



Sino-American Pharmaceutical Professionals Association
-Greater Philadelphia Chapter
 美中医药开发协会大费城分会



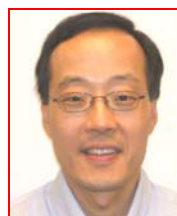
SAPA-GP Conference 2008 -2009 Series

Clinical Trials & Innovative Drug Development Conference

Keynote Speakers



Michael Krams, MD
 Vice President
 Adaptive Trials & Applied Program Strategies
 Clinical Research & Development
Wyeth Research



David Chang, MD, MPH
 Vice President
 Clinical Development
GlaxoSmithKline
 Adjunct Assistant Professor of Medicine
University of Pennsylvania

Saturday, March 21, 2009

Crowne Plaza Valley Forge

260 Mall Boulevard, King of Prussia, PA 19406. Phone: 610-265-7500

Organizing Co-Chairs:

Jingsong Wang, MD
 Director
 Discovery Medicine & Clinical Pharmacology
Bristol-Myers Squibb, Co.
 Adjunct Assistant Professor of Medicine
University of Pennsylvania

Joan Shen, MD, PhD
 Director
 CNS, Clinical Research & Development
Wyeth Research

The SAPA-GP Clinical Trials & Innovative Drug Development Conference is a one day event, which encompasses the introduction of the general principles of all spectrum of clinical trials, provides attendees with an overview of the challenges and opportunities in clinical trials for drug development.

A number of CRO companies will also actively recruit scientists and executives at all levels at this conference. For those who are interested in finding and expanding opportunities in clinical trials, there are plenty of networking opportunities with the senior executives of large pharmaceutical companies, the Founders and CEOs of various Biotech and CRO companies throughout the conference.

Why Should You Attend?

- To learn the general concept and process of clinical trials for drug development
- To better understand the current trend and challenges for clinical trials
- To enhance your career by learning innovative approaches for clinical study design and execution
- To better understand the opportunities and challenges for conducting clinical trials in China and Asia
- To explore career opportunities by learning the roles and career paths of typical clinical trial team members
- To understand the role of CRO in current clinical trials and identify job opportunities
- To networking with executives from major pharmaceuticals, founders & CEOs of leading CROs, and your fellow members

To register, please log on to SAPA-GP website
www.sapa-gp.org

Agenda

8:00-8:30 Registration

Morning Session

Moderator: Jingsong Wang, MD

8:30-8:35 **Welcome and Introduction**

Li Yan, MD, PhD

President, SAPA-GP

Associate Director, Oncology Clinical Development, Merck & Co

8:35-8:40 **Opening Remarks and Program Overview**

Jingsong Wang, MD

Director, Discovery Medicine & Clinical Pharmacology, Bristol-Myers Squibb, Co.

Adjunct Assistant Professor of Medicine, University of Pennsylvania

8:40-9:20

Keynote Presentation

Innovative Designs in Clinical Drug Development

Michael Krams, MD

Vice President, Adaptive Trials & Applied Program Strategies

Clinical Research & Development, Wyeth Research

Our ambition is to bring innovative approaches to clinical drug development, to facilitate better and earlier decision making. We will describe an infrastructure to enable designing, implementing and executing adaptive designs and real-time learning in Learn and Confirm studies. We apply Modeling & Simulation techniques and integrate input from clinical, translational medicine, biostatistics, discovery and commercial. The emphasis is on applying innovative designs across therapeutic areas, including small molecules, vaccines and biologics in a large pharmaceutical R&D organization.

We will then illustrate the general principles by describing a case study which uses a clinical utility and a Bayesian POC/response adaptive dose-ranging study. A highlight of this case study is a strategic approach to the recruitment strategy.

9:20-9:50

Phase I to IIa Early Drug Development from First in Human (FIH) to Proof of Concept (PoC): SAD, MAD or Both?

Sean Zhang, MD

Clinical Leader & Associate Director, Early Development

Johnson & Johnson Pharmaceutical R&D

This presentation will overview the basic concepts and study designs for early drug development including Phase I First in Human (FIH) Single Ascending Dose (SAD), Food Effect (EF), Multiple Ascending Dose (MAD) and Phase IIa Proof of Concept (POC) studies. The presentation will focus on the FIH SAD study which will cover the First In Human (FIH) starting dose calculation, dose escalation scheme (sequential vs alternative), exposure ceiling estimation, dose escalation stopping criteria and FIH protocol review process. An "All-In-One" protocol approach will be introduced.

9:50-10:10

Coffee Break & Networking

10:10-10:40

Phase II-III Late Stage Global Clinical Trials - Effective Planning and the Challenges

Joan Shen, MD, PhD

Director, CNS, Clinical Research & Development, Wyeth Research

As we are all aware drug development is facing a tougher challenge than any other time before: higher public expectations, stricter regulatory requirement, generic drug erosions, commercial demand for blockbusters and etc. These only make the jobs in phase 2 and 3 clinical trials more difficult. How could we cope with these challenges? What are the strategies and solutions?

In this presentation, the speaker will discuss the concept and roles of phase 2 and 3, the research questions intended to answer and the study design needed to answer those questions, the risk and benefit assessment during/after the clinical studies and the decision making process. Also will discussed are the current status of clinical studies worldwide, the pros and cons of conducting global trials, the specific challenges in different countries/regions, as well as the operational tactics and strategies.

10:40-11:10 **Clinical Pharmacology in Phase I to IV Clinical Trials**
Simon Zhou, PhD
Director, Early Development & Clinical Pharmacology, Wyeth Research

Clinical pharmacology provides basic understanding of what human body does to drug molecules and how drug molecules affect human body. Basic clinical pharmacological profiling of a drug candidate is the first step in clinical development. While quantitative characterization of pharmacological effect of drugs is carried out through all phases of clinical development, the ultimate goal is to define the dose-exposure-response relationship of drugs in terms of efficacy and safety. It enables the selection of optimal doses to optimize efficacy while minimizing adverse effect. Effective and efficient determination of drug pharmacology underscores the concept of model-based drug development and is the driver of the critical path initiative of FDA to curb escalating clinical developmental cost.

The presentation will offer an overview of clinical pharmacology studies in clinical development and take the audience through sections of a drug label with examples to illustrate and highlight the roles of clinical pharmacology played from early clinical development to life-cycle management of a drug.

11:10-11:40 **Biostatistics in Clinical Trials**
Zhengqing Li, PhD
Executive Director, Global Biometrics Science, Bristol-Myers Squibb

While the pharmaceutical industry continues to face challenges such as loss of exclusivity, health care policy changes, and increasing regulatory requirement, significant advances in sciences at the genetic, molecular and cellular levels, combined with progress made in developing and utilization innovative study design bring new opportunities in drug discovery, development and commercialization. These challenges and opportunities allow statisticians to become increasing involved in strategic issues and help business and regulatory leaders make good decisions about drug development and market authorization as quickly and efficiently as possible in the presence of uncertainty.

In this presentation, I will discuss how the role of statisticians and statistical thinking has evolved over the past several decades in drug development. To continue to add value to the enterprise and to seize the opportunities, statisticians in the industry have to prepare themselves ready in their mind and skill sets.

11:40-1:00 ***Lunch (free for registered attendees) and Networking***

Afternoon Session

Moderator: Joan Shen, MD, PhD

1:00-1:40 ***Keynote Presentation***
Current Challenges & Opportunities for Innovative Therapeutics Development
David Chang, MD, MPH
Vice President, Clinical Development, GlaxoSmithKline
Adjunct Assistant Professor of Medicine, University of Pennsylvania

The development of innovative therapeutics that offers value to patients is facing increasing challenges and pressures from various fronts. The cost and time to conduct clinical trials are increasing; regulatory hurdles are getting higher; patent protections are being challenged; competition is rising; payers are becoming more selective and restrictive; the political climate is volatile; and public perception is at an all-time low.

Even with the gloomy predictions, drug developers and approvers are seizing the opportunity to improve the process of delivering medicines to patients. Both the FDA and the European regulatory body, the European Medicines Agency (EMA), have focused on partnering with pharmaceutical companies to optimize drug development and published reports on innovative approaches. The pharmaceutical industry, similarly, is implementing innovative drug development strategies to maximize the success rate, focusing on operational, technical, and strategic innovations.

1:40-2:10 **Translational Medicine & Biomarkers in Clinical Trials**
Jingsong Wang, MD
Director, Discovery Medicine & Clinical Pharmacology, Bristol-Myers Squibb Co.
Adjunct Assistant Professor of Medicine, University of Pennsylvania

Translational medicine strategy and biomarker plan have been increasingly used to eliminate the bottlenecks in clinical development program. Biomarker provides valuable information for clinical development program in multiple ways. It can be used to assess the biologic effect, safety and to better monitor the clinical efficacy in both early and late stages of the program. However, how to optimally apply the vast array of biomarkers in various clinical trials is a challenging task. It is pivotal to have a good understanding for any given biomarker on its utility, limitation and the effort needed to incorporate both the exploratory and validated ones into clinical trials. The time and resources required for transforming a biologic measurement into a validated biomarker, complex logistic issues on implementing a biomarker plan in clinical trials are often underestimated. Hence, multi facet alignment of biomarker discovery and development effort with clinical trial activity holds the key for maximizing the value of biomarkers in clinical development program.

This presentation will highlight the practical applications for translational medicine strategy and biomarker plans for drug development program and clinical trials.

2:10- 2:40

Phase IV Trials and Life Cycle Management/ Paradigm Shift from Network Marketing to Evidence Based Medicine in China

Danyi Zhang, MD

Chief Medical Officer, VitalStrategic Research Institute

When does drug development end? When does commercialization start? Does Phase IV study start at Phase IV? How will the concept of Evidence Based Medicine impact drug development and commercialization? Under the current economic crisis, pharmaceutical industry is pressed to work more stream-lined, more innovative and cost effective, while deliver more values to patients, physicians, and payers. Randomized, double-blinded, and controlled clinical trials have always been the gold standard to demonstrate clinical efficacy and safety of a new therapy. However, since most of these trials are conducted under a careful design and scrutinized inclusion and exclusion criteria, in order to enhance the chance of confirming a testing hypothesis for which the trial is executed, they are limited by the small sample size and short duration of safety monitoring. Regulators and healthcare providers have been increasingly demanding for evidence of justified risk and benefit of a given therapy that is established in much bigger sample sizes and in non-interventional environments.

In this talk, the author will discuss the challenges facing delivery of innovative medical therapy to the real world, as well as how scientists, statisticians, clinicians, marketers, and others could each play an important role in this process. An integrated health solution is an outcome of integrated skill sets and creative mind set.

2:40- 3:00

Coffee Break & Networking

3:00-3:20

Conducting Clinical Trials in China

Xiaoxiang Chen, MD

Associate Director, Clinical R & D, Wyeth Research
(Former Head of CR&D China, Wyeth Research)

Without any question, China has become one of the most attractive regions for global clinical trials in the past years, most international pharmaceuticals have increased their reliance on China for its rapid patient enrollments and relatively lower costs. But in the mean time, there are some special hurdles on introducing global clinical trial into China, including complicated regulatory process, IP protection, logistic issues, sample exportation, culture difference, local language barrier etc. The presentation will discuss the practical strategies on dealing with these hurdles, and share some real experience on how to successfully conduct a global clinical trial in China.

3:20- 3:40

Opportunities and Challenges for Conducting Clinical Trials in Asia Pacific

Rose Qiu, MD, PhD

Senior Director, Internal Medicine, J & J Pharmaceutical R & D
(Former Head of Asia Pacific Global Clinical Operation, J & J)

Multinational company (MNC) has been shifting global clinical trials to emerging regions and contribution from Asia Pacific has increased substantially in the past few years. While the region has a lot to offer, including large patient population and comprehensive disease profile, there are also unique challenges such as regulatory approval, hospital infrastructure, drug supply, insurance system, among others, in different Asian countries. MNC need to modify internal process, define therapeutic area strategy, understand data from different regions, and build a efficient resource structure to optimize the capacity in AP.

Clinical Development Career Forum

Moderators: Jingsong Wang, MD & Joan Shen, MD, PhD

3:40- 4:10 **Virtual Clinical Trial Team Forum**

- Clinical Trial Team Member Function Overview & Career Path Inspiration
- The main goal of this session is to highlight the key expertise needed for planning and executing clinical trials

Team Members:

- Clinical Scientist/Protocol Manager -**Frank Gan, PharmD**, BMS
- PK Scientist - **Baiteng Zhao, PhD**, Merck
- Biomarker Specialist - **Xi-de Wang, PhD**, BMS
- Biostatistician - **Fang Liu, PhD**, Merck
- Data Manager - **Gary Huang, MD**, Q² Business Intelligence
- Project Manager - **Jian Lu, PhD**, Merck
- Regulatory Affairs - **Jiwen Zhang, PhD**, Sanofi-Aventis

4:10- 5:10 **Career Opportunities -CRO Industry Roundtable**

- Representative clinical trial CRO company profiling
- Career opportunity in clinical trials option discussion -Pharma vs. CRO; US vs. China

Distinguished Panelists:

Dan Zhang, MD, PhD

CEO, Fountain Medical Development, Tianjin, China

Maria Song, MD, PhD, MBA

President, VPSCRO

Member of Venturepharm Group, Beijing, China

Hongjun Yang, PhD

Shanghai Clinical Research Center, Shanghai, China

Derek Zhang, PhD

Vice President

Regulatory Affairs and Clinical Pharmacology
Frontage Laboratories, Inc. Malvern, PA

Jason Jin, MD, PhD

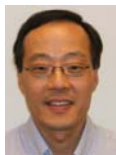
President & CEO

ShanghaiBio, New Brunswick, NJ

5:10

Wrap Up & Conference Adjourn

Speaker Biographies (Listed Alphabetically)



David J. Chang, M.D., M.P.H.

David J. Chang is currently Vice-President, Global Clinical Development, GlaxoSmithKline for Immuno-Inflammation. Prior to joining GSK, David was involved in clinical research at Wyeth and Merck.

After earning his undergraduate degree from Yale University and medical degree from New York University School of Medicine, David completed his Internal Medicine internship and residency at The New York Hospital—Cornell University Medical Center and Rheumatology fellowship from The Hospital for Special Surgery—Cornell University Medical Center. He also completed a degree program for a Masters of Public Health from Emory University with a concentration in health outcomes and epidemiology.

For several years, David served as a full-time academic faculty member, most recently at the University of Pennsylvania prior to joining the pharmaceutical industry. He is a Board-Certified rheumatologist and Fellow of the American College of Rheumatology and holds a faculty appointment at the University of Pennsylvania as an Adjunct Assistant Professor in the Division of Rheumatology.



Xiaoxiang Chen, M.D.

Xiaoxiang graduated from Nanjing Medical University after the graduation training in Clinical cardiology. Since entering into pharmaceutical industry from Suzhou Medical College hospital, Xiaoxiang has worked across several functional areas including regulatory, global medical and clinical research for 12 years.

As the founder of Wyeth CR&D organization in China, Xiaoxiang started conducting global CR&D trials in China since 2000, successfully built up a full-functioning CR&D group, including clinical development/medical monitor/Clinical logistics/safety review teams. In March 2007, as the key team member successfully established the first ECDC (early clinical development center) of the world in Peking Union Medical Collegeville Hospital, established 2 others in Beijing in 2008. Xiaoxiang was granted with Wyeth Research President's award as the recognition in setting up new CR&D organization in Asia Pacific.

Xiaoxiang was the head of CR&D China with Wyeth Research until Oct 2008, responsible for all clinical development programs in China, also acted as the regional medical monitor for eastern Asia including China/Taiwan/Hongkong/Singapore/Korea. While on this role, Xiaoxiang successfully explored the feasibility and strategy in participating early phase global trials (Proof of Concept study) from China, participated in the first phase II study of global development for several new drugs. Up to 2008, the contribution of China/Asia to global clinical development has been sharply increased to about 20% from 2% in 2001. Xiaoxiang currently is associate director in Neuroscience division of global CR&D, Wyeth Research. On this position, Xiaoxiang is the global medical monitor for clinical trials on chronic pain diseases, providing medical instructions on protocol design, study conduct, data review and interpretation.



Frank Gan, PharmD.

Frank is a clinical scientist and protocol manager in Discovery Medicine and Clinical Pharmacology Department of Bristol-Myers Squibb Co.

Frank has more than 11 years working experiences as a research scientist in both academia and biopharmaceutical industry. He switched his career path from basic research to clinical research in 2004 while working at Merck. Frank graduated from Shanghai Medical University with BS and MS in pharmaceutical sciences and earned his PharmD degree from Shenandoah University.



Gary Huang, M.D.

Dr. Gary Huang got his MD from Sun Yat-sen University of Medical Sciences. He started his clinical trail experience at Tulane University Medical center clinical trail unit where he was in charge of clinical lab database. He started his first company when he was a scientist at University of Michigan in 1993. He is the co-founder of InfoStat Inc. and has provided clinical trail service to many pharmaceutical companies. Last year he and his partner started Q-Square Business Intelligences (Q2BI) to concentrate on providing CDISC service to pharmaceutical industry. Before that, he was senior manager of Biostatistics and Data Management at Hana Biosciences Inc.



Jason (Gang) Jin, M.D., Ph.D.

Dr. Jason (Gang) Jin is the President & CEO of ShanghaiBio Corporation (SBC for CRO), and Co-Founder & Executive VP of Global Business of Shanghai Biochip Co. Ltd (SBC), a leading biotech in China with lab operations at Shanghai and global business office at New Jersey in U.S. Dr. Jin is also an adjunct professor at the Shanghai Institutes of Biological Sciences (SIBS), Chinese Academy of Sciences (CAS). Dr. Jin has extensive scientific and business development experience in drug discovery and development. He has successfully developed and managed a number of R&D collaborative projects in biology discovery, preclinical research, and clinical trials with top global pharmaceutical and biotech companies. Dr. Jin has held the former positions of Director of Genomics Lab at Purdue Pharma (USA), Director of Functional Genomics at Salk Institute (USA), Founder Director of National Engineering Center for Biochip at Shanghai (China), and radiologist at Shanghai Zhongshan Hospital (China). He received Ph.D. and Postdoctoral Fellow in biology from University of California, San Diego (USA), and medical degree from School of Medicine, Fudan University (Shanghai Medical University, China).



Zhengqing Li, Ph.D.

Dr. Li received his PhD from the University of Wisconsin –Madison in Statistics in 1996. After graduation, Dr. Li started his career as an Assistant Professor in the School of Public Health in State University of New York at Albany first. In 1998, Dr Li moved to pharmaceutical industry. Since then, he has been worked in pharmaceutical industry with several companies (Proctor &Gamble Pharmaceuticals, Pfizer, and Bristol-Myers Squibb) over the past 10 years. Dr. Li has published 20+ papers in statistical journal as well as medical journals. Currently, Dr. Li is an Executive Director for Global Biometric Sciences in BMS with responsibility for Oncology and Neuroscience Therapeutic Areas.



Fang Liu, Ph.D.

Dr. Fang Liu is Senior Biometrician in Clinical Biostatistics and Decision Sciences at Merck Research Lab. Dr. Liu collaborates with biomedical research scientists on all statistical aspects of early clinical drug development. Dr. Liu holds a Ph.D. in Biostatistics from University of Michigan, Ann Arbor. Her statistical research interest includes experimental designs, analysis of missing data, exploratory data analysis, Bayesian Statistics, and statistical methods in pharmacokinetics and pharmacodynamics studies.



Jason Lu, Ph.D.

Dr. Jason Lu has 12 plus years experience in the pharmaceutical industry in US starting as a post-doctoral fellow in target discovery and validation at AstraZeneca after he earned his PhD in Biochemistry and Genetics from Rutgers University. He then worked as senior scientist at Schering-Plough in drug discovery for many years.

Dr. Jason Lu entered business and management functions by working as the vice president business development for Shanghai Pharmaceutical Group Company, one of the largest pharmaceutical companies in China, marketing and selling contract chemical manufacturing services in the North America markets. He then worked as a consultant in many global companies as a contracts and project manager in the clinical operation function in recent years.

Prior to his PhD training in US, Dr. Jason Lu obtained his medical training in Pediatrics from Shanghai Jiaotong University School of Medicine, completed graduate study in Chinese CDC and then practiced in the area of Pediatric Hematology. He is currently the Leader, Outcome Research and Reimbursement at Merck, managing studies projects that lead to the product value dossiers.



Michael Krams, M.D.

Michael Krams is Vice President for Adaptive Trials and Applied Program Strategies at Wyeth Research. Mike's ambition is to bring innovative approaches to clinical drug development, to facilitate better and earlier decision making. He is recognized as an expert in designing, implementing and executing adaptive designs, enabling real-time learning in Learn and Confirm studies. He has built an industry leading cross-functional team of drug developers, applying Modeling & Simulation techniques and integrating input from clinical, translational medicine, biostatistics, discovery and commercial. The emphasis is on applying innovative designs across therapeutic areas, including small molecules, vaccines and biologics. Mike co-chairs clinical review committees and continuously challenges teams to apply scientific rigor to decision problems without losing sight of the business case.

As co-chair of PhRMA's working group on adaptive designs Mike has contributed to an ongoing debate with regulatory agencies, with a goal to establish a common position on "Good Adaptive Practices". A neurologist by training, Mike has a background in functional brain imaging and worked with Dick Passingham and Richard Frackowiak at the Wellcome Dept Cognitive Neurology in London. In his spare time Mike plays the piano and swims (using similar body movements for both activities).



Rose Qiu, M.D., Ph.D.

Rose completed her training in clinical medicine in China and continued her study in pharmacology with a PhD and post-doc. from University of Toronto and Stanford University. Since entering pharmaceutical industry, Rose has gained extensive experiences in clinical R & D, regulatory affairs and pharmacovigilance.

Rose is currently senior director, Internal medicine, Johnson & Johnson Pharmaceutical Research and Development, with focus on clinical trial design, study management, and Asia Pacific regulatory/clinical strategy. Prior to that, Rose was the head of Global Clinical Operation (GCO), Asia Pacific, Johnson and Johnson. She is responsible for leading the Asia Pacific GCO team to strengthen infrastructure and contribute to global clinical development programs, ensuring optimal resource planning and management of quality, speed and cost efficiency of clinical studies conducted in AP, driving regional strategy and demonstrating therapeutic area and operational advantages in AP region.

Prior to her Asia Pacific role, Rose was the head of R & D with Xian-Janssen Pharmaceutical and global clinical organization of J & J, China. She was responsible for the functions of clinical research, regulatory affairs and drug safety.



Joan Huaqiong Shen, M.D., Ph.D.

Earning a medical degree in Nanjing and a graduate degree in Chengdu, Joan began her career in China as a surgeon. She later pursued the PhD degree in Indiana University School of Medicine, where she also obtained her residency training in the dept. of psychiatry, 3 fellowships in endocrinology, clinical pharmacology and psychopharmacology. Having been board certified in psychiatry and board eligible in clinical pharmacology, Joan soon joined Eli Lilly and Company as a clinical research physician working on phase 3 and 4 clinical studies and safety monitoring of drug development. Simultaneously as an adjunctive professor, Joan continued to work in IU Hospital outpatient clinic and as a part time staff physician in Wabash Valley Hospital until she made the move to Wyeth.

Currently holding a position in Wyeth as a medical director and medical monitor, Joan is in charge of clinical programs with compounds for psychiatric indications in phase 2 & 3 clinical studies. Her recent contributions include a successful study of proof of concept on a compound with a brand new target. She is also leading the efforts for Wyeth CNS global trials to move to China, India, Japan, South Africa, East Europe and etc. Particularly, she is leading the neuroscience China/Asian initiative, which includes conducting clinical studies in that region, helping with the SFDA regulatory interactions, building up relationships with the key opinion leaders, vendor selections, site set-ups and etc. Her accomplishments also include multiple publications in scientific journals and as an invited speaker to national/international conferences.



Maria Song, M.D., Ph.D., M.B.A.

Dr. Song, Pharmacist, Chairman of VPSCRO. Chief of Regulatory Affairs. Dr. Song got her Ph.D. from Peking Union Medical University, and is the member of AAPS. She has had over 15 years of experience in drug development, and conducted a great number of multi-center clinical trials and local registration trials, as well as Phase IV studies for domestic and international clients. In addition, being an expert in SFDA regulation, Dr Song' has been often sought for advice by the regulatory authority in State drug policy making, and by clients from the industry for various pharmaceutical product registration with SFDA.



Jingsong Wang, M.D., F.A.C.R.

Jingsong Wang is a Director, Discovery Medicine & Clinical Pharmacology, at Bristol-Myers Squibb Co (BMS). More recently, Jingsong has taken on a leadership role as the Exploratory Development Team (EDT) leader oversees a clinical development program with multiple assets targeting several diseases.

Jingsong joined BMS from Wyeth where he served Associate Director, and later as the group leader for Translational Medicine and Biomarker Development in Inflammation and Rheumatologic Disease Area. Prior to that, Jingsong was at Brigham and Women's Hospital and Harvard Medical School where he was an attending rheumatologist and faculty member. Jingsong has also completed a research fellowship in the laboratory of Dr. Laurie Glimcher at the Harvard School of Public Health.

Jingsong has published in numerous leading scientific journals and authored a number of textbook chapters related to inflammation and autoimmune diseases. Jingsong is a Board-Certified rheumatologist and Fellow of the American College of Rheumatology, a Diplomate of American Board of Internal Medicine. Jingsong's academic appointments include visiting professorships in China, and he is an Adjunct Assistant Professor of Medicine at University of Pennsylvania, and an attending physician at the Hospital of The University of Pennsylvania. He has served on the Research Grant Review Committee on Immunology, National Natural Science Foundation of China (NSFC), and as a member of the expert panel for Biotechnology Industry Organization (BIO) congressional staff briefing on biotechnology and autoimmune diseases, Capitol Hill, Washington DC.



Xi-De Wang, Ph.D.

Xi-De Wang, Ph.D., is currently a Senior Research Investigator in the Oncology Clinical Biomarker group of Discovery Medicine and Clinical Pharmacology at Bristol-Myers Squibb. Prior to joining BMS at 2006, he was a postdoctoral fellow at Genentech in South San Francisco for three years. He obtained his BS degree from Xiamen University in 1993, MS degree from Institute of Biophysics, Chinese Academy of Sciences in 1996 and Ph.D. degree from Michigan State University in 2002.



Hongjun Yang, Ph.D.

Dr. Hongjun Yang has been Sr. Advisor to CEO at Shanghai Clinical Research Center (SCRC) since last September while he also serves as a founding member, president and COO at Suzhou Sirnaomics Biopharmaceuticals. His main role at SCRC is helping CEO to define the infrastructure and business direction, especially in translational research field for its future growth, as well as to explore the global business opportunity. Prior to being recruited as an executive director in 2003 for the National Center for biochip Technology in Shanghai, Dr. Yang had over 18 years of combined education and industrial experience in the US. Dr. Yang is a renowned expert in the design and development of biochip and diagnostic technologies and products. He started his career in US as a research scientist at IGEN with a variety of research interests. He successfully developed and commercialized a novel diagnostic electrochemiluminescence technology and product that is now licensed and used in Roche Cobas instrument series. Subsequently he discovered multiwavelength ECL, lanthanide chelates ECL, miniaturized ECL instrument for POC product, etc. His first author paper in Nature/Biotechnology was published in 1994. Because of his diversified experience and background in scientific research and engineering, because of his success and accomplishment at IGEN, from 1995 Dr. Yang was recruited as a technical management executive for a series of start up biochip companies such as Genometrix, Nanogen, and finally Gene Logic, etc. At Gene Logic, Dr. Yang has developed and commercialized new generation of biochip platform, flow-thru chip technology and its system. Dr. Yang also actively involved in gene expression database business and used the database to developed disease-focused chips for diagnostic and prognostic applications.

In 2003 Dr. Yang was returned to his hometown, Shanghai to help to establish the National Center for biochip Technology, Shanghai. Then, he further transformed this academic oriented institute into a CRO type commercial company that was recognized internationally. Afterward, Dr. Yang transformed another academic institute, Tianjin Biochip Corporation to a business driven CRO that complied with US GLP requirements. To recognize his leadership, dedication, devotion, Dr. Yang received Outstanding Contribution Award from TEDA in 2007. Dr. Yang was also involved in making China hi-tech development plan, 863 program and in charge of the biochip and diagnostic technology parts of the program. Dr. Yang was also invited to be a co-chairman of the first international forum on IVD in China.

Dr. Yang has been selected as a member and co-founder of American Academy of Nanomedicine, a member of Chinese Biochip Association, a member of Chinese Nanotechnology Association, and a member of Shanghai Bioinformatics Association, and a visiting professor at Wasada University. Dr. Yang received his Ph.D. in Chemistry under the supervision of Prof. Allen J. Bard, Dept. of Chemistry and Biochemistry, The University of Texas at Austin in 1991.



Dan Zhang, M.D. M.P.H.

Dr. Dan Zhang has more than 10 year of drug development experience. He is the Chief Executive Officer of Fountain Medical Development, a full-service clinical CRO with primary operation in China. Previously, Dr. Zhang was the Head of Clinical Development and Global Safety Assessment at Sigma-Tau Research Inc, a US research arm of Sigma-Tau S.P.A., one of the largest Italy-based pharmaceutical firms with employees of 2300. Dr. Zhang managed the firm's entire clinical development program in North American market, including oncology, cardiovascular, CNS, and metabolic development projects, in addition to his global role of drug safety handling.

Prior to his life at Sigma-Tau, Dr. Dan Zhang was a vice president at the Quintiles Transnational Corp.-the largest contract research organization (CRO) in the world, responsible for the planning and implementation of business development strategies in Greater China Area. He was also a member of Executive Operating Committee of Quintiles Transnational Corp. Dr. Zhang was also the Chairman of the Board, Quintiles Medical Development (Shanghai) Company Ltd., a wholly-owned subsidiary of Quintiles Transnational Corp. Before joining Quintiles, Dr. Zhang provided consulting services to many pharmaceutical, medical device and health insurance companies, such as Eli Lilly and Company, Pharmacia & Upjohn, Inc., Medtronic, Inc., and CIGNA Health Care, etc.

Over last ten years, Dr. Zhang established a strong working relationship with government and academic institutions in China. He was a member of the Overseas Expert Committee on New Drug R&D for the Ministry of Science and Technology of China. He was also a visiting professor at the Harbin Medical University of China. In addition, Dr. Zhang was a Ph.D. advisor and consultant for then Shanghai Medical University in the field of Pharmacoeconomic study and clinical trials. He is currently a senior consultant to Chinese Academy of Medical Sciences/Peking Union Medical College. Dr. Zhang was an Executive Director of Sino-American Professional Pharmaceutical Society (SAPA). He was the President (2006-2007), Chinese Biopharmaceutical Association-USA (CBA).

Dr. Zhang received his pre-med training from Beijing University and received his M.D. from Peking Union Medical College. He continued his study at the Harvard School of Public Health and received an MPH in health policy and management. Then he continued his training at the Wharton Business School of the University of Pennsylvania, where he obtained his master's degree in healthcare management in 1998 and is working on his Ph.D. dissertation in the field of health economics and finance. Dr. Zhang has published several papers in the fields of medical research and health economics, and is a frequent speaker at various health care-related conferences.



Danyi Zhang, M.D.

After almost 15 years of successful experience in pharmaceutical industry across several function areas including clinical research, strategic marketing, and medical affairs, Dr. Danyi Zhang left her most recent role as the medical director in global medical affairs of Bristol-Myers Squibb and founded VitalStrategic Research Institute (VSRI). The VSRI's mission is to partner with global biopharmaceutical and medical device corporations and collaborate with worldwide academic institutions to create solutions for bettering evidence-based medicine. VSRI designs and executes clinical trials and outcomes research, produces Medical Expert Reports, develops health informatics and health economic measuring tools, and conducts medical educations for physicians and patients.

Dr. Zhang is the executive director of Fudan University, School of Public Health, Evidence Based Medicine Research Center, a senior scholar of Thomas Jefferson Medical College, Department of Health Policy, and Chairman of Operation Committee of China Cardiometabolic Registries (CCMR), the largest registry program ever launched in China. Danyi graduated from Shanghai Medical School of Fudan University, and received post graduate education at Massachusetts Institute of Technology and research training at Harvard Medical School.



Derek Yuanchao Zhang, Ph.D.

Derek is Vice President, Regulatory Affairs and Clinical Pharmacology, Frontage Laboratories Inc. Derek recently joined Frontage from the FDA. Derek has more than 10 years of experience in drug research, development and regulatory approval, including 4 years of industrial experience at Pfizer and over 6 years of regulatory experience at the FDA.

Derek was Senior Clinical Pharmacology Reviewer in the Office of Clinical Pharmacology, the Center for Drug Evaluation and Research, the Food and Drug Administration. He successfully reviewed numerous NDAs (including several NME NDAs and BLAs), NDA supplements, and IND submissions. He also contributed to several guidance document development and revision. Derek has extensive experience in clinical pharmacology drug development plans/strategies and regulatory requirements. Prior to the FDA, Derek was Senior Research Scientist at Pharmacokinetics, Dynamics & Drug Metabolism (PDM), Groton Laboratories, Pfizer Global Research & Development, Pfizer Inc.

Derek received his Ph.D. from the University of California, San Francisco (UCSF) under Professor Leslie Z. Benet. Derek is a member of American Association of Pharmaceutical Scientists (AAPS) and American Society for Clinical Pharmacology and Therapeutics (ASCPT). His major scientific interests include PK/PD, drug interactions, interplay of drug metabolism enzymes and transporters, pharmacogenomics, and effect of renal impairment on enzymes and transporters. He has authored or co-authored many papers, book chapters, abstracts, and invited presentations in the areas of clinical pharmacology.



Jiwen Zhang, Ph.D.

Dr. Jiwen Zhang obtained her B.S. in Biology from University of Science and Technology of China and her Ph.D. in Neuroscience from the joint Physiology and Neurobiology program at Rutgers University and University of Medicine and Dentistry of New Jersey.

Dr. Zhang currently is an Associate Director in Corporate Regulatory Affairs at Sanofi-Aventis. Following her postdoctoral training in the Immunology Department at Schering-Plough, Dr. Zhang transferred to Regulatory Affairs, working at Chimeric Therapies, Inc., Centocor/Johnson & Johnson, Merck & Co., and Wyeth Pharmaceuticals. Her regulatory experience includes marketed products, such as Enbrel for rheumatic diseases and psoriasis, Infuse/InductOs (biologic/device combination product) for spinal fusion and tibia fracture repair, Crixivan and Stocrin for treatment of HIV disease, and Maxalt for migraine headache. Dr. Zhang has also served as Global Regulatory Lead on development compounds for respiratory indications, bone/tendon repair treatments, inflammatory disease therapies, and bone marrow transplant (cellular therapy to treat leukemia). Dr. Zhang has given speeches and published essays on pharmaceutical product regulations.



Sean Zhang, M.D.

Dr. Zhang is the Clinical Leader and Safety Physician at Johnson and Johnson PRD, he held clinical leadership responsibility for several projects in early development from Phase 0 to Phase IIa, which include candidate evaluation, protocol design, clinical plan development, communication with KOLs, regulatory interactions, IND submission and clinical trial execution. Prior to his current position, Dr. Zhang completed three years clinical fellowship program in Clinical Pharmacology and Early Drug Development at NIH Clinical Center under Dr. Arthur Atkinson, who is one of the most renowned authorities in Clinical Pharmacology.

Dr. Zhang is a medical graduate from Third Military Medical University in Chongqing, China. He worked as a Staff Physician and Clinical Investigator at 301 Hospital in Beijing for eight years before headed to USA for his postdoctoral fellowship at UCLA School of Medicine and Michigan State University. Dr. Zhang also devoted several years of his early career at drug research and discovery in multiple therapeutic areas. Dr. Zhang has published more than 30 peer-reviewed papers.



Baiteng Zhao, Ph.D.

Baiteng Zhao, Ph.D., is a Sr. Research Pharmacokineticist at Clinical PK/PD, DMPK, Merck Research Laboratories, Merck & Co., Inc. He is responsible for the design of and evaluation of data from clinical and preclinical studies relating to the kinetics of drug absorption and disposition, applying pharmacokinetic concepts and techniques in the design and evaluation of dosage forms and dosage regimens; the design of PK/PD and population PK analysis plans; and the conduct of PK/PD modeling and simulation to support both small molecule and biologics drug development in multiple therapeutic areas. He obtained his B.S. degree in Biology from Peking University and Ph.D. degree in Pharmaceutics from the University of Texas at Austin and trained as a post-doctoral fellow in the Department of Pharmaceutical Sciences at SUNY Buffalo before joining Merck in 2006.



Simon Zhou, Ph.D.

Dr. Zhou is currently a director in the department of Early Development Clinical Pharmacology at Wyeth Research in Collegeville, PA. In this capacity, he has been responsible for the clinical pharmacology characterization of drug candidates from phase I to phase IV, participated in development and implementation of overall clinical development strategy to determine clinical pharmacokinetics, pharmacodynamics and exposure-response of drug candidates, designed and analyzed clinical protocols, submitted INDs and NDAs and interacted with regulatory agencies around the globe. Prior to his current position, he has worked in preclinical and clinical drug development functions addressing clinical pharmacology, biopharmaceutical and trial design issues at Pfizer and Bristol-Myers Squibb.

Dr. Zhou has received recognition and awards in Bristol-Myers and Wyeth for his work to advance drug candidates in clinical development and obtain regulatory approval of expanded indications and patent extension of marketed drugs. In 2009, he is one of the 7 winners of R&D Presidential Award in Research at Wyeth. He has published manuscripts in biopharmaceutics, drug delivery and pharmacokinetic and pharmacodynamic modeling. Dr. Zhou holds Bachelor and Master degrees in Chemistry, a Ph.D. in Pharmaceutics and a Graduate Certificate on Modeling of Complex System from the University of Michigan.

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ShanghaiBio is the CRO subsidiary of Shanghai Biochip Co., Ltd (SBC). SBC/ShanghaiBio, a leading biotech in China with business operations in the U.S., performs a full spectrum of R&D services for global pharma/biotech companies. Situated on its own 10-acre campus in the heart of Shanghai's Zhangjiang Hi-Tech Park, considered to be China's Bio/Pharma Valley, SBC/ShanghaiBio operates in seven buildings totaling 220,000 SQF that contain offices and laboratories. State-of-the-art labs provide GLP/GMP-compliant services and continually undergo rigorous QA audits. The scientific staff, which numbers around 300, is chiefly home-grown talent trained by professionals schooled in western ways. SBC/ShanghaiBio's global headquarters for business development and customer service support are located in New Jersey. By establishing its US base in the "Medicine Cabinet of the World," SBC/ShanghaiBio is easily accessible to its primary multinational client base and able to address concerns and challenges that arise from outsourcing critical R&D functions to a partner half-a-world away.

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