

Clinical Trials & Innovative Drug Development Conference Report

2009 SAPA-GP Conference Series

Reporter: Xi Ouyang

On March 21th, 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.



The conference started with Dr. Li Yan, 2009 President for SAPA-GP, 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 designs 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 the international reputation for clinical research and development.



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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.

With skyrocketing costs to develop new drugs, more and more multinational pharmaceutical companies resort to emerging markets with a hope to lower the cost and exploit new market potential, the conference invited Dr. Xiaoxiang Chen to refer to his experience with China for clinical trials. He is the Former Head of CR&D China at Wyeth Research. His presentation gave the audience a well-rounded view of Chinese market for clinical trials. To build on that, Dr. Rose Qiu, Senior Director of Internal Medicine at Johnson & Johnson broadened the topic to Asia Pacific. Specifically, she addressed how her team built up an efficient evaluation structure to help choose the right country/region for particular clinical trials while leveraging internal resources and maximizing external capabilities.

The highlight of the conference came from a virtual clinical trial team forum. What does it take to conduct a successful clinical trial? What is the role of each team member? The forum showcased a cross-functional, cross-company high performance team with seven distinguished professionals, each explaining major responsibilities as a team member and career progression. One of the attendees stated, "This really helps me to evaluate potential career directions."



Towards the end of the program, representatives from four rising CROs based in China introduced their companies' research capabilities. Those companies were all financially successful and eager to recruit top talents with US-trained bilingual background. Their passion and sincerity was well received by the audience. After their presentations, members also got face-to-face meeting times with those companies to explore career opportunities.



The success of the first SAPA-GP member conference exemplified again its ability in fostering the communications and cooperation between drug discovery and development as well as pharmaceutical/biotech enterprises in the US and China. We thank all the speakers for their spectacular presentations. We appreciate the excellent work by co-chair Dr. Jingsong Wang and Dr Joan Shen, and Dr. James Mu, our VIP guest and photographer. Thanks to

our organization committee for their contribution as well. We look forward to the next program

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