



Presents

Clinical Trial Congress Dubai

East meets west in clinical development and outsourcing

27-28 April 2008, Dubai International Exhibition Centre, UAE

Part of the PABME exhibition – Pharmaceutical and Biotech Middle East

And meet our outstanding international speaker line-up:

- **Dilip Shah**, Secretary General, **Indian Pharmaceutical Alliance, India**
- **Dr Vinod Mattoo**, Chief Scientific Officer, **Eli Lilly India**
- **Heinrich Klech**, MD, PhD, Senior Area Director, Medical & Regulatory, Europe (EMS), **Eli Lilly**
- **Ann Devos**, Clinical Project Manager, **Clinical Development & Medical Affairs dept. GENimmune NV**
- **David Davies**, Product Development Director, **Futura Medical Development Ltd**
- **Vinka Ljubimir**, independent consultant, formerly of **Pfizer**
- **Francis P. Crawley**, Executive Director, Good Clinical Practice Alliance – Europe & Co-founder, **Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)**
- **Dr Antal K. Hajos**, Managing Director, **Nycomed, Mumbai, India**
- **Professor Anthony C Woodman**, Associate Dean and Chief Executive Officer, **Institute of Clinical Research (India)**
- **Dr Heidi Liu**, Director, **Forum for Ethical Review Committees in Asia & Western Pacific Region (FERCAP) Singapore**
- **Professor Ellick Wong**, **University of Singapore**
- **Graham P Belgrave**, Vice President, Clinical Operations, Development Group, **Vernalis R&D Ltd.**
- **Harold Glass**, Professor of Pharmaceutical Business, **University of the Sciences in Philadelphia**
- **Rikke Winther**, Head of Outsourcing Management, **Lundbeck**
- **Roy Gomez**, Director Clinical Research for CEE, **Pfizer Belgium**
- **Gerlinde Langthaler**, Regional Head, Central & Eastern Europe, **Clinical Monitoring Merck Serono International S.A.**

Key agenda topics include:

- Challenges for multiregional trials - complying with European and US regulatory requirements
- Ethical aspects of running clinical trials in emerging markets
- Key components for success when running a global clinical trial
- Good Clinical Practice in emerging markets: Developing standards and practices to meet local conditions
- Understanding the landscape for clinical development in India – advantages, challenges and regulatory considerations
- Ethical consideration when conducting clinical trials in India and China
- Case study: GCP in South East Asia
- “Looking back to look ahead” – The current landscape of conducting clinical trials in India
- Tools and techniques for successful CRO selection
- What are CROs and Pharma really thinking about each other?
- How to create value in your outsourcing relationships
- Drawing conclusions from a true comparison between outsourcing & internal costs
- Conducting clinical trials in CEE: Sponsor perspective
- The globalisation of clinical trials in china: oversight and ethics in an expanding market

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clinical development
partners from Europe,
India, Asia, the Middle East

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Conference Day One – 27th April

- 9:00 **Opening Remarks from the Chair**
David Davies, Product Development Director, **Futura Medical Development Ltd**
- 9:10 **Challenges for multiregional trials - complying with European and US regulatory requirements**
- Professional training for Investigators and CT personnel - what level of personal qualification does the FDA expect?
 - Acceptance of the data from emerging markets by the western authorities: special requirements, experience of FDA, and EU inspections in these countries
 - Understanding of the FDA's position on conducting clinical trials in Central and Eastern Europe
 - Responding to the demands of the FDA during inspections
 - Delivering good quality trials in the eyes of the FDA
 - Regulatory Affairs and hurdles SMO's effectiveness
 - Utilizing services of local SMO/ CRO in emerging markets
 - How to handle SAE-Reporting in emerging markets
 - Pharmacovigilance in emerging markets
- Heinrich Klech**, MD, PhD, Senior Area Director, Medical & Regulatory, Europe (EMS), **Eli Lilly**
- 9:50 **Ethical aspects of running clinical trials in emerging markets**
 Is the Declaration of Helsinki relevant to how clinical trials are designed? The Declaration of Helsinki states that: 'At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study'. Yet do trial subjects always have access to the therapeutic methods identified by the study?
This session will examine the following questions:
- To what extent is this declaration currently relevant to the design of clinical trials
 - Should industry be running trials in places where the drugs are not marketed?
 - To what extent is industry currently adhering to the Declaration?
 - What are the further ethical considerations for running trials in areas where the drug is not marketed
 - Patient motivation for trial participation in such countries compared to western countries
 - Patient information/Informed consent in countries with high numbers of analphabets
- Ann Devos**, Clinical Project Manager, Clinical Development & Medical Affairs dept. **GENimmune NV**
- 10:30 **Morning Tea**
- 11:00 **Key components for success when running a global clinical trial**
- Designing a framework for choosing the right countries for your trial
 - What are the key advantages of running a global clinical trial?
 - Proven methods for ensuring efficiency & high quality data
 - Comprehensive methods for vendor selection in unfamiliar territory
 - Importance of training your personnel in cross-cultural communication
- Accounting for the different levels of quality in different geographies
 - Pros & cons of local vs. global CROs
- Vinka Ljubimir**, independent consultant, formerly of **Pfizer**
- 11:40 **Good Clinical Practice in emerging markets: Developing standards and practices to meet local conditions**
- The impact of current ICH, WHO, European, & US GCP standards
 - Current GCP standards in China, India, Singapore and other emerging markets
 - GCP monitoring, audits, and inspections in emerging markets
 - The impact of GCP on clinical trial sites and ethics committees in emerging markets
 - The development of new global standards for GCP
- Francis P. Crawley**, Executive Director, Good Clinical Practice Alliance – Europe & Co-founder, **Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)**
- 12:20 Lunch

INDIA FOCUS

- 1:20 **Understanding the landscape for clinical development in India – advantages, challenges and regulatory considerations**
- Overcoming the challenges of infrastructure & clinical trials supply in India
 - Determining an accurate start-up time and unlocking efficiency
 - Developing a rigorous process for choosing investigator sites
 - How important is it to have own representatives on the ground?
 - Key points in ensuring GCP compliance and high quality
 - Ethical considerations in conducting trials in India
- Dilip Shah**, Secretary General, **Indian Pharmaceutical Alliance, India**
- 2:00 **Successful outsourcing strategies in India**
- Changes in Indian law to facilitate clinical trials
 - Selecting the correct CRO for your project
 - Advantages of patient size and availability
 - Infrastructure and staffing
- Dr Vinod Mattoo**, Chief Scientific Officer, **Eli Lilly India**
- 2:40 **Case study: The Future of Clinical Outsourcing in India: Opportunities, Strategies & Risk Management**
- Overcoming the challenges of infrastructure & clinical trials supply in India
 - Determining an accurate start-up time and unlocking efficiency
 - Developing a rigorous process for choosing investigator sites
 - How important is it to have own representatives on the ground ?
 - Key points in ensuring GCP compliance and high quality
 - Ethical considerations in conducting trials in India
- Dr Antal K. Hajos**, Managing Director, **Nycomed, Mumbai, India**
- 3:20 **Afternoon Tea**
- 3:40 **Logistics of clinical trials in India**
- Clinical trial feasibility
 - Clinical supply issues – effectively getting your materials into India
 - Analysis of the legal and regulatory requirements
 - Investigator responsibilities
- Professor Anthony C Woodman**, Associate Dean and Chief Executive Officer, **Institute of Clinical Research (India)**

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4:20 **Ethical consideration when conducting clinical trials in India and China**

- Understanding the ethical framework for conducting clinical trials in India and China
- Recruitment of patients and communication of informed consent
- The quality and standard of medical staff
- Analysis of the regulatory approval mechanism
- Patient motivation for trial participation in such countries compared to western countries

Dr Heidi Liu, Director, **Forum for Ethical Review Committees in Asia & Western Pacific Region (FERCAP)** Singapore

5:40 **End of day one**

Networking reception: Opportunity for Pharma companies to meet new CRO contacts from all over the world. Your platform to meet and improve Pharma-CRO relationships between East and West.

Conference Day Two – 28th April

9:00 **Opening Remarks from the Chair**

David Davies, Product Development Director, **Futura Medical Development Ltd**

Best practice outsourcing strategies

9:10 **Tools and techniques for successful CRO selection**

- Cost/benefits of establishing long-term partnerships
- Using a thorough & reliable process of preferred supplier selection
- Designing a CRO selection to satisfy all clinical functions
- How realistic is it to achieve a like-to-like comparison between CROs?

Graham P Belgrave, Vice President, Clinical Operations, Development Group, **Vernalis R&D Ltd.**

9:50 **What are CROs and Pharma really thinking about each other?**

- The Results of a Major Industry Survey
- Selecting and using CROs – perceptions vs. realities
- How do CROs imagine the industry in three years time? How different is this view from Pharma?

Harold Glass, Professor of Pharmaceutical Business, **University of the Sciences in Philadelphia**

10:30 **Morning Tea**

11:00 **How to create value in your outsourcing relationships**

- Exploring the concerns Pharma has about working with CROs
- Uncovering the issues CROs have with their relationship with Pharma
- teamwork and expectations - how to make the best out of the relationship,
- conflict resolution,
- operational quality in legal contracts

Rikke Winther, Head of Outsourcing Management, **Lundbeck**

11:40 **Drawing conclusions from a true comparison between outsourcing & internal costs**

- Which parameters can be used to obtain a true assessment of the value of outsourcing?

- Viewing the decision to in- or outsource from a cross-functional perspective
- Qualifying whether or not your outsourcing processes are truly more efficient than your internal operation
- Reducing the amount of internal spending on each outsourcing dollar
- Minimising costs through choosing the appropriate costing model for each project
- Impact of inflation on comparing internal & outsourced costs

Emerging Economies focus

12:20 **Case study: GCP in South East Asia**

- Opportunities in Clinical Trials in Asia: drug development, clinical trials and regulatory affairs
- Regulatory environment in Asia: Ensuring GCP
- Local regulations of the countries which are new to clinical research but which are growing and are very important (for example China, India, Philippines)

Professor Ellick Wong, **University of Singapore**

1:00 **Lunch**

2:00 **Strategies for effective clinical outsourcing in CEE**

- Pfizer's strategy for country allocation for Global/European studies
- How to maximize the partnership between industry and CRO
- Understand the current CRO environment in CEER
- Case study on successful partnership with 'flexible' resourcing
- Recruitment problems in CEE
- GCP standards in CEE

Roy Gomez, Director Clinical Research for CEE, **Pfizer Belgium**

2:40 **Conducting clinical trials in CEE: Sponsor perspective**

- Overview of the experience of Merck Serono
- Overcoming the challenges faced
- The value of conducting clinical trials in CEE
- Future directions for clinical trials in CEE

Gerlinde Langthaler, Regional Head, Central & Eastern Europe, Clinical Monitoring, **MERCK SERONO International S.A.**

3:20 **Afternoon tea**

3:40 **The globalisation of clinical trials in china: oversight and ethics in an expanding market**

- The current landscape of conducting clinical trials in China
- The current Good Clinical Practice framework for clinical trials in China
- What the State Food & Drug Administration (SFDA) regulations mean for your trial
- China and the Asia-Pacific region working in collaboration with Europe and the United States
- Investigator responsibilities and collaborations

4:20 **End of Conference**

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