

Conference Agenda

Day 1 – 19th September 2011

8.00 – 8.50

Registration

8.50 – 9.00

Chairman's opening remarks

9.00 – 9.40

Presentation

An overview of the current clinical trial landscape in China

- China 2011: A summary of developments over the last 12 months
- Future challenges and opportunities

Patrecia Flynn Valone, Director, Development Operations at Takeda Global Research & Development (TGRD) Asia Singapore

9.40 – 10.20

Presentation

Major Issues with conducting Clinical trials in China

- Dynamic/fluid Environment
- Ethical concerns & corruption is endemic

Proposed solutions

- Talents – “Hai Gui”
- Regulatory and compliance
- Communication and client interface
- Supporting mechanism – infrastructure and funding
- Training – start with a clean slate

Stephen Porter, CEO, VDDI Pharmaceutical and Chief Scientific Officer, Dragon-BioConsulting, USA (Confirmed)

10.20 – 11.30

Morning refreshments – Sponsored by Corelabs**One to One meetings**

11.30 – 12.10

Presentation

Presentation by Choice Pharma – Gold Sponsors of the 3rd China Clinical Trials Outsourcing Congress

Chris Toller, Director of New Projects, Choice Pharma, UK

12.10 – 12.50

Presentation

Possible future scenarios relevant to outsourcing clinical trials to China

Combining scenarios with business model innovation efforts is indispensable to help organization prepare for the future. Based on first-hand experience at European Perspectives in Personalized Medicine (Brussels, 12-13 May 2011), organized by European commission, it is increasing evidence that the landscape of both the academic scientific community and patient group-driven pharmaceutical industry will change towards two trends - the rise of personalized drugs and the increasing importance of prevention. In preparation for which combinations of the two trends that will eventually becoming the mainstream, it is important to investigate what are the peripheral opportunities in terms of new technology development, societal and cultural and socioeconomic trends in China. These investigations are important not only to recognize what forces could potentially influence the future of China healthcare reform (especially in the area of healthcare IT), but also to explore new possible ways to outsource clinical trials to China that would help to prepare the pharmaceutical industry for the future trends in Europe.

Kah Tong SEOW, CEO, WEI Medicine

12.50 – 13.50

Lunch – Sponsored by World Courier

13.50 – 14.30
Presentation

Presentation by World Courier –
Silver Sponsor of the 3rd China Clinical Trials Outsourcing Congress

Clinical Trial Supply Management in China

- China market and challenges
- Clinical trial supply management strategies
- Local warehousing solutions V Integrated service suppliers
- Case study of clinical trials supply in China

Andy Teo, Director Business Development, Asia Pacific, World Courier, China

14.30 – 15.10
Panel Discussion

Panel discussion: Maintaining costs and delivering trials on time in China

- Current trends in outsourcing clinical trials in China
- Regulatory issues and legal requirements
- Logistical considerations
- Examining cross-cultural considerations that may affect your business activities

Patrecia Flynn Valone Director, Development Operations at Takeda Global Research & Development (TGRD) Asia Singapore

Stephen Porter, CEO, VDDI Pharmaceutical and Chief Scientific Officer, Dragon-BioConsulting, USA

Chris Toller, Director of New Projects, Choice Pharma, UK

15.10 – 16.20

Afternoon refreshments – Sponsored by Corelabs

One to One meeting sessions

16.20 – 17.00
Presentation

Case study: Assuring quality and safety during the operation of the trial

- Identifying and addressing the key challenges
- Risk management and contingency planning
- Complying with ongoing quality audits and inspections

Li Ding, AP Trial Operation Department Head, Sanofi Aventis, China

17.10 – 18.00

Round-tables: Drug development opportunities in China:

Facilitated round-table discussions examining drug development in China:

1. Regulatory Affairs
2. Logistics
3. Patient Recruitment

18.00 – 19.00

Networking Drinks Reception

9.00 – 9.10

Chairman's opening remarks

9.10 – 9.50
Presentation

Tapping into new business models to grow your business

- An overview of the trend for partnerships and collaborative networks in China
- Examining the options for large, medium and small companies
- Future business opportunities in China

Horst Fischer, Head of Strategy and Portfolio Management, Bayer Pharma AG, Germany

9.50 – 10.30
Presentation

A guide to intellectual property protection

- An overview of the regulations around intellectual property
- Patenting drug product inventions
- Administrative protection

Hiroshi Sheraton, Partner, McDermott, Will & Emery

10.30 – 11.40

Morning refreshments – Sponsored by Corelabs

One to One meetings

11.40 – 12.20
Presentation

Regulatory Affairs in China

- Landscape in China: general overview of the regulatory system in China
- What is required for regulatory approval in China?
- Common pitfalls and guidance for Regulatory Success in China

Andrew Notley, Director Regulatory Affairs Asia Pacific, Research Pharmaceutical Services (RPS), Australia

12.20 – 13.20

Lunch – Sponsored by World Courier

13.20 – 14.00
Panel Discussion

Panel discussion: Optimizing clinical trial supply and distribution logistics in China

- Examining the most effective transportation routes
- Customs clearance processes
- Making arrangements for time- and temperature-sensitive supplies
- Vetting third-party freight carriers and storage facilities

Alex Klim, Product Manager Clinical Trial Logistics, DHL Supply Chain
(further participants to be confirmed)

14.00 – 14.40
Presentation

Strategies for successful patient recruitment and retention

- Examining the avenues for recruiting patients
- Selecting the right clinical site for the study
- Enrolling the right patients for your trial
- Putting effective measures in place to retain patients

Yan Cai, Senior Director, Johnson and Johnson (China)

14.40 – 15.20
Presentation

The necessity for ethics scrutiny in Chinese-European trials

- Ensuring equivalent protection of clinical-trial participants
- Ensuring that legal, political, social and cultural differences between China and European nations don't lead to multiple standards
- Recommendations to assist transparency and mutual understanding

Catherine Elliott, MD, MPhil, MRCOG, Head of Clinical Research Support and Ethics, Medical Research Council (UK)

15.20 – 15.30

Chairman's closing remarks

15.30 – 16.00

Afternoon refreshments and Questionnaire Prize Draw