

SAPA-GP Clinical Trials & Innovative Drug Development Conference

Reported by Xi Ouyang



On March 21, Sino-American Pharmaceutical Professionals Association – the Greater Philadelphia Chapter (SAPA-GP) started off 2009 with a successful member conference, “Clinical Trials & Innovative Drug Development Conference” at Crowne Plaza Valley Forge. Despite the current economic crisis, this one-day event attracted nearly 200 attendees from top pharmaceutical companies, as well as leading contract research organizations (CRO) based in the US or China. The high quality program attracted participants from not only the Greater Philadelphia area but also from New Jersey, New York, Connecticut, Massachusetts, Maryland and North Carolina. There were attendees from China as well.

Carefully orchestrated by Dr. Jingsong Wang, Director of Discovery Medicine & Clinical Pharmacology at Bristol-Myers Squibb, and Joan Shen, Director of Clinical Research & Development at Wyeth Research, the program featured ten speakers at top executive or management level from five major pharmaceutical companies. The speakers covered the general principles of all spectrums of clinical trials and shared their insights on the challenges and opportunities in clinical drug development. This event also provided a superb networking opportunity for SAPA members to meet with executives of large pharmaceutical companies, the founders and CEOs of various Biotech and CRO companies.

Dr. Li Yan, 2009 President for SAPA-GP, started the conference with an enthusiastic kickoff speech on SAPA-GP’s mission and aspiration to enter the mainstream of American professional organizations. Dr. Jingsong Wang, co-chair of the conference, then introduced the program and invited Dr. Michael Krams, Vice President of Clinical Research & Development at Wyeth Research, to give the morning keynote speech.

With a focus on adaptive trials and applied program strategies, Dr. Krams enumerated Wyeth’s innovative approaches to expedite clinical drug development through a learn-and-confirm decision making process, which has been adopted across the industry. “By integrating input from clinical, translational medicine, biostatistics, discovery and commercial”, Dr. Krams explained, “modeling & simulation techniques and teamwork leveraged the brain power and unparalleled resources within Wyeth to fast track high quality drug development for small molecules, vaccines and biologics.” He successfully set the theme for this conference: innovation, motivation, and collaboration.

The second speaker was Dr. Sean Zhang, Clinical Leader and Associate Director in the Early R&D development at Johnson & Johnson. He gave a scientific overview of clinical study design for early drug development. The presentation encompassed both technical aspects from phase I to IIa clinical



development and a strategic review of the “All-In-One” protocol approach by Johnson & Johnson.

After a brief coffee break, the session resumed with a feature presentation by Dr. Joan Shen, Director of Clinical Research & Development at Wyeth Research. She first discussed the concepts of phase II and III and key aspects in balancing the risk and benefit during/after the clinical studies. She then compared multiple countries, such as Russia, India, China, and Japan, for conducting clinical studies, in terms of infrastructure, culture, and regulatory environment. The presentation raised quite a few interesting questions from the audience on how to help China build China’s international reputation for clinical research and development.

To explain the role of clinical pharmacology in laymen’s terms, Dr. Simon Zhou, Director of Early Development & Clinical Pharmacology at Wyeth Research, used Lipitor’s package insert as an example to describe 70% of clinical topics is related to clinical pharmacology. By the end of his speech, it was clear that 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 morning session concluded with an inspirational speech by Dr. Zhengqing Li, Executive Director of Global Biometrics Science at Bristol-Myers Squibb. He elaborated how biostatistics has evolved as an integral part of clinical development and how professionals in this arena could add value to their firm by offering strategic and tactical insights on drug development.

The second part of the conference started with a keynote speech by Dr. David Chang, Vice President of Clinical Development at GlaxoSmithKline and Adjunct Assistant Professor of Medicine at University of Pennsylvania. With vivid exhibitions and a sense of humor, he enlightened the gloomy outlook for the pharmaceutical industry. For example, both the US 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.

Transitioning back to science, Dr. Jingsong Wang demonstrated the importance of transitional medicine and biomarkers and highlighted their practical applications in clinical development. Whereas, Dr. Danyi Zhang, Chief Medical Officer of Vital Strategic Research Institute, stressed that the life cycle management for a new medicine will ensure its life-time success. The talk evoked critical thinking for strategic planning and tactical approach of any product development.

