

# Conducting Clinical Trials in Emerging Economies

Winning strategies for utilising under-developed markets

20-21 May 2008, Hesperia London Victoria, London, UK

*"Excellent overview of these countries.  
Good arguments to convince my management"*

## Hear from industry experts, including:

- **David McIntosh**, Medical Director Infectious Diseases (Europe, the Middle East and Africa), **Wyeth Europa, UK**
- **Chandrashekar Potker**, Clinical Research Director, **Pfizer, India**
- **Kamala Rai**, Medical Director, **Merck, India**
- **James Cai**, Vice President, R&D Business Development, **AstraZeneca, China**
- **Gangadhar Sunkara**, Associate Director, **Novartis Pharmaceuticals, USA**

## Highlights:

- Discover why emerging market countries are such an attractive target for clinical trials
- Learn about the demographics and economic drivers of emerging economies
- Hear from industry and CROs about how to make the perfect partnerships
- Avoid cultural slip ups by investigating the common pitfalls
- Improve your knowledge of Good Clinical Practice considerations in emerging markets
- Ensure your Intellectual Property is secure by understanding local laws
- Hear case studies from industry leaders, detailing their experiences in India, China, Africa and Russia

### Pre-conference Workshop • 19 May 2008

Essential knowledge for setting up  
clinical trials in China

Workshop Leader: Linda Zhao, President and CEO, Draco Healthcare Consulting LLC, USA

### Post-conference Workshop • 22 May 2008

Clinical Trials in Africa: Strategies for the Last Frontier  
Workshop Leaders:

Ifeoma Okoye, Association for Good Clinical Practice in Nigeria  
Anthony C. Ikeme, ClinTriad Pharma Services  
Francis P. Crawley, Good Clinical Practice Alliance - Europe

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*"Excellent networking opportunities"*

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# Conducting Clinical Trials in Emerging Economies, Winning strategies

## Conference Day 1 – Tuesday 20 May 2008

08:30	Registration	14:50	<b>Ethical issues with running clinical trials in emerging economies</b> <i>Challenges in research design</i> <ul style="list-style-type: none"><li>- standard of care</li><li>- access to fair benefits</li><li>- collaborative partnership</li></ul> <i>Considerations for informed consent</i> <ul style="list-style-type: none"><li>- understanding the "fully informed"</li><li>- obtaining consent in areas of high illiteracy</li><li>- exploring alternative forms of presenting information</li><li>- is consent valid within a paternalistic medical structure?</li></ul> <i>Current status of ethical review practice in Asian countries</i> <b>Heidi Liu, Medical Officer, Forum for Ethical Review Committees in Asia and the Western Pacific, Thailand</b>						
09:00	<b>Opening remarks from the Chair</b> <b>Francis P. Crawley, Executive Director, Good Clinical Practice Alliance – Europe &amp; Coordinator, Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Belgium</b>	15:30	<b>The Development of Good Clinical Practice in emerging economies</b> <ul style="list-style-type: none"><li>• Recent developments affecting GCP in emerging economies</li><li>• International and national GCP guidelines: an ongoing dialogue</li><li>• Examples of best practices in GCP from Asia and Africa</li><li>• How to implement Good Clinical Practice in your clinical trials across multiple countries</li><li>• The development of GCP inspections in Asia and Africa</li></ul> <b>Francis P. Crawley, Executive Director, Good Clinical Practice Alliance – Europe &amp; Coordinator, Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), Belgium</b>						
09:10	<b>Why relocate your trials? Advantages and disadvantages</b> <ul style="list-style-type: none"><li>• Naïve patient population</li><li>• Increased patient pool</li><li>• High volume of low-cost staff</li><li>• Ethical concerns</li><li>• Lack of experience</li><li>• Bringing 'Western' drugs to developing countries</li><li>• Increasing costs compared with reductions in timelines</li></ul> <b>Ian Holmes, Senior Vice President, Corporate Development, PharmaNet, Switzerland</b>	16:10	Afternoon tea						
09:50	<b>Population and disease demographics</b> <ul style="list-style-type: none"><li>• The importance of good epidemiological data when looking to emerging economies for clinical trials</li><li>• Key prevalent diseases in developing countries</li><li>• Diseases with urgent demands for better therapies in China</li><li>• The impact of patient segments (geographic and economic) to efficient clinical trial recruitments in China</li><li>• The rise of 'Western' diseases in these countries</li></ul> <b>Linda Zhao, President and CEO, Draco Healthcare Consulting LLC, USA</b>	16:30	<b>Experiences of working with local CROs in emerging economies</b> <ul style="list-style-type: none"><li>• Issues to consider when choosing a CRO partner</li><li>• What can a good local CRO do for you?</li><li>• Examples of innovative CROs improving clinical trials</li><li>• How to optimise your partnership with a local CRO</li></ul> <b>Irina Bogatyreva, Associate Director Global Drug Safety, UCB Pharma, Belgium</b>						
10:30	Morning coffee	17:50	<b>Avoiding crossed wires – improving cross cultural understanding</b> <ul style="list-style-type: none"><li>• Watch your language – understanding how we use language and ensuring that what we say is understood</li><li>• Who really makes the decisions? Making it obvious who is in charge</li><li>• Does yes really mean yes, or is it a polite way of saying, "I'll ask my boss"?</li><li>• Avoiding historical elephant traps – appreciate the friendliness or enmity between countries</li><li>• How important is the group? Cultural differences in emphasis on individual or group responsibilities</li><li>• A stitch in time... Other cultures may have very different views on time</li><li>• Attitudes to financial management – can you avoid greasing the palm in a society where it is expected?</li></ul> <b>Richard Barrett, Consultant, Contract &amp; Outsourcing Services Ltd., UK</b>						
11:00	<b>Analysis of the economic drivers of emerging economies – a venture capital perspective</b> <ul style="list-style-type: none"><li>• Current market size and growth</li><li>• Market drivers and inhibitors</li></ul> <i>Speaker to be confirmed</i>	17:50	Closing remarks from the Chair						
11:40	<b>Intellectual Property protection and patenting issues</b> <ul style="list-style-type: none"><li>• How safe is your data in emerging market countries?</li><li>• What can you do to safeguard your intellectual property?</li><li>• The impact of the Doha Declaration on the TRIPS agreement for intellectual property laws in developing countries: India, China, Russia, Nigeria, Uganda</li><li>• Case study of IP protection in China</li></ul> <i>Speaker to be confirmed</i>	18:00	<b>Networking drinks reception</b>						
12:20	<b>Understanding the regulatory and clinical environment to ensure success in conducting clinical trials in South East Asia</b> <ul style="list-style-type: none"><li>• Current status of clinical trials in SE Asia – the emerging region for global drug development activities</li><li>• GCP and regulatory environment</li><li>• Current clinical environment and infrastructure</li><li>• Clinical trial service providers – CRO, SMO, Central labs, etc.</li><li>• Success stories, challenges and success factors</li></ul> <b>Prof Ellick C. K. Wong, Department of Pharmacy, National University of Singapore</b>	<b>Sponsorship and exhibition opportunities</b> Raise your corporate profile by sponsoring or exhibiting at this conference. This event provides great opportunities to network and conduct business with key decision makers in the industry. For details of sponsorship and exhibition packages please contact: <b>Linda Cole, Tel +44 (0) 207 017 6631 or email: linda.cole@informa.com</b>							
13:00	Lunch	<table border="0"><tr><td>Conference Sponsor:</td><td>Exhibitor:</td><td>Promotional Participant:</td></tr><tr><td></td><td></td><td></td></tr></table>		Conference Sponsor:	Exhibitor:	Promotional Participant:			
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14:10	<b>The winds of change: attaining global standards in Indian regulation</b> <ul style="list-style-type: none"><li>• The evolution of Indian regulations</li><li>• Status of implementation</li><li>• Examining the current initiatives</li><li>• What does the future hold?</li></ul> <b>Ranjani Nellore RAC, President, PharMantra Consulting Services, India</b>								

## Conference Day 2 – Wednesday 21 May 2008

09:00	Opening remarks from the Chair <b>David McIntosh, Medical Director Infectious Diseases (Europe, the Middle East and Africa), Wyeth Europa, UK</b>	11:10	Morning coffee
09:10	<b>Clinical Trial Application and pre-trial approval requirements in India</b> <ul style="list-style-type: none"><li>• The regulatory and ethical authorities involved</li><li>• What needs to be submitted, to whom, and when</li></ul> <b>Gangadhar Sunkara, Associate Director, Novartis Pharmaceuticals, USA</b>	11:30	<b>Overcoming logistical challenges with setting up a clinical trial in India</b> <ul style="list-style-type: none"><li>• Supply chain and transport</li><li>• External and internal depots</li><li>• Ensuring a robust chain of custody</li><li>• Applying for transport permits – who and when?</li><li>• Planning ahead for smooth transport through customs</li><li>• Issues with local corruption</li></ul> <b>Kamala Rai, Medical Director, Merck, India</b>
09:50	<b>Clinical Trial Application and pre-trial approval requirements in China</b> <ul style="list-style-type: none"><li>• The regulatory and ethical authorities involved</li><li>• What needs to be submitted, to whom, and when</li></ul> <b>James Cai, Vice President, R&amp;D and Business Development, AstraZeneca, China</b>	12:20	<b>Spotlight Session</b> This session will be hosted by a leading company within the service provider industry. This session offers an opportunity to hear and learn about the latest developments in the industry. <b>To take advantage of this, please contact Linda Cole at linda.cole@informa.com, +44 (0) 207 017 6631</b>
10:00	<b>Experiences of staffing challenges in India</b> <ul style="list-style-type: none"><li>• Education and training</li><li>• Recruitment and retention</li><li>• Coping with and planning for high turnover rates</li></ul> <b>Chandrashekar Potker, Clinical Research Director, Pfizer, India</b>	12:50	Lunch

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**14:00 Giving the trial a firm base – ensuring adequate infrastructure for clinical trials in East and Southeast Asia**

- Assessing the current status and trends in infrastructure development
- Incorporating infrastructural concerns in development plans
- Defining key success factors for conducting clinical trials in Asia
- Addressing the sophisticated sampling and device requirement for complex trials
- Evaluating and selecting optimal clinical trial sites for exploratory and Phase II/III trials

**Michael Shi, Director, Biomarker Project Leader, Exploratory Oncology Department, Novartis Pharmaceuticals, USA**

**14:40 The clinical trial landscape in Africa**

- Political concerns
- Geographical and infrastructural obstacles
- Overcoming the difficulties involved in using central labs
- The regulatory and ethical players
- Comparing regulatory timelines in African countries
- How many countries to trial the drug in
- Which countries to choose and why
- Considering infrastructure, patient population and political landscape
- Comparing urban versus rural populations and access to basic healthcare
- Recruiting and training staff

**David McIntosh, Medical Director Infectious Diseases (Europe, the Middle East and Africa), Wyeth Europa, UK**

**15:20** Afternoon tea

**16:00 Opportunities for clinical trials in Africa: A case study on Nigeria**

- Nigeria within the African clinical trial landscape
  - The evolution of Nigerian clinical trial regulations
  - The emergence of NGOs and advocacy for GCPs in Nigeria
  - The emergence of CROs in Nigeria and current clinical trial capacity-building initiatives
  - Dispelling myths about clinical trial in Nigeria
  - The next frontier for the Nigerian clinical research industry
- Professor Ifeoma Okoye, Chairman, Association for Good Clinical Practice in Nigeria (AGCPN) & Chair of Radiology, University of Enugu, Nigeria**  
**Anthony C. Ikeme, President & CEO, Clintriad Pharma Services, USA**

**16:40 Effective clinical trials in Russia – coping with the challenges**

- Approvals
  - Selection of sites
  - Logistical challenges
  - Staffing
- Ramil Abdrachitov, Clinical Research Manager, AstraZeneca CRR, CEE, Russia**

**17:20** Closing remarks from the chair

**17:30** End of conference

## Pre-Conference Workshop W • Monday 19 May 2008

### Essential knowledge for setting up trials in China

Registration is at 9:30 for a 10:00 start. The workshop will finish no later than 17:00

A successful clinical trial in China demands thorough understanding of the Chinese drug regulatory system and efficient utilization of China's capacity for clinical trials. The 2007 turbulence in China's healthcare sector brought on board a new leader to its drug regulatory authority, the State Food and Drug Administration (SFDA), the new Drug Registration Procedure effective on October 1, 2007 and a new Drug Recall Procedure effective on December 10, 2007. 2008 is set to be a year of more changes with the Chinese government new healthcare reform plan around the corner.

Through a series of interactive discussions, this workshop will give you the opportunity to explore how these changes will affect your clinical trial operations, and ensure that you feel confident moving into China this year.

**This workshop will specifically cover:**

- The current market forces at work in China
- The availability of high quality clinical trial sites
- Motivations for Chinese physicians participating in clinical trials
- Using epidemiological data strategically to dramatically improve trial efficiency
- The current Good Clinical Practice guidelines in China
- Clinical Trial Application for biologics, chemical drugs and natural products (timeline and documents required)
- What changes are expected from the SFDA, and how will this affect clinical trial operation excellence in China?

Delegates are encouraged to submit their questions and areas of interest in advance, so that all pressing concerns will be covered.



**About your workshop leader: Linda Zhao, President and CEO, Draco Healthcare Consulting LLC, USA**

*Dr. Zhao has more than 20 years experience in biotech and pharmaceutical industries in China, Japan and the United States. She and her team have provided consulting services to world leading pharmaceutical companies in areas of product pipeline assessment, new product testing and pricing/reimbursement etc. Dr. Zhao is an internationally recognized expert on the Chinese pharmaceutical industry. She has published many review articles about the Chinese healthcare market and has been a frequent speaker at national and international conferences. As the CEO of Draco Healthcare, Dr. Zhao is committed to provide enabling services for pharmaceutical and biotech companies to bring better medicine to the Greater China region. Dr. Zhao holds a Ph.D. from Purdue University and a MBA from the California State University.*

## Post-Conference Workshop X • Thursday, 22 May 2008

### Clinical Trials in Africa: Strategies for the Last Frontier

Registration is at 8:30 for a 9:00 start. The workshop will finish no later than 16:00

Over the past 10 years clinical trials have expanded enormously on a global scale. Africa is now poised as the last frontier of this expansion. The challenges to performing clinical trials in Africa are well known; however, the possibilities – especially in recent years – have grown enormously. This workshop focuses on the practical realities of initiating and performing clinical trials in Africa, provided by two of the foremost experts in this area. The workshop confronts the expectations for clinical trials in Africa, with the hard realities; and it confronts the hard realities with both the expectations and the needs. The legal, regulatory, and ethical requirements are carefully presented and explored in an interactive format that presents not only the facts but also responds to the nuances of the workshop participants experiences and questions.

**This workshop will cover specifically:**

- The current legal and regulatory frameworks within countries and across the continent for clinical trials in Africa
- The current best practices guidelines as they exist in South Africa, Nigeria, Sudan, Kenya, Uganda, and Tanzania
- The development of new health research guidelines in Africa, specifically GCP guidelines
- Successful strategies for working with existing professional associations and groups in Africa
- Ethical review practices in different African countries
- Individual and community informed consent practices
- How to ensure and maintain best ethical practices within your company or organisation when carrying out clinical trials in Africa

**About your workshop leaders:**



**Professor Ifeoma Okoye, Chairman, Association for Good Clinical Practice in Nigeria (AGCPN)**

*Professor Ifeoma Okoye is Chairman of the Association for Good Clinical Practice in Nigeria (AGCPN) and Chairman of the Radiology Department, College of Medicine Postgraduate School, University of Nigeria Teaching Hospital Ituku Ozalla, Enugu State, Nigeria. She is also the African Coordinator for the Collaborative Institutional Training Initiative (CITI). She is currently Editor of the Journal of Medical Sciences and Hospital Management and Assistant Editor of the West African Journal of Radiology. In addition, she is the past Clinical Dean of the Faculty of Medical Sciences and Dentistry at the College of Medicine, University of Nigeria Nsukka and the immediate Past President of the Association of Radiologists of West Africa.*



**Anthony C. Ikeme, President & CEO, Clintriad Pharma Services, USA**

*Dr Anthony Ikeme is the President and CEO of Clintriad Inc., a US based corporation focused on providing clinical research consultancy and site management services to pharmaceutical companies. He has over 10 years experience in the pharmaceutical industry and have worked for leading pharmaceutical and clinical research corporations such as Pfizer, Schering Plough, MDS Pharma Services, PPD and a host of others.*



**Francis P. Crawley, Executive Director, Good Clinical Practice Alliance – Europe**

*Francis P. Crawley is the Executive Director of the Good Clinical Practice Alliance – Europe (Brussels, Belgium) and a World Health Organization (WHO) expert in ethics. He is co-founder and coordinator of the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER). He served for four years on the UNAIDS Ethical Review Committee. He is currently Chairman of the Ethical Review Committee of the International Network for Cancer Treatment and Research (INCTR). He is a member of the Scientific Advisory Committee for the World Health Organization's International Clinical Trials Registry Platform (ICTRP). He also serves on several editorial boards for international journals, including Applied Clinical Trials, the International Journal of Pharmaceutical Medicine, Good Clinical Practice Journal, and the Journal of Empirical Research on Human Research Ethics. He is an Honorary Member of the Faculty of Pharmaceutical Medicine, UK.*

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