELISTS:

Janet Brennan, *Executive Vice President & Chief International Affairs Officer*

RPS

Jennifer Jin, *Executive Director, Human Resources*

BEIJING NOVARTIS PHARMA

Chris Kao, *Associate Principal, Global Life Sciences Practice*

HEIDRICK & STRUGGLES

Jeff Lee, *Director, Northern China*

MERCER

3:45PM - 4:00PM

Mid-Afternoon Networking Break & Exhibits

4:00PM - 4:25PM

Globalization and Global Outsourcing: The Human & Organizational Factors

Kon K. Fung, Ph.D., *Senior Director, Biometrics & Clinical Data Systems*

JOHNSON & JOHNSON CONSUMER HEALTHCARE



PROGRAM AGENDA

● DATA MANAGEMENT & ELECTRONIC DATA CAPTURE IN CHINA ●

4:25PM - 5:15PM

Creating Global Standards For Clinical Data Interchange: CDISC'S China Initiative

MODERATOR:

Claire Tan, *Senior Director, Biostatistics*

QUINTILES

PANELISTS:

Ding Li, *Clinical Data Management Site Director*

SANOFI-AVENTIS CHINA

Daniel Liu, *Director, China Development*

MEDIDATA SOLUTIONS

Simon Wang, *Manager*

PAREXEL

5:45PM

End of Track B & Day One

TRACK C: ONCOLOGY CLINICAL DEVELOPMENT IN CHINA I

Organized with US CHINESE ANTI-CANCER ASSOCIATION (USCACA)

1:45PM - 1:50PM

Session Chairpersons' Opening Remarks

Kenneth J. Pienta, M.D., *Director, Michigan Institute for Clinical & Health Research*

UNIVERSITY OF MICHIGAN SCHOOL OF MEDICINE

Li Yan, M.D., Ph.D., *Director, Clinical Oncology,*

MERCK & CO.

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



PROGRAM AGENDA

EVOLVING EARLY PHASE ONCOLOGY CLINICAL TRIALS IN THE ERA OF MOLECULAR TARGETS DRUGS

1:50PM - 2:10PM

Critical Role of High Quality Phase I Studies in Oncology Drug Development

Anthony Tolcher, M.D., *Director of Clinical Research*

SOUTH TEXAS ACCELERATED RESEARCH THERAPEUTICS

2:10PM - 2:30PM

Adaptive Clinical Trials in Finding Responsive Patient Populations

Eric Rubin, Ph.D., *Vice President, Oncology Clinical Research*

MERCK & CO.

2:30PM - 2:50PM

Population-Based Design of Phase I Trials for Anticancer Drugs

Derick Lau, M.D., Ph.D., *Professor, Division of Hematology/Oncology*

UNIVERSITY OF CALIFORNIA AT DAVIS- SCHOOL OF MEDICINE

2:50PM - 3:10PM

Aspects of Early Clinical Trials Including Design & Biomarker Issues

Helen Chen, M.D., *Associate Chief & Senior Investigator- Investigational Drug Branch*

NATIONAL CANCER INSTITUTE

3:10PM - 3:30PM

Session Panel Discussion

3:30PM - 4:00PM

Mid-Afternoon Networking Break & Exhibits



PROGRAM AGENDA

● BIOMARKER-DRIVEN TRIAL DESIGN TO ACHIEVE EARLY DECISION IN EARLY PHASE TRIALS ●

Session Chair:

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

4:00PM - 4:20PM

Translating Biomarkers from Theory to Practice

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

4:20PM - 4:40PM

Utilizing Imaging in Decision Making During Early Phase Oncology Drug Development

Michael O'Neal, M.D., *Chief Medical Officer*
RADPHARM

4:40PM - 5:00PM

Proof-of-Concept Determination in Oncology through Randomized Phase II Trial Designs

Peter T.C. Ho, M.D., Ph.D., *President*
BEIGENE

5:00PM - 5:15PM

Molecular Epidemiology in Oncology Drug Development

Wei Zhou, Ph.D., *Director, Molecular Epidemiology*
PFIZER ONCOLOGY

5:15PM - 5:30PM

Biomarker Platforms for Analysis of Angiogenesis & Inflammation in Oncology Clinical Trials

Christine Burns, Ph.D., *Vice President, Research & Development*
AUSHON BIOSYSTEMS

5:30PM - 6:00PM

Session Panel Discussion



PROGRAM AGENDA

TUESDAY, NOVEMBER 9, 2010

7:00AM - 8:00AM

Registration, Breakfast & Exhibits

8:00AM - 8:15AM

Session Chair's Opening Remarks for Morning Session

Ruiping Dong, M.D., Ph.D., *Vice President, Head of R&D, Japan & China*
BRISTOL-MYERS SQUIBB

8:10AM - 8:40AM

New Initiatives of Japan/China/Korea Harmonization in Drug Development

8:40AM - 9:10AM

Introduction on Regulatory Review & Approval Process in Korea

9:10AM - 9:40AM

Cooperation of Taiwan and Asian Clinical Trials: From the Aspect of Taiwan

- The involving regulatory infrastructure in Taiwan
- Competitiveness of regulatory infrastructure for clinical trial in Taiwan
- Bridging evaluation in Taiwan

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

9:40AM - 10:10AM

Mid-Morning Networking Break & Exhibits

10:10AM - 10:40AM

Productivity Innovation: How To Secure The Synergistic Effect In The Pan-Asian Framework Of New Clinical Development

Hiroshi Sugii., *Vice President, Development Division/Director, Clinical Development Department*
NOVO NORDISK JAPAN

10:40AM - 12:10PM

North Asia Simultaneous Drug Development Strategies

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

MODERATOR:

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

PANELISTS:

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



PROGRAM AGENDA

James Garner, M.D., *Vice President & General Manager*
TAKEDA CLINICAL RESEARCH SINGAPORE

Hiroshi Sugii, *Vice President, Development Division/Director, Clinical Development Department*
NOVO NORDISK JAPAN

Hyunju Yang, *Director of Medical Division*
DAIICHI SANKYO KOREA

12:10PM - 1:10PM

Networking Lunch

1:10PM - 1:15PM

Session Chair's Opening Remarks for Afternoon Session

Simon Li, M.D., Ph.D., *Global Clinical Leader*
BAYER GLOBAL R&D CENTER

1:15PM - 1:45PM

Clinical Pharmacology Package to Support IMCT and Registration in Asia

Zaiqi Wang, M.D., Ph.D., *Director of Clinical Research*
MSD TRANSLATIONAL MEDICINE RESEARCH CENTRE SINGAPORE

1:45PM - 2:15PM

Conducting IMCT Studies for Registration of Category III Drugs in China & AP Countries

This talk will cover the key factors when planning for IMCTs, such as whether significant results in Chinese patients are needed for approval, when the CTA could be submitted to save time, how to define the reference country, etc. The talk will also discuss the factors to be considered when selecting 2 more countries in AP areas in order to ensure the approval in those countries with the IMCT data.

Simon Li, M.D., Ph.D., *Global Clinical Leader*
BAYER GLOBAL R&D CENTER

2:15PM-2:45PM

Multinational Clinical Trials in Asia: Perspective of a Head of Medical Division of a Japanese Firm in Korea

Nowadays, Asian countries are contributing a lot to global drug development by participating in global clinical trials. According to the data in the www.ClinicalTrials.gov database (Oct 2005 to Sep 2007), Asia is involved in more sponsored trials than any other emerging region with 18.1%* of all protocols globally. So, it is meaningful to observe some clinical trial environment in Asia and in addition, to introduce infrastructure of clinical trial in Korea which is one of the most active locations in Asia.

Hyunju Yang, *Director of Medical Division*
DAIICHI SANKYO KOREA

2:45PM - 3:05PM

Mid-Afternoon Short Break

3:05PM - 3:35PM

What Are the Challenges the CRO Industry is Facing When Conducting Multinational Clinical Trials in Asia Pacific?



PROGRAM AGENDA

3:35PM - 4:05PM

Working With CROs to Conduct Multinational Clinical Trials in Asia Pacific

James Garner, M.D., *Vice President & General Manager*

TAKEDA CLINICAL RESEARCH SINGAPORE

4:30PM

Track A & Conference Concludes

TRACK B: INNOVATION IN DEVELOPING OTC PRODUCTS

7:00AM - 8:00AM

Registration & Breakfast

8:00AM - 8:10AM

Chairpersons' Opening Remarks

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

JOHNSON & JOHNSON

8:10AM - 8:40AM

OTC Drug Regulations in China

Jieming Zhou, *Deputy Director, Division of EDL*

CHINESE STATE FOOD & DRUG ADMINISTRATION (SFDA)

8:40AM - 9:10AM

Overview of US OTC Drugs: Regulations & Registration Requirements

Lynn Pawelski, *Vice President, Regulatory Affairs*

JOHNSON & JOHNSON

9:10AM - 9:40AM

Understanding the Customers: From Consumer Insights to Innovative Products

Traditional areas for the use of OTC medicines include the treatment of mild to moderate pain, symptoms of the common cold, hay fever, heartburn, diarrhea, constipation, hemorrhoids, gingivitis, eczema, acne, as well as caries and sunburn prevention. New indications for which OTC medicines have been approved in the U.S. in recent years include smoking cessation, emergency contraception, and weight management. Outside the U.S., in particular in the United Kingdom, several medicines were "switched" from prescription only (Rx) to OTC in further new self-medication areas such as cholesterol lowering, bacterial conjunctivitis, lower urinary tract infections, and benign prostatic hyperplasia. The purpose of this presentation is to examine the data supporting and the factors driving the important role of OTC medicines in the U.S. healthcare system and the consumer benefits these products provide from a medical, convenience, economic, and unmet consumer need perspective. Ultimately, an innovative OTC product should meet the needs of consumer self care, provide unique "at hand" benefits, help to decrease Rx treatment gaps, be more convenient to maintain a good health, and eventually, lead to a happier life.

Ding Ming, M.D., Ph.D., *Senior Director, CHC Medicine*

BOEHRINGER-INGELHEIM



PROGRAM AGENDA

9:40AM- 10:10AM

Mid-Morning Networking Break & Exhibits

10:10AM - 10:40AM

Rx-to-OTC Switch Strategies

"Rx-to-OTC Switch" encompasses a multitude of clinical, regulatory, and behavioral issues. Every switch is different in each market; however there are common themes that drive switch strategies globally. This presentation will highlight several of these themes and the ways in which sponsors have tried to implement these strategies.

Sandy Furey, M.D., Ph.D., *Vice President*

PFIZER CONSUMER HEALTHCARE

10:40AM - 11:10AM

Creating a World-Class Innovative Culture to Drive Growth

The session will examine the steps taken by GlaxoSmithKline management to turn-around an organization that delivered less than average industry growth. Specifically, in 2006, GlaxoSmithKline Consumer Healthcare moved to a new R&D and Business operating model to drive growth and business sustainability. This new model involved refreshing the Leadership, significant changes in the physical space which allow high levels of collaboration across the organization, a move to a global marketing model called "Future Teams" and the creation of an Open Innovation model to source breakthrough innovation. As a result, GlaxoSmithKline Consumer Healthcare has been recognized as a world leader in product innovation with its #1 innovation rating by UBS in 2009 and numerous awards for product innovation. Since implementing the new model, GlaxoSmithKline has been a consistent leader in sales growth within the consumer healthcare segment.

Yan-Yan Starkey, M.D., MBA, *Medical Director- Global Medical Affairs*

GLAXOSMITHKLINE CONSUMER HEALTHCARE

11:10AM - 11:40AM

OTC Traditional Chinese Medicine: Evaluating Safety & Efficacy

Traditional Chinese Medicine (TCM) products represent about half of the OTC market in China. TCM has a long history of use and is widely accepted and believed by consumers in China and surrounding Asian countries. Comprehensive literature reviews, however, reveal limited evidence of efficacy and safety, i.e., results from double-blind, placebo-controlled studies. Generation of high quality clinical data of TCM is key for its modernization and acceptance in US and European markets.

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

JOHNSON & JOHNSON

11:40AM - 12:10PM

What Are the Opportunities for Growth Within the China OTC Market?

- Perceived Mega-Trend areas within China
- Relative attractiveness and acceptance of OTC Switches, Western Branded Products, Medical Devices and TCM's
- Current Consumer habits, attitudes and challenges with self-medication
- Consumer and Professional perception of Branded vs. Generics products
- Key Challenges/Barriers to success

MODERATOR:

Stanley Lech, B.S. Chem, MBA, *Vice President of Venture Group & Strategic Relationships*

GLAXOSMITHKLINE CONSUMER HEALTHCARE

PANELISTS:

Sandy Furey, M.D., Ph.D., *Vice President*



PROGRAM AGENDA

PFIZER CONSUMER HEALTHCARE

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

JOHNSON & JOHNSON

Ding Ming, Ph.D., *Senior Director, CHC Medicine*

BOEHRINGER INGELHEIM

Yan-Yan Starkey, M.D., MBA, *Medical Director- Global Medical Affairs*

GLAXOSMITHKLINE CONSUMER HEALTHCARE

12:10PM - 1:10PM

Networking Lunch

EARLY CLINICAL DEVELOPMENT IN CHINA: WHAT & HOW TO DO?

1:10PM - 1:15PM

Chairpersons' Opening Remarks

Roger Luo, Ph.D., *Director, Translational Medicine & Early Development*

ORTHO BIOTECH ONCOLOGY R&D/CENTOCOR R&D

1:15PM - 1:40PM

Early Clinical Trials Carried Out in China: Experience from Past, Current status, and Path Forward

Ji Jiang, M.D., *Deputy Director of Clinical Pharmacology Research Center*

PEKING UNION MEDICAL COLLEGE HOSPITAL/CHINESE ACADEMY OF MEDICAL SCIENCES (INVITED)

1:40PM - 2:05PM

Translational Phase I FIH study: Quick Path to POC and Its Potential Applications for Early Clinical Development in China

Zaiqi Wang, M.D., Ph.D., *Director of Clinical Research*

MSD TRANSLATIONAL MEDICINE RESEARCH CENTRE SINGAPORE

2:05PM - 2:30PM

Phase I PK/Safety Bridging Study in China

Tong Li, M.D., Ph.D., *Director of CV & Metabolic Disease/Discovery Medicine & Clinical Pharmacology*

BRISTOL-MYERS SQUIBB

2:45PM - 3:05PM

Mid-Afternoon Short Break

2:45PM - 3:10PM

First in Human Study in China: from IND Application to Study Completion

Jie Hou, *Director, Phase I Center*

FOUNTAIN MEDICAL DEVELOPMENT



PROGRAM AGENDA

3:10PM - 3:35PM

Icotinib Phase I Study and its Impact on the Development Path

Fenlai Tan, M.D., Ph.D., *Director, Beijing R&D Center*

ZHEJIANG BETA PHARMA

3:35PM - 4:00PM

Panel Discussion

4:30PM

Track B & Conference Concludes

TRACK C: ONCOLOGY CLINICAL DEVELOPMENT IN CHINA I

Organized with 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)

● CURRENT STATE OF ONCOLOGY TRIALS IN CHINA: ●

PERSPECTIVES FROM INVESTIGATORS, REGULATORY AGENCY, SPONSORS & CROS

8:10AM - 8:25AM

Oncology Drug Development in China- Lessons Learned

Xiaoxiang Chen, M.D., *Vice President*

BOEHRINGER INGELHEIM CHINA

8:25AM - 9:00AM

SFDA Regulatory View On Oncology Development In China

Xiaoyuan Chen, M.D.

CHINA SFDA CENTER FOR DRUG EVALUATION

9:00AM - 9:15AM

Expedited SFDA Review: Approval of Phase I First-in-Human Oncology Clinical Trial Permit

Tom Tang, M.D., Ph.D., *Vice President, Clinical & Regulatory Affairs*

HUTCHISON MEDIPHARMA



PROGRAM AGENDA

9:15AM - 9:25AM

Early Clinical Development for Oncology Drugs- Experiences and Lessons

Bin Peng, M.D., Ph.D., *Senior Director, Head of Oncology Translational Medicine China*
NOVARTIS

9:25AM - 9:40AM

Preclinical & Early Phase Development Acceleration Between US & China: Strategy & Regulatory Considerations

Dajun Yang, M.D., Ph.D., *President & Chief Executive Officer*
ASCENTAGE PHARMA

9:40AM - 10:10AM

Mid-Morning Networking Break & Exhibits

● GLOBAL COLLABORATION: CLINICAL TRIALS NETWORK, USCACA/CSCO/SFDA ● TRAINING PROGRAM

Session Chair:

George Wilding, M.D., *Director, Assistant Dean for Oncology*
UNIVERSITY OF WISCONSIN

10:10AM - 10:25AM

The University of Michigan-Peking University Health Sciences Center Joint Institute for Translational and Clinical Research: Goals, Strategies, and Tactics

Kenneth Pienta, M.D., *Director, Michigan Institute for Clinical & Health Research*
UNIVERSITY OF MICHIGAN SCHOOL OF MEDICINES

10:25AM - 10:40AM

Title TBA

George Wilding, M.D., *Director, Assistant Dean for Oncology*
UNIVERSITY OF WISCONSIN

10:40AM - 10:55AM

The Moffitt Cancer Center-TianJin Cancer Hospital Collaboration

Richard Lush, M.D., *Executive Director, Clinical Research Operations*
MOFFITT CANCER CENTER

10:55AM - 11:10AM

IT Support for Oncology Studies in NCI/USA

Peter Yan, *Technical Manager, caBIG Program/CBIIT*
SAIC-FREDERIC



PROGRAM AGENDA

TRANSLATIONAL MEDICINE CAPABILITIES IN CHINA

Session Chair:

Wei Zhang, M.D., *Professor & Director- Cancer Genomics Core Laboratory*
M.D. ANDERSON CANCER CENTER

11:10AM - 11:25AM

Biomarker and Personalized Medicine in Early Phase Trials in China

Jason Jin, M.D., Ph.D., *Chief Executive Officer*
SHANGHAI BIOCHIP CORPORATION

11:25AM - 11:40AM

Integration & Outsourcing of Molecular Biomarkers in Oncology Clinical Trials

Christopher Ung, *Vice President, Strategic Business & Operations, Oncology*
QUINTILES

COLLABORATIVE TISSUE BANKS IN CHINA

11:40AM - 11:50AM

Collaborative Tissue Bank at Tianjin Cancer Hospital

Kexin Chen, M.D., Ph.D., *Director & Professor*
TIANJIN MEDICAL UNIVERSITY CANCER INSTITUTE & HOSPITAL

11:50AM - 12:00PM

Collaborative Tissue Bank at TianTan Hospital

Tao Jiang., *Professor*
TIANTAN HOSPITAL

12:00PM - 12:10PM

Maximizing the Value of Tissue Banks: Coordination & Collaboration

Michael Wang, *Chief Scientific Officer*
NATIONAL FOUNDATION FOR CANCER RESEARCH

12:10PM - 1:10PM

Networking Lunch



PROGRAM AGENDA

OTHER THERAPEUTIC AREAS FOR CLINICAL TRIALS IN CHINA & ASIA

1:10PM - 1:40PM

Opportunities & Challenges for Biologic Clinical Trials in China

This presentation will present a case study of a biologic clinical trial in China. It will cover regulatory strategy, Phase III clinical protocol design, patient selection criteria, site selection, investigator training, and other logistic issues etc. Considerations in respect to biologic compound development in China will be discussed.

Michael Song, M.D., *Medical Director, Immunology*
CENTOCOR R&D

1:40PM - 2:10PM

Opportunities & Challenges in Conducting Ophthalmology Clinical Studies in China & Asia: A Sponsor's Perspective

Esther Chu, *Director, Global Clinical Operations- Asia Pacific*
BAUSCH & LOMB

2:20PM - 2:40PM

Hemophilia Clinical Program at Biogen Idec China: Overcoming the Challenges in the Translational Process

Yan Wu, Ph.D., *Medical & Clinical Development Director*
BIOGEN IDEC CHINA

2:40PM - 3:00PM

Mid-Afternoon Short Break

MEDICAL DEVICE & IVD TRIALS IN CHINA

3:05PM - 3:45PM

A Broad Outline Of Clinical Trials For Medical Devices And IVD In China

- When are clinical trials required in China?
- Key regulations and considerations
- Pitfalls and success factors

Janice Ma, *Managing Director*
CHINAGATE

3:45PM - 4:10PM

In-Vitro Diagnostics (IVDs) Clinical Studies & Registration in China: Roche's Experiences

- Opportunities and challenges in China
- Critical considerations and relevant regulations/guidance
- Practical issues: minimizing risks, lowering costs, improving speed for product registration

Vicky Tao, M.D., *Director, Medical Regulatory Affairs*
ROCHE DIAGNOSTICS SHANGHAI



PROGRAM AGENDA

4:10PM-4:30PM

Medical Devices Clinical Studies & Registration in China: J&J's Experiences

Vivian Li, M.D., *Medical Director*

JOHNSON & JOHNSON (INVITED)

4:30PM

Track C & Conference Concludes