



# 2nd Annual Data Collection and Management in Clinical Trials Asia 2011

Main Conference: 6 & 7 December 2011 • Post-Conference workshops: 8 December 2011  
Venue: Renaissance Beijing Capital Hotel

Book before  
**16 September 2011**  
and save up to **USD 800**

Effectively Collecting, Analysing and Managing Clinical Trial Data to Enhance Data Quality, Save Costs, Increase Clinical Trial Efficiency and Reduce Time to Market

The **ONLY** dedicated platform in Asia for data collection and management in clinical trials

## Featuring the following experts:



**Bruce Xue**  
Biostatistical Manager, Medical Affairs Department  
**Xian-Janssen Pharmaceutical**



**Jessie Chen**  
Head of Global Clinical Data Services  
**Pfizer (China) Research & Development Center**



**Charles Yan**  
Senior Director, Clinical Data Management  
**Shanghai Clinical Research Center**



**Julia Zhang**  
Associate Director, Standard Programme Manager  
**Genzyme**



**Charlie Chen**  
Vice President  
**GCP ClinPlus**



**Li Ding**  
Director, Trial Operations  
Asia Pacific Coordinator, Trial Operations China Group Leader  
**sanofi-aventis China**



**Charlie Xu**  
Vice President  
**Frontage Clinical Services**



**Mubarak Naqvi**  
CRU Director, India  
**sanofi-aventis**



**Ian O'Shaughnessy**  
Director, Data Management Asia Pacific  
**ICON Clinical Research**



**Randy Dai**  
Data Manager  
**AstraZeneca**



**Christopher Huang**  
Founder & General Manager  
**Pharmacons Tech**



**Shabbir Rangwala**  
Executive Director, Global Services and Site Head  
**INC Research India**



**Deng YaZhong**  
Head of CDARO China  
**Covance**



**Sun HuaLong**  
Manager GRO, Data Processing  
**Parexel**



**Jessica Liu**  
Senior Director of Clinical Operations, Head of Asia-Pacific  
**INC Research**



**Xu LieDong**  
Director, Data Management, R&D Beijing Hub  
**Merck Serono China**

If you are a **regulatory officer within FDA/EMA/MHRA/SFDA/Ministry of Health** and would like to attend this event, **complimentary VIP passes are available!** For more information, please contact **Ms April Ng** at [enquiry@iqpc.com.sg](mailto:enquiry@iqpc.com.sg)

## **PLUS!** Featuring Two Separately Bookable Workshops

**A** Be the Next Data Management Leader - Necessary Skill-Sets to Evolve into Senior Executives in Emerging Markets

**B** Streamlining Execution of Clinical Trials through Optimising Efficiency of Clinical Data Management

*Limited spaces are available so book now to secure your seat!*



Media Partners:



Dear Colleagues,

With more clinical trials being conducted in Asia, improving the integrity, quality, efficiency of data collection, and management have been brought to the fore.

The **2nd Annual Data Collection and Management in Clinical Trials Asia 2011** event will create a high-level platform from which to find answers to challenges and issues – in order to deliver quality data and efficient data management in the clinical trials, for example:

- How shall the local and global regulations be met?
- How shall sponsor-CRO cooperate?
- How shall the needed advanced technology be applied – within affordable budget guidelines?

The **2nd Annual Data Collection and Management in Clinical Trials Asia 2011** is an unique gathering of its kind in the region. With a global reach gathering clinical data professionals to discover how to overcome key technical, regulatory, strategic, and budgetary challenges posed by clinical data collection and management in the region and worldwide.

While focusing on the always important topics – regulatory compliance, integrity, and quality of data collection and management – this event will also discuss solutions and strategies for:

- How shall global pharmaceuticals **respond to the increasingly demanding data management of clinical trials** in the region and globally?
- How shall CROs or service providers organise themselves to play the role of strategic partners to **meet the sponsors' requirements – to reduce trial time, and cost, while safeguarding the data quality?**
- How shall the industry's foremost considerations be solved regarding **data collection, transmission and security**
- How shall pharmaceuticals and CROs leverage the **latest development in software and hardware** to improve the efficiency, quality, and security of clinical data collection and management

This is an excellent platform for you to exchange ideas and reinforce working relationships with some of the most influential leaders in Asia's clinical trial data collection and management industry.

I am very excited in speaking at the **2nd Annual Data Collection and Management in Clinical Trials in Asia 2011** and looking forward to meeting you in Beijing this December!

**Charlie Xu**  
Vice President

**FRONTAGE CLINICAL SERVICES**

**Over 6 hours of networking opportunities**  
plus a dedicated speed networking session to  
interact with your industry peers!

## Clinical Data and Biostatistics Professionals Will Reveal Key Clinical Data Collection and Management Strategies through a Series of Insightful **Case Studies**

### Global Patient Data Collection Strategies

**Bruce Xue, Biostatistical Manager, Medical Affairs Department, Xian-Janssen Pharmaceutical** will reveal how you can successfully collect and manage patient data in large scale and complex clinical trials

### Data Compliance and Reporting

**Jessie Chen, Head of Global Clinical Data Services, Pfizer (China) Research & Development Center** will disclose how you can report global clinical data efficiently and fulfil FDA requirements through global clinical data standardisation

### Clinical Data Interchange Standards Consortium (CDISC)

**Julia Zhang, Associate Director, Standard Programme Manager, Genzyme** will update you the latest development in Clinical Data Interchange Standards Consortium (CDISC)

### Building World Class Data Management Centre

**Li Ding, Director, Trial Operations Asia Pacific Coordinator, Trial Operations China Group Leader, sanofi-aventis China** will discuss how to build a world class data management centre through outsourcing and considerations when outsourcing your clinical data management

### Multi-Center Clinical Trial Operations

**Liedong Xu, Director, Data Management, R&D Beijing Hub, Merck Serono China** will share his experience in improving data transmission security and meeting international regulatory standards in the multi-center clinical trial operations

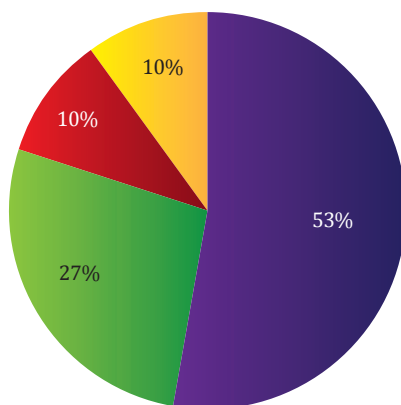
### Process to Reduce Analysis Time

**Mrunalini Jagtap CCDM, PMP, Assistant Manager (CDM), Wockhardt** will explore processes and workflows to maximise efficiency and reduce the time taken to generate meaningful results from high throughput data

“The event has been valuable in terms of networking, making new contacts, meeting up with global colleagues and gaining an insight of the clinical trial opportunities available in China.”

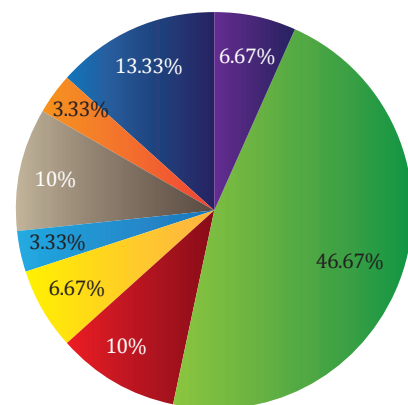
**Data Management Executive Director,  
Pharmanet Ltd**

## Past Attendees Profile



### Job Titles Breakdown

- Directors, Head of, Senior Managers:
- Data Management / Biometrics
- Clinical Research/Operation
- Biostatistics
- Others



### Geographical Breakdown

- Australia
- China
- India
- Japan
- Korea
- Singapore
- United Kingdom
- United States

# CONFERENCE DAY ONE

Tuesday, 6 December 2011

08.15

## Registration and Welcome Coffee

09.00

## Open Remarks from the Chairperson

**Charlie Xu**, Vice President, **FRONTAGE CLINICAL SERVICES**

09.10

## Clinical Trials in the 21st Century: Optimising the Business Value of Clinical Informatics

- Aligning the lab with the wider business to turn data into information and increase operational efficiency and effectiveness
- What challenges does this introduce and what solutions are we presented with?
- With the range of novel technologies now available, which are useful for your facility's purposes versus merely new and appealing?
- Integrating lab operation workflows with to optimise IT processes
- Using technology to improve compliance-risk control
- Case study - demonstrating the increasing demands and identify the needs of the 21st century

**Christopher Huang**, Founder & General Manager, **PHARMACONS TECH**

09:50

## The Evolving Role of the Data Manager in the Pharma /Biotech /Healthcare Industries

- Showcasing how the introduction of technology has changed the landscape of data management in the last 10 years
- Focusing on how standardisation of formats and process across the industry will prompt even more pronounced changes in the clinical data manager's role
- Examining how the introduction and integration of e-sources has and will further promote a shift from processes centred on cleaning data to a focus on managing data flow
- Exploring the move towards the provision of real-time data to the different stakeholders of a clinical trial
- Understanding how the clinical data manager's role will be defined in an automated e-future

Moderator:

**Charlie Xu**, Vice President  
**FRONTAGE CLINICAL SERVICES**

Panelists :

**Jessie Chen**, Head of Global Clinical Data Services  
**PFIZER (CHINA) RESEARCH & DEVELOPMENT CENTER**

**Randy Dai**, Data Manager  
**ASTRAZENECA**

**Deng YaZhong**, Head of CDARO China, **COVANCE**

**Li Ding**, Director, Trial Operations Asia Pacific Coordinator, Trial Operations China Group Leader, **SANOFI-AVENTIS CHINA**

10:30

## SPEED NETWORKING

Speed networking will enable you to meet all conference attendees within a short time and ensure an open discussion throughout the conference

10:50

## Morning Tea and Networking Break

11:20

## Global Patient Data Collection and Management in Clinical Trials

- The differences in conducting clinical trials in Asia, US and Europe
- Asia: What are the differences between China, India and rest of Asia
- Best practice in patient data collection and integration in conducting large scale and complex clinical trials
- Building a world class data management centre

**Bruce Xue**, Biostatistical Manager, Medical Affairs Department  
**XIAN-JANSSEN PHARMACEUTICAL**

12:00

## The Regulatory Environment and Requirements for Clinical Trial Data Collection and Management

- Understanding the Good Clinical Practice (GCP) in patient recruitment and data collection
- Examining the clinical trial site hardware and system requirements
- What are the investigator's training and qualification required to meet the regulatory guidelines
- Pharmacovigilance reporting and monitoring in clinical trials
- Proposing good practice for drug research and development

**Shabbir Rangwala**, Executive Director, Global Services and Site Head,  
**INC RESEARCH INDIA**

12:40

## Lunch and Networking Break

13:40

## Managing Global Clinical Trial Data: Data Compliance and Reporting

- Examining FDA requirements and the implications for patient data reporting
- Aligning the global clinical data standardisation processes
- Organisational structuring for efficient clinical data reporting on a global scale
- Example of standard clinical data reporting

**Jessie Chen**, Head of Global Clinical Data Services  
**PFIZER (CHINA) RESEARCH & DEVELOPMENT CENTER**

14:20

## Working with Site Investigators for Improved Patient Recruitment and Compliance Practice

- Discussing with project team the considerations in designing clinical trial protocols
- Finding out the current practice in patient recruitment and challenges to overcome
- Case report form used in data collection and challenges
- Integrating patient records into the clinical trial data collection process
- Further improving working standards for site investigators - staff training and equipment update

**Jessica Liu**, Senior Director of Clinical Operations, Head of Asia-Pacific  
**INC RESEARCH**

15:00

## The Impact of CDISC on e-Clinical Trials

- Outlining the latest developments in Clinical Data Interchange Standards Consortium (CDISC)
- Increasing the efficiency of data management with CDISC and Clinical Data Acquisition Standards Harmonisation (CDASH)
- Discussing standardisation and interoperability through CDISC and CDASH

**Julia Zhang**, Associate Director, Standard Programme Manager  
**GENZYME**

15:40

## Afternoon Tea and Networking Break

16:10

## Clinical Trial Data Management Outsourcing in Asia - Building World Class Data Management Centre through Strategic Partnerships

- What are the sponsors' considerations in site selection for patient data collection
- What are the sponsors' considerations in solution provider selection for streamlining data management and statistical analysis
- Roles and responsibilities of CROs and functional service providers in building a global data management center

**Li Ding**

Director, Trial Operations Asia Pacific Coordinator, Trial Operations China Group Leader  
**SANOFI-AVENTIS CHINA**

16:50

## Developing a Continuous Improvement Culture to Drive Enterprise Wide Data and Information Management

- Reviewing continuous improvement in the research data management domain, and the development of operational excellence
- Leveraging the opportunity to rethink how you implement and integrate laboratory informatics products and achieve greater business value in the form of increased productivity and reduced cycle times
- Optimising data and information management for better planning, reporting and analysis
- Connecting data management with process improvement to increase data ownership and governance
- Future plans: Assessing where you are, and how to plan to embed (and sustain) a Continuous Improvement culture

**Ian O'Shaughnessy**, Director, Data Management Asia Pacific  
**ICON CLINICAL RESEARCH**

17:30

## Closing Remark from the Chairperson

17:40

## End of Conference Day One



# CONFERENCE DAY TWO

Wednesday, 7 December 2011

08.15 **Registration and Welcome Coffee**

09.00 **Open Remarks from the Chairperson**

**Charlie Xu**, Vice President, **FRONTAGE CLINICAL SERVICES**

09.10 **Overcoming the Data Challenges in Multi-Center Clinical Trial Operations - Data Transmission and Integration to Meet International Regulatory Standards**

- Understanding the benchmarks in patient recruitment and data entry
- Building a single data management platform
- Proposed solutions for improving security in data transmission

**Xu LieDong**, Director, Data Management, R&D Beijing Hub  
**MERCK SERONO CHINA**

09:50 **The Best-Practice Case In The Offshoring Of Statistical Programming: Important Points to Consider When Offshoring Statistical Programming**

- Assessing the position that offshoring is essential to gain access to a wider talent pool
- Appreciating the pros and cons of offshoring: potential cost savings vs. oversight, training etc.
- Exploring the best offshoring model for your business
- Understanding that an offshored workload has to be truly transactional to obviate large hidden costs
- Keeping an eye on the economic variables: inflation, turnover and productivity
- Considering the case for automation of transactional activities rather than offshoring

**Deng YaZhong**, Head of CDARO China, **COVANCE**

10:30 **Morning Tea and Networking Break**

11:00 **Using Informatics to Overcome Data Analysis Bottlenecks, Streamline Processes and Improve Innovation through Reduced Analysis Time**

- Processes and workflows to maximise efficiency and reduce the time taken to generate meaningful results from high throughput data
- Automating processes and work flows, integrating them to into one single step combining data preprocessing, quality control and feature selection
- Development of a 'one-stop' exploratory analysis workflow that reduces analysis time from days to minutes
- Implementation of a classification pipeline that incorporates all classification steps into a single pipeline covering initial data filtering, feature selection, classification, and evaluation of the results

**Mrunalini Jagtap**, CCDM, PMP, Assistant Manager (CDM), **WOCKHARDT**

11:40 **Maximising Trial Efficiency by Effectively Integrating Data into One Platform**

- Discussing challenges of data integration across the clinical data lifecycle
- Sharing, managing, analysing and integrating varied and increasing sources of data
- Debating interoperability between different systems

Moderator:

**Charlie Xu**, Vice President, **FRONTAGE CLINICAL SERVICES**

Panelists:

**Bruce Xue**, Biostatistical Manager, Medical Affairs Department  
**XIAN-JANSSEN PHARMACEUTICAL**

**Shabbir Rangwala**, Executive Director, Global Services and Site Head  
**INC RESEARCH INDIA**

**Charlie Chen**, Vice President, **GCP CLINPLUS**

12:20 **Lunch and Networking Break**

13:20 **Overcoming the Most Common Challenges Facing Clinical Data and Information Integration**

- Understanding that replacing paper with electronic systems is the catalyst for demanding seamless data interchange between laboratory and other business systems
- Understanding how business and scientific demands are driving requirements for integration
- Outlining the technical barriers and constraints that challenge a way forward

- Raising questions about the available resources, knowledge and skills required to progress

Moderator:

**Charlie Xu**, Vice President, **FRONTAGE CLINICAL SERVICES**

Panelists:

**Mrunalini Jagtap** CCDM, PMP, Assistant Manager (CDM)  
**WOCKHARDT**

**Ian O'Shaughnessy**, Director, Data Management Asia Pacific  
**ICON CLINICAL RESEARCH**

**Sun HuaLong**, Manager GRO, Data Processing, **PAREXEL**

**Xu LieDong**, Director, Data Management, R&D Beijing Hub  
**MERCK SERONO CHINA**

14:00 **Optimising The Sponsor-CRO Relationship**

- Assessing the factors that influence pharmaceutical research sponsors in their selection and retention of contract research vendors and partners
- Exploring the full project to the full function/task outsourcing continuum
- Understanding the type of sponsor project manager would serve each outsourcing "style" best?
- Data flow vs. data quality reports: examining score-cards, performance evaluators and due diligence
- Specialised procedures, central readers/adjudication committees, central laboratory and whether it is project or functional outsourcing?
- Appreciating the crucial need for standardising template contract agreements and benchmarking partners vs. in-sourced activities

**Charlie Chen**, Vice President, **GCP CLINPLUS**

14:40 **Minimising Mistakes and Fraud Prevention in Data Collection and Management**

- Understand the Good Clinical Practice (GCP) of audit process
- Ensure that your data and supporting documentation are accurate and presentable for inspection
- Gain knowledge concerning common outcomes and findings in clinical trials
- Understand how to respond to an audit to avoid further regulatory consequences
- Learn how to detect and prevent fraud and mistakes in clinical trials data
- Fully understand the consequences which result when proper procedures are not followed

**Charlie Xu**, Vice President, **FRONTAGE CLINICAL SERVICES**

15:20 **Afternoon Tea and Networking Break**

15:30 **Offshoring in Data Management to Reduce Cost and Improve Productivity - Case Study in Supporting an Operation in Japan**

- Establishing an offshore location in China to support Data Management activities from Japan
- Requirements for different project team model
- Challenges and benefits of managing such an offshoring operation including cultural differences, communication, quality, and staff training & retention.
- How offshoring from Japan can be successful and continue to grow to mirror the success of countries such as India

**Sun HuaLong**, Manager GRO, Data Processing, **PAREXEL**

16:30 **Data Transmission and Safety Considerations**

- Regional and global regulatory requirements for secure data transmission
- Strategies in reducing data transmission time through global multi-center cooperation
- Data safety solutions

**Charles Yan**, Senior Director, Clinical Data Management  
**SHANGHAI CLINICAL RESEARCH CENTRE**

17:10 **Closing Remark from the Chairperson**

17:20 **End of Conference**



## WORKSHOP A

09.00-12.00

### Working Together to Develop a Healthy Talent Pipeline in China on Clinical Data Management

Attend the workshop to learn and share your insights in:

- How to build a fast learning organisation of clinical trial data management in China
- The impact of the cultural capabilities for a data manager working in global study team
- The importance of collaborating with other functions to grow data management capacity in emerging market
- The feasibility of cross company collaborations to enlarge the volume and improve the quality of talents on clinical data management in China

Your Workshop Leader:

**Jessie Chen**

Head of Global Clinical Data Services

**Pfizer (China) Research & Development Center**

Jessie Chen is the head of Global Clinical Data Services (GCDS) Department in Pfizer China R&D Center (CRDC) since 2008. The department provides data processing, database build and data management services to Pfizer global phase 1 to phase 4 clinical trials and post marketing non-interventional studies on close to 70 products in 11 therapeutic areas since it established in 2006.

Before that, Jessie had worked on SOPs, training, and process implementation for 2 years supporting multiple functions of Pfizer Development Operations in CRDC as well as the medical/clinical operations organisations in 12 countries of Asia/Australia region.

Prior to joining CRDC, Jessie had worked in Pfizer China Medical department for 8 years where she obtained extensive experiences on clinical operations.



## WORKSHOP B

14.00-17.00

### Streamlining Execution of Clinical Trials through Optimising Efficiency of Clinical Data Management

- Demonstrating how standards can provide consistency and lessen the burden of formatting and configuration for technical staff
- Simplifying extraction and pooling of data by maintaining designed standards throughout each stage of the trial
- Moving towards full automation through integration in an effort to minimise the challenge of data transfer and lower the need for maintenance
- Analysing to what extent full automation could affect personnel within technical and programming fields
- Using outsourcing partners to share tasks and allow in-house resource to be spent elsewhere
- Determining whether true outsourcing partnerships could act as a buffer to job losses within data management through CRO adoption of sponsor sites
- Investigating offshoring as a way to lower costs and whether this is a long-term solution
- Addressing industry anxiety associated with company restructure and the role of the data manager

Your Workshop Leader:

**Julia Zhang**

Associate Director, Standard Programme Manager

**Genzyme Pharmaceuticals**

Dr. Zhang has worked in Pharmaceutical and Biotechnology Industries for 14+ years. She is an active member of HL7 and CDISC standard organizations. Her expertise is in the following areas:

1. regulatory submissions both in paper and electronic
2. development/implement industry standards (HL7, CDISC) for submission, statistical analysis reporting and clinical trial data collection
3. statistical analysis on clinical trial
4. data management, such as clinical data collection (EDC), reviewing, cleaning, and exchange, etc.
5. Clinical trial database design
6. Program/project management. Her broad clinical experiences across different therapeutic areas include Infectious Diseases, Respiratory, Oncology, Rare Inherited Disorders, etc.

## Why Sponsor?

The 2nd Annual Data Collection and Management in Clinical Trials Asia 2011 is the ONLY event in Asia that focuses on technologies, strategies and trends in the data collection and management in clinical trials industry.

You will be meeting forward-thinking leaders in the industry who have chosen to invest their money and most importantly, time, in attending the conference with the main goal of improving their existing systems. These are the people who are actively seeking solutions to keep themselves up-to-date in this highly competitive market so as to attract and retain their customers.

The 2nd Annual Data Collection and Management in Clinical Trials Asia 2011 summit attendees are actively seeking the following:

- Biometrics Software/Solution
- Clinical Data Management System/Software
- Biostatistics Systems/Solution
- EDC Systems/Software
- EPro/ Patient Diaries Technologies
- IVRS
- Clinical Research Services
- Consultants
- Phase 1 Clinical Automation Systems
- Safety Solutions

We aim to meet these delegates' needs by matching them with their ideal solution provider. Hence, sponsoring the conference places you on a platform to demonstrate your expertise in front of these industry leaders and demonstrate how your solutions are capable of placing them at the forefront of the clinical data collection and management industry. You can be guaranteed networking opportunities with these leading industry professionals within your primary target audience and effectively position yourself as the market leader!

To find out how we can tailor make sponsorship packages that suit your company's distinct commercial requirements and maximise your exposure, please call +65 6722 9388 or email [sponsorship@iqpc.com.sg](mailto:sponsorship@iqpc.com.sg).

“Very valuable because very focussed and interactive.”

CDM Senior Manager, RPS