

Clinical Trials in Emerging Economies Conference 2009 Draft Agenda

Location:

Angelo Hotel, Prague, Czech Republic

Conference Dates:

21 - 22 April 2009

Conference Day 1: Tuesday 21 April 2009

Keynote Presentation: Guidance on implementing global clinical trial strategies to conduct global clinical trials which include emerging economy regions

- Which regions fall under the term 'emerging economy' and why?
- Exploring the regions which are well positioned to exploit opportunities and overcome challenges
- What are the main advantages and disadvantages of choosing each region?
- Which countries have strong records in regulations, ethics and GCP?
- Directions on choosing which regions are best for which types of trials
- Guidance on the calibration and cross validation of clinical trials run across different emerging economy countries

Keynote Presentation: An overall view of the economic considerations when running clinical trials in emerging economies

- An overview of hard clinical trial data to see how the market has changed over the past few years
- Is it really cheaper to run clinical trials in emerging economies?
- In what regions is it cheaper?
- Where do cost savings hold true?
- What are the economic benefits of running clinical trials in emerging economies?
- How much does it cost – not just per patient, but the infrastructure, the training and the CROs?
- What are the trend predictions for conducting clinical trials in emerging economies?

Regulatory authority and ethics committee requirements: The latest updates and practical implementation

Case Study - India: Vital guidance on the regulatory authority and ethics committee requirements

- Highlighting the important Indian regulatory and legal requirements
- A draft of the upcoming changes for 2009
- Useful practical guidance on complying with the Indian regulations
- Advice on how to best communicate with the Indian regulatory authorities
- How long does approval take from regulatory authority and the ethics committees and are the applications run sequentially or in parallel?
- How long does clinical trial data acceptance take?
- What are the regulations with importing and exporting drugs and biological samples?
- How aware are the Indian authorities about changes in Western European regulations and are there any major differences?
- Dealing with the ethics committees and guidance on how they are organised

Case Study – China: Essential regulatory authority and ethics committee information

- Indicating the most important Chinese regulatory and legal requirements
- Successful strategies on how to comply with the Chinese regulations
- Guidance on communicating with the Chinese regulatory authorities
- How long does approval take from regulatory authority and the ethics committees and are the applications run sequentially or in parallel?
- What are the regulations with importing and exporting drugs and biological samples?
- How aware are the Chinese authorities about changes in Western European regulations and are there any major differences?
- Dealing with the ethics committees and guidance on how they are organised

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Case Study - Latin America (Brazil, Argentina and Chile): Successfully meeting the requirements of the regulatory authority and ethics committee

- Underlining the most vital regulatory and legal requirements
- Directions in how to practically comply with the regulations
- Vital advice on how to communicate with the regulatory authorities
- What is the standpoint of Brazil in restricting the use of placebos in clinical trials?
- How long does approval take from regulatory authority and the ethics committees and are the applications run sequentially or in parallel?
- How long does clinical trial data acceptance take?
- What are the regulations on importing and exporting drugs and biological samples?
- How aware are the Latin American authorities regarding changes in Western European regulations and are they any major differences?
- Dealing with the ethics committees and guidance on how they are organised

Case Study – Central and Eastern Europe (Russia, Ukraine and Bulgaria): Crucial directions on how to comply with the requirements of the regulatory authority and ethics committee

- Identifying the most crucial regulatory and legal requirements
- Guidance on practically complying with the regulations
- Directions on how best to communicate with the regulatory authorities
- How long does approval take from regulatory authority and the ethics committees and are the applications run sequentially or in parallel?
- What are the regulations on importing and exporting drugs and biological samples?
- How aware are the authorities regarding changes in Western European regulations and are they any major differences?
- Dealing with the ethics committees and guidance on how they are organised

Case Study - South East Asia (Korea and Taiwan): Winning approaches on how to meet the regulatory and ethics committee requirements

- Drawing attention to the most important regulatory and legal requirements
- Implementing effective strategies to comply with the regulations
- Vital advice on communicating with the regulatory authorities
- How long does approval take from regulatory authority and the ethics committees and are the applications run sequentially or in parallel?
- How long does clinical trial data acceptance take?
- What are the regulations on importing and exporting drugs and biological samples?
- How aware are the authorities regarding changes in Western European regulations and are they any major differences?
- Dealing with the ethics committees and guidance on how they are organised

Essential ethical and cultural considerations to speed up your clinical trial approval
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Case study: Guidance on how you can successfully achieve quicker ethics committee and regulatory approval

- Directions on how to overcome cultural and language barriers
- How cultural factors may affect clinical data and how this should be taken into consideration
- Improving the image of the pharmaceutical company – how far can the Declaration of Helsinki be followed - will the drugs still be provided after the clinical trial has finished?
- Implementing a patient assistant programme
- Modifying your SOPs to fit in with the culture of the region

Vital issues concerning patient informed consent

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- Ensuring that cultural sensitivity is taken into consideration
- Making sure that patients are fully aware of the risks, benefits and incentives
- Overcoming problems including patient excessive trust in the investigator
- Practical guidance on preparing patient informed consent procedures for emerging economies

The quality of clinical trials and GCP in emerging economies: Critical comparisons and considerations

A focus on India: What are the most important factors in ensuring the quality of the clinical trial?

- A summary of the quality of clinical trial sites in India
- Guidance on how to ensure that clinical trial data is correct
- Exploring the demographics and therapeutic areas in India and how to choose the right patients
- Preventing violations of GCP, including site qualification visits, what to do if there are issues with GCP and how GCP is enforced
- Ensuring that quality is retained with fast patient recruitment rates
- The difficulties in auditing in India
- Where are the opportunities to save money, but retain quality?

Essential guidance on how to ensure the quality of clinical trials in China

- Is it possible to harmonise clinical trial data with the rest of South East Asia?
- Ensuring that your clinical trial data is accurate
- How does the GCP and quality of clinical trials sites in China compare with those in Western Europe?
- How closely the GCP guidelines are adhered to and how to monitor this
- With the high rate of patient recruitment, how can you ensure that your clinical trial data is of high quality?
- Examining the Chinese demographics and therapeutic areas in order to choose the right patients

Ensuring high quality clinical trials in Latin America (Brazil, Argentina and Chile)

- How does the quality of clinical trials in Latin America compare to those held in the USA?
- Ensuring that GCP guidelines are implemented as closely as possible and what to do if this does not happen
- How to monitor your clinical trials to make sure that the data will be accepted by the regulatory authorities
- With the high rate of patient recruitment, how can you ensure that your clinical trial data is of high quality?
- Considering the demographics and clinical trial therapeutic areas in Latin America to help with patient recruitment

Conference Day 2: Wednesday 22 April 2009

Vital information on clinical trial infrastructure and overcoming logistical challenges

Focus on China: Clinical trial infrastructure and overcoming the logistical challenges

- Overcoming the difficulties in exporting biological samples from China
- How to find enough sites with the right capabilities for your clinical trials
- Obtaining an import license, and how long this will take in China
- What is the quality of transportation?
- Effectively overcoming problems with your clinical trial data management
- Difficulties with distance and availability

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Focus on Central and Eastern Europe (Russia, Ukraine, Bulgaria, Romania): Latest updates on the logistical challenges

- The status of customs clearance and storage for drugs in Central and Eastern Europe
- Finding clinical trial sites with the right capabilities
- The requirements for import and export licences
- Effectively overcoming problems with your clinical trial data management
- What are the differences in infrastructure between Eastern Europe and Western Europe
- The quality of transportation in Central and Eastern Europe?
- Overcoming the difficulties with distance and availability

Focus on Africa: Strategies for overcoming logistical challenges with little clinical trial infrastructure

- Overcoming the challenges of import customs procedures
- The difficulties in the cost of transporting drugs and tissue samples
- Finding well trained CROs and investigators in Africa
- The possibility of investing in infrastructure and whether this will be beneficial in the long term
- Working with local governments to establish local infrastructure

Crucial information on investigator training and qualifying: Ensuring that the regulatory authorities will approve your clinical trial sites as quickly as possible

Keynote Presentation: Improving your clinical trials in emerging economies by training and qualifying investigators

- Overcoming the problem of investigator compliance
- Providing training incentives for the investigators
- How to implement distance learning techniques
- Ensuring targeted and suitable training for investigators

Indispensable information on outsourcing in emerging economies
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Keynote Presentation: Vital tips from a global outsourcing specialist

- Strategies on how to select your CRO
- In which situations should you choose local or global CROs?
- Ensuring that you find flexible and innovative CROs
- What is the industry trend for outsourcing?
- Maintaining an effective monitoring system and implementing controls for the CRO
- Obtaining a critical review of the CRO – past records and references
- Sponsor involvement in emerging economies - doing your own homework and not just relying on the CRO

Case study – China: Finding the most effective outsourcing partners

- Conducting a feasibility study to ensure that the outsourcing partner can cope with your protocol before making the contract
- Maintaining the relationship between the outsourcing partners and the sponsor
- Understanding the culture of the outsourcing partner
- Making sure that the outsourcing partners ensure compliance with the clinical trial protocol

Case study – Latin America: Guidance on obtaining outsourcing partners

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- Developing contracts and negotiating fees
- What is the set up of the health system in Latin America?
- Using assessment points to choose the most appropriate outsourcing partners
- Maintaining the relationship the outsourcing partners and the sponsor
- Feasibility study – ensuring that the outsourcing partner can cope with your protocol before making the contract

Essential guidance on outsourcing in South East Asia

- What are the advantages and disadvantages of using local or global CROs?
- Finding flexible CROs who know the area
- Maintaining the relationship with the CRO after the contract has been signed
- Making sure that the outsourcing partners ensure compliance with the clinical trial protocol

Considerations for the future of clinical trials in emerging economies
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Evaluating the feasibility of running clinical trials in the Middle East and North Africa (Egypt, Morocco, Tunisia)

- The viability of running clinical trials in the Middle East and North Africa
- What is the status of the clinical trial infrastructure?
- Will the investment in training investigators and staff be worthwhile?
- Information on the CROs that are looking to develop in these regions
- Overcoming the cultural barriers

Panel Discussion: Phase I and paediatrics trials – will these be feasible in the future?

- What is the feasibility for Phase I trials to be conducted in emerging economies?
- Will Phase I trials be allowed in India and China in the future?
- Will paediatric trials ever be outsourced to emerging economies?
- Will Chinese law ever allow paediatric trials to be conducted – are the views on paediatric trials shifting in line with Europe and US?
- Phase I can only be carried out if the drugs are developed in India/China – will this change?