

Clinical Trials Asia Summit 2010

19, 20, August 2010, Taj Residency (M.G. Road), Bangalore, India

"Improving clinical practice & trial success rates with improved technologies, strategies & alliance management"

Key Speakers Include:

Akhilesh Sharma, Vice President & Global head Clinical management & Global Pharmacovigilance, **Dr. Reddy's**

Bakulesh Khamar, Executive Director – Research, **Cadila**

R. Jha, Senior Vice President - Clinical Research, **Wockhardt**

Shashidhar Rao, India Operations Head (IID and IA&R), **Novartis**

Mohan Bangalore, Senior Director & Site Head, **Pfizer**

Parminder Kaur, Managing Director, **RegPak BioPharma Consulting, Netherlands**

Shashidhar Rao, India Operations Head (IID and IA&R), **Novartis**

Arun Bhatt, President, **Clininvent Research**

Milind Antani, Head-Pharma LifeSciences group, **Nishith Desai Associates**

Sanjay Zodpey, Director, **Indian Institute of Public Health**

S.K.Bhattacharya, Medical Officer, Depart of Communicable Diseases, **WHO (World Health Organisation)**

Shailesh Mehta, Director Clinical R&D and Med Affairs, South Asia, **Glaxosmithkline**

Roopa Basrur, Associate Director - Clinical Writing and Document Quality, **Pfizer**

Veena Rajan, Patient Safety Manager, **Astrazeneca**

Yamin 'Mo' Khan, Executive Vice President, Clinical Development **Pharma-Olam (U.K)**

Marcus Hompesch, President – CEO, **Profil Institute - Clinical Research, USA**

Larisa Nagra Singh, Senior Director Clinical Operations, Asia Pacific, **ICON Clinical Research**

Darshan Bhatt, Chair, **Data & Safety Monitoring Board**

Mala Srivastava, Partner, **Nextvel Consulting**

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Clinical Trials Asia Summit 2010

August 19th - 20th 2010, Bangalore, India.

Conference Info:

Clinical trials in India are finally becoming transparent. There has been a dramatic increase in the number of trials that have got officially registered in Clinical Trials Registry-India (CTRI). According to records collected by the Indian Council of Medical Research and the Drug Controller General's office, between July-December 2007, only 11 trials were registered. The number increased to 137 between Jan-Dec 2008 and then to an all-time high of 546 between Jan-Dec 2009. This year, while January saw 58 trials registered, February recorded 60. India has all the competitive advantages for conducting clinical trials. As the country is increasingly becoming a favoured destination for clinical trials, a gap analysis needs to be done to scale up all resources for clinical trials. This scale up is essential for India to cope with the large global clinical trial projects. It is no coincidence over the last decade or more of economic liberalization, and years of unprecedented growth, that India and parts of South Asia are becoming a preferred clinical research destination for multinational pharmaceutical and biotechnology corporations.

CTAS 2010 will examine the current issues faced in clinical trials operations, addressing the risks, timeline and budget stipulations, while effectively tackling key challenges in overcoming trials agreement and site contract arbitration problems. This summit will discuss the operational element of trial site management, strategic partnership with CROs and SMOs, patient, talent & investigators management in order to improve & optimise the overall drug development effectiveness and ROI. Discover on how to implement and benefit from electronic data management & monitoring cost effectively. This conference will be shared by leading industrial practitioners across the region to promote practical discussions; especially on the know-how to manage needs, variability of different countries and institutions to enhance clinical operational excellence and vigilance. Attendees will have the chance to learn, network and benchmark against the global top pharma and local industry leaders on the best practices in talent, site, budget and performance management in clinical trials. The conference aims to provide a detailed analysis of what it takes to conduct clinical trials from a biopharmaceuticals and vaccines perspective in India and China and also addressing risk/benefit balance, anecdotal experiences of the multinational pharmaceutical industry in India and China, selection and role of CROs, logistics of operations, clinical trials management, government policies and pharmacovigilance.

CTAS 2010 will provide you with the data that you need to recognize this complex and rapidly-expanding sector. Knowing the future market, and what impact will that have on future business opportunities? This is your opportunity to stay ahead by learning the latest trends and networking with the trend setters.

It gives us immense pleasure in welcoming you to the Clinical Trials Asia Summit '2010.

Key Themes Discussed at this conference

- Current trends of clinical trials environment
- How can you take advantage of the global market for clinical trials?
- Discovering technologies and strategies for successful clinical trial management
- Analyzing the successes and challenges of Phase I and Phase II clinical trials
- Setting up clinical trial research hub & techniques for applying risk management principles.
- Discover how to improve your supplier-client relationships
- Complete trials on schedule & budget by overcoming hurdles in investigator/patient recruitment
- Avoiding potential pitfalls of trials agreement
- Gather the latest regulatory updates impacting global and Indian clinical development
- Explore innovative strategies for outsourcing, what should you be looking for in a CRO?
- Improving and optimizing site management and overall productivity of clinical operations
- Data management, CMC SCM, operational requirements & CRO infrastructure in India & South Asia
- Optimising clinical trials operation effectiveness and ROI through strategic site, patient, data and risk management in the regulated markets
- What are the issues with off-shoring trials to countries such as India & South Asia? – Solutions?
- Working with limited budget to ensure on time study completion
- Motivating and managing clinical project teams to improve timeline and progress
- Exploring the efficacy and safety of new interventions in clinical trials
- Drawing and retaining clinical talent pool to minimise turnover in clinical studies
- Next generation of clinical trials – How big will the market be?

Who Should Attend:

Vice Presidents, Directors Heads & Managers of: Clinical Research & Development, Clinical Research Services, Clinical Operations, Clinical Data Management, Clinical IT, Clinical Trials, Medical Affairs, Regulatory Affairs, Compliance, Quality Control/Assurance/GCP, Clinical Study Design, Safety Surveillance, Subject Recruitment, E-Clinical Systems

Target Audience - Industry:

Pharmaceutical Organisations, Generic pharmaceutical companies, Contract Research Organisations, Patient Recruitment Companies, Government- Department of Health, Non-profit Organisations/Association, Academics, Consultants

Why should you attend:

Clinical Trials Asia Summit 2010 - "Improving clinical practice & trial success rates with improved technologies, strategies & alliance management"

Get more from the event, with a broader scope bringing the whole communications value chain together. Enjoy and make the best out of our **dedicated networking drinks time, meet the leading international vendors** showcasing the technology of tomorrow in the co-located exhibition. **Expand your knowledge** of the latest business models and technologies in the high-level conference.

Delegate Registration:

To register and to book your seats at the conference - please email your interest & queries to delegate@virtueinsight.com

Sponsorship Opportunities:

To register & to book your sponsorship package - please email your interest & queries to sponsor@virtueinsight.com

Clinical Trials Asia Summit 2010

August 19th 2010, Bangalore, India.

08:30 – Coffee and registration

09:30 – Chair's opening remarks

09:40 – Examining the evolution of clinical trials

- Where does India stand in the current global clinical trials market?
- How can you take advantage of the global market for clinical trials?
- Identify the significance of the clinical trial in India and South Asia market
- Emerging technologies that can be deployed to generate revenue
- Allied services - Data Management & IT services – Can they play significant role in outsourcing clinical trials?

10:20 – Changing concept of conducting clinical trials

- Challenges in conduct of investigator initiated research
- Biomarkers and newer endpoints in oncology
- Structure of existing system for training and monitoring staff performance
- What are the common problems of staff monitoring and effective solutions to minimise cost for your trials
- Challenges in conducting medical device trials

11:00 – Morning coffee & Discussion

11:20 – “Factors limiting acceptability of foreign clinical data: EMEA perspective”

**Parminder Kaur, Managing Director,
RegPak BioPharma Consulting, Netherlands**

12:00 – Panel Discussion: Evaluating key emerging markets for improved strategy

- Which emerging markets are hottest today?
- Offshoring - Balancing the right opportunities and risks
- What makes each market unique and how do markets compare?
- Successful budget development & analysis - How do sponsors develop study budgets? How do sites price their services?
- How to go about tracking & collecting payments properly?

Moderator –

Shashidhar Rao, India Operations Head (IID and IA&R), Novartis

Panelists –

Arun Bhatt, President, Clininvent Research

12:40 – Networking luncheon

14:00 – Impact of advanced technology in today's clinical trials

- Enable more reliable, smaller, faster, safer trials
- Benefits of Information Technology in clinical trials - (EDC), (CTMS), (CDMS), (DBMS)
- Overcoming issues related with managing security, confidentiality and ethical concerns

14:40 – Relationships: Sponsor – Site - CRO

- Three-way relationship between sponsors, sites and CROs realistic expectations, clear communications, shared understandings, practical policies, and efficient problem resolution
- Identifying the anticipated advantages of a collaborative clinical trial alliance for greater efficiency and cost reduction
- Developing programs for successful partnership
- Quantitative analysis reveals rapid changes in the industry and trends for the future. How can sponsors, sites and CROs meet the challenges?

Arun Bhatt, President, Clininvent Research

15:20 – Afternoon tea

15:40 – Panel Discussion: Overcoming regulatory challenges in Asian clinical trials

- Introducing recent developments in regulatory affairs and legal challenges for clinical trials
- Understanding how Indian companies can work in harmony with the European legal framework
- Analysing the current scope and strategies of pharmaceutical / biopharmaceutical regulatory harmonization
- Government incentives for Clinical Research in India
- Quality standards in clinical trials

Moderator –

Milind Antani, Head-Pharma LifeSciences group, Nishith Desai Associates

Panelists –

Sanjay Zodpey, Director, Indian Institute of Public Health

16:20 – Safety data Management

Darshan Bhatt, Chair, Data & Safety Monitoring Board

17:00 - Start-up teams to manage clinical trials: Advantages and Limitations

- Structure and set-up of an effective start-up team
- Communication channels between start-up team, operations and Investigator sites
- Advantages and Limitations of managing projects under above structure

Larisa Nagra Singh, Senior Director Clinical Operations, Asia Pacific, ICON Clinical Research

17:30 - Logistics as a facilitator of growth in the pharma industry

- What are the current logistics challenges in pharma industry?
- What are the recent applications of technology to aid the Clinical SCM?
- Secure strategies – for maintaining your materials during transits
- Efficiency of a potential logistics – transforming the pharma sector

18:00 - Chairperson's closing remarks and end of conference

17:40 - Networking Drinks - Take your discussions further & build new relationships in a relaxed & informal setting...



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08:30 – Coffee and registration

09:30 – Chair's opening remarks

09:40 – Opportunity trials of Clinical Research in India: Focusing on Phase I and Phase II

- Reviewing the phase I and II clinical research environment in India
- Focus on related business models in conducting clinical trials in India
- Evaluating the opportunities of potential collaborations

R. Jha, Senior Vice President - Clinical Research, Wockhardt

10:20: Clinical Data Management (CDM) – Guidelines for a successful future

- Safety data management
- Good data review and validation practices
- Challenges! In medical coding
- Consideration in database designing & edit check programming
- Good programming practices and where can one go wrong in query management?
- Developing protocols that generate useful data, practical for sites to implement, acceptable to subjects, and work internationally.

11:00 – Morning coffee & discussion

11:20 – Innovative designing of clinical trials

Akhilesh Sharma, Vice President & Global head Clinical management & Global Pharmacovigilance, Dr. Reddy's

12:00 – Panel Discussion: Sourcing the right partners, Sponsor – Vendor partnerships

- How to work with your sponsor for a profitable study
- What do CRO look for in a good sponsor?
- Analysing India's offering in large scale global trials: cost, resources, patient pool
- Avoiding mistakes in selecting an outsourcing partner to conduct clinical trials
- Quantitative analysis reveals rapid changes in the industry and trends for the future. How can sponsors, sites and CROs meet the challenges?

Moderator –

Shashidhar Rao, India Operations Head (IID and IA&R), Novartis

Panelists –

Mohan Bangalore, Senior Director & Site Head, Pfizer

Marcus Hompesch, President – CEO, Profil Institute - Clinical Research, USA

Yamin 'Mo' Khan, Executive Vice President, Clinical Development, Pharm-Olam (UK)

Mala Srivastava, Partner, Nextvel Consulting

12:40 – Networking luncheon

14:00 – Challenges of conducting Phase III cancer trails in India

Bakulesh Khamar, Executive Director – Research, Cadila

14:40 – Conducting large-scale community trials

S.K.Bhattacharya, Medical Officer, Depart of Communicable Diseases, WHO (World Health Organisation)

15:20 – Afternoon tea

15:40 – Exploring the efficacy and safety of new interventions in clinical trials

Shailesh Mehta, Director Clinical R&D and Med Affairs, South Asia, Glaxosmithkline

16:20 - Setting up a medical writing unit in India

- Outsourcing medical writing to India – a novel business model.
- What factors are important at start-up and later on?
- Measuring success in a subjective domain – metrics.
- Challenges and solutions.

Roopa Basrur, Associate Director - Clinical Writing and Document Quality, Pfizer

17:00 – Panel Discussion – SWOT analysis - Strength, Weakness, Opportunities & Threats of Clinical Trials in India (Overall review of this Clinical Trials Asia Summit 2010 conference)

- Identifying market potential strengths and weakness
- Benefits of India - reducing costs, accelerating time to market?
- Analysing India's offering in large scale global trials: cost, resources, patient pool
- Avoiding mistakes in selecting an outsourcing partner to conduct clinical trials

Moderator:

Panellists:

Veena Rajan, Patient Safety Manager, Astrazeneca

17:30 Chairperson's closing remarks and end of conference

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- 1 Day conference Fee: INR 08,000 + Tax
- 2 Day conference Fee: INR 10,000 + Tax

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General information Venue:

Taj Residency - MG Road, Bangalore, India,

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