

6TH ANNUAL CLINICAL TRIALS SUMMIT 2015

“A critical guide for successfully conducting clinical trials”

28th & 29th May 2015, Kohinoor Continental Hotel, Mumbai, India

KEY SPEAKERS INCLUDE:-

K. Bangarurajan, Dy. Drugs Controller (I) CDSCO, **DCGI**

Arun Bhatt, President, **Clininvent Research**

Bhaswat S. Chakraborty, Senior VP, R&D, **Cadila**

Richard Young, Vice President, EMEA, **Medidata (UK)**

Amit Arora, Head Medical Affairs, **Merck Serono**

Ashwani Pandita, Head Quality Management and Training, Global Clinical Research Operations, **Glenmark**

Kedar Suvarnapathaki, Head - Regulatory Affairs, **Boehringer Ingelheim**

Chirag Trivedi, Director & Head of Clinical Study Unit, **Sanofi Aventis**

Babita Kirodian, Head of Country Pharmacovigilance, **Bristol Myers Squibb**

Sunit Maity, AVP Product Development, **Theramyt Novobiologics**

Pratik Shah, Head- Clinical, Medical & Regulatory Affairs, PV and QA, **Astellas Pharma**

Jyotsna Patwardhan, Head Development QA, **Novartis**

Piyush Gupta, Associate Director, **GNH India**

Mazhar Maruf, Regional Head of Pharmacovigilance- Asia Pacific, **Glenmark**

Sujay Salvi, Head, Clinical Trial Supplies Management, **SIRO Clinpharm**

Chitra Bargaje, Consultant, **ADAMAS Consulting**

V.K. Sharma, Associate Vice President, **Unichem Laboratories**

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

Deepti Sanghavi, Senior Medical Writer-Medical Writing, **SIRO Clinpharm**

Vandana Jolad Shivangi, Director, **VIaTAL Pharma Consulting**

Plus Many More...

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CONFERENCE INTRODUCTION:-

The International Registry of Clinical trials, the data bank maintained by the NIH in U.S. (clinical trials.gov), has around 203,394 trials being carried out worldwide. As per this registry, the number of trials carried out in India is only 3043, which is <1.5 % of global trials. The Indian registry set up under the aegis of WHO and the Indian Council of Medical Research (ICMR) in 2T008 which made registration of all trials mandatory from June 15th of 2009 also corroborates this number. Understandably > 40 % of all global trials are carried out in the U.S. China has registered 17198 trials (> 8%) , substantially higher than India. The fear that there is an avalanche of trials moving out to India ,risking our population to trial drugs is thus unfounded. As of now India is by no means a preferred hub for clinical trials, but the the potential to become one, in view of many favourable factors, such as state-of-the-art skills of investigators, level of quality healthcare institutions, the availability of patient populations with diverse genetic pools, language advantage and information technology based analytical tools.

The events of the last two years which severely affected the clinical trial scenario in India may have even consolidated and tightened the system to bring in more transparency and quality assurance which will enhance the credibility of Indian efforts in the area. What is required is a systematic, time bound regulatory evaluation and approval system for all phases of trials and better and transparent communication between the stake holders and the regulatory agency. Without new drugs discovery, much of the disease problems of the world will remain unattended and neglected. The new government, in one of its early policy statements had emphasized the need to encourage properly conducted clinical trials in India with appropriate regulatory controls. It is fervently hoped that realising the importance of this segment in New Drug Discovery Research, the concerned authorities will take a pragmatic view and through time bound and more diligent approval processes encourage clinical research.

6th annual clinical trials summit 2015 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 & optimize the overall drug development effectiveness and ROI. 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 pharmas 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 also addressing risk/benefit balance, anecdotal experiences of the multinational pharmaceutical industry in India and other parts of Asia, selection and role of CROs, logistics of operations, clinical trials management, government policies and pharmacovigilance. 6th annual clinical trials summit 2015 will provide you with the data that you need to recognize this complex and rapidly expanding sector. Knowing the future market, and what impacts will that has on future business opportunities? This is your opportunity to stay ahead by learning the latest trends and networking with the trendsetters.

It gives us immense pleasure in welcoming you to the **6th Annual Clinical Trials Summit 2015**. I wish and pray that all our efforts will be beneficial to our industries and to our country at large

KEY THEMES DISCUSSED AT THIS SUMMIT:-

- Update yourself with respect to terms of legislation, policies, systems, technology, communication strategies and best practices
- Determining the steps and strategies for enhancing quality in healthcare
- Discovering the new trends in global clinical trials and their role in India
- Technologies that drive efficiencies in global clinical trials
- Strategies to conduct successful interventional oncology trials in India
- Quality by design
- Monitoring, managing and leading clinical trials: An integrated approach for better trial success
- Maintaining proper balance in relationships: Sponsor – Site – CRO & Patients
- Margin of safety: Identifying ideal clinical sites and strategizing patient recruitment and clinical sites management in India to develop appropriate clinical studies
- Effectively incorporating GCP & GCPs – Knowing what TO-DO and what NOT TO-DO
- Re-Thinking patient recruitment and patient experience
- Finding the ideal partner in outsourcing your logistics operations in India how to identify smart packaging solutions to balance quality and costs
- Identifying the decision criteria for partnering with the right vendors in Asia
- How to manage risks in clinical trials effectively and how to successfully incorporate risk sharing models in clinical trials
- Avoiding mistakes in data collection and ensuring profitability and to understand the long term operation strategies for managing clinical trials.
- Overcoming challenges faced in regulatory approval processes – obtaining drug/ clinical supplies import and export licenses in Asia
- Regulatory review at the drugs controller general of India (DCGI) and central drugs standard control organization (CDSCO): science, quality, and speed
- Analyzing the recent government rules and guidelines
- Next generations of clinical trials – How big will the market be?
- Be part of a major networking opportunity

TARGET AUDIANCE-INDUSTRY:-

Pharmaceutical organisations, Generic pharmaceutical companies, Contract research organisations, Patient recruitment companies, Government- Department of health, Non-profit organisations/ Association, Consultants

WHO SHOULD ATTEND:-

CEO's, CTO's, CIO's, Presidents, 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.

WHY SHOULD YOU ATTEND:-

6th Annual Clinical Trials Summit 2015 - "A critical guide for successfully conducting clinical trials" - 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 expand your knowledge of the latest business models and strategies in the high-level conference. Show casing the products of tomorrow in the co-located exhibition.

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DAY 1 - 28th MAY 2015

08:30 – Coffee and registration – An opportunity to meet and to network with your conference colleagues.

09:30 – Chairperson opening remarks

V.K. Sharma, Associate Vice President, Unichem Laboratories
(<https://www.linkedin.com/pub/v-k-sharma/23/ba/197>)

MARKET OVERVIEW & ANALYSIS

09:40 – Morning Keynote Address 1: Indian Clinical Trials: Current challenges and future focus

- Evolving Indian Regulatory scenario
- Challenges to India's potential in clinical research
- Focussing the future on fundamentals

Arun Bhatt, President, Clininvent Research
(<https://www.linkedin.com/pub/arun-bhatt-dr/4/9bb/658>)

10:10 – Morning Keynote Address 2: Clinical trial outsourcing: Concerns and guidelines

- Status of India in current global clinical research market
- Conducting clinical trials in India
- Latest guidelines & scrutinizing for investigators
- Possible remedies for Indian market to match regulatory guidelines
- How to improve quality assurance in Indian clinical research industry

10:40 – Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

11:00 – Keynote Panel Discussion: Challenges and Opportunities for now and future

- What are the current problems faced in today's market and how to successfully overcome them in this highly competitive market?
- 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?
- Recruitment and retention of patients

Moderator:

V.K. Sharma, Associate Vice President, Unichem Laboratories
(<https://www.linkedin.com/pub/v-k-sharma/23/ba/197>)

Panellists:

Bhaswat S. Chakraborty, Senior VP, R&D, Cadila
(<https://www.linkedin.com/pub/bhaswat-chakraborty/18/34/27>)

Sunit Maity, AVP Product Development, Theramyt Novobiologics (<https://www.linkedin.com/profile/view?id=50995319>)

Richard Young, Vice President, EMEA, Medidata (UK)
(<https://www.linkedin.com/pub/richard-young/4/29a/960>)

RMP

11:40 – Risk based approach

- Onsite and remote monitoring approaches
- Recurrent risks and mitigation through monitoring
- Quality-by-design
- Risk management and risk minimization
- Risk minimization effectiveness measurement

Richard Young, Vice President, EMEA, Medidata (UK)
(<https://www.linkedin.com/pub/richard-young/4/29a/960>)

12:10 – Busting Myths - Comparator sourcing from India

- Common myths, Common assumptions
- How sourcing mistakes escalate sourcing costs and delay trials
- Regulatory Facts for innovator registrations in India
- Take an informed decision - Based on facts
- Role of Specialized Comparator suppliers

Piyush Gupta, Associate Director, GNH India

12:40 - Networking luncheon - Take your discussions further & build new relationships in a relaxed & informal setting...

SPONSOR – SITE – CRO – PATIENTS

14:00 - Afternoon Keynote Panel Discussion - Maintaining proper balance in relationships: Sponsor – Site – CRO & Patients

- Four-way relationship between sponsors, sites, CROs & patients - Realistic expectations, clear communications, shared understandings, practical policies, and efficient problem resolution
- Quantitative analysis reveals rapid changes in the industry and trends for the future. How can sponsors, sites and CROs meet the challenges?
- Choosing a partner who can take necessary steps to rectify the situation when things go wrong
- Understanding sponsors principle for selecting the local clinical research organization
- Identifying the anticipated advantages of a collaborative clinical trial alliance for greater efficiency and cost reduction
- What are the current perspectives on the future of outsourcing in Asia?

Moderator:

Vandana Jolad Shivangi, Director, VIaTAL Pharma Consulting

Panellists:

Amit Arora, Head Medical Affairs, Merck Serono
(<https://www.linkedin.com/in/arora007>)

Ashwani Pandita, Head Quality Management and Training, Global Clinical Research Operations, Glenmark
(<https://www.linkedin.com/pub/ashwani-pandita-rqap-gcp/14/997/590>)

Sujay Salvi, Head, Clinical Trial Supplies Management, SIRO Clinpharm (<https://www.linkedin.com/pub/sujay-salvi/5/73b/82a>)

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QUALITY - SAFETY - SIGNAL DETECTION

14:40 - Panel Discussion - Margin of safety: Identifying ideal clinical sites and strategizing patient recruitment and clinical sites management in India to develop appropriate clinical studies

- To implement correct safety and healthy measures.
- Ensuring security of clinical data and non-disclosure.
- Challenges for quality assurance in clinical trials.
- Using pharmacovigilance databases to facilitate the detection of adverse events and the generation of safety signals
- Examining information provided in Individual Case Safety Reports (ICSRs) to determine whether a signal should be investigated or not
- Start-up teams to manage clinical trials: advantages and limitations

Moderator:

Deepti Sanghavi, Senior Medical Writer-Medical Writing, SIRO Clinpharm (<https://www.linkedin.com/pub/dr-deepti-sanghavi/5/591/b76>)

Panellists:

Chirag Trivedi, Director & Head of Clinical Study Unit, Sanofi Aventis (<https://www.linkedin.com/pub/dr-chirag-trivedi/21/b0/344>)

Pratik Shah, Head- Clinical, Medical & Regulatory Affairs, PV and QA, Astellas Pharma (<https://www.linkedin.com/in/drpratikshah>)

Jyotsna Patwardhan, Head Development QA, Novartis

Chitra Bargaje, Consultant, ADAMAS Consulting (<https://www.linkedin.com/in/chitrabargaje>)

15:20 – Afternoon Tea/Coffee

15:40 – Monitoring, managing and leading clinical trials: An integrated approach for better trial success

- Clinical research staff should understand the difference between tactile execution and strategic execution in clinical operations
- It is important to gain new insights into an integrated role which addresses many unmet needs of a clinical trial
- The 'Next Generation Clinical Research Professionals' should adapt to their new role by looking inside to face the outside
- Clinical trial success depends greatly on creating and nourishing a collaborative and learning culture in this new role

REGULATORY

16:10 – Panel Discussion: The developing regulatory framework in advanced and developing markets – for Today & Tomorrow

- Adapting to India's transformed regulatory landscapes to conduct clinical trials
- A brief recap of recent regulatory developments. Ensuring you comply with market requirements
- What is to be learnt on how Indian companies can work in harmony with the RoW legal frameworks
- Effectively incorporating GCP & GCPs – Knowing what TO-DO and what NOT TO-DO

Moderator:

Milind Antani, Head - Pharma LifeSciences, Nishith Desai Associates (<https://www.linkedin.com/in/milindantani>)

Panellists:

K. Bangarurajan, Dy. Drugs Controller (I) CDSCO, DCGI

Mazhar Maruf, Regional Head of Pharmacovigilance- Asia Pacific, Glenmark (<https://www.linkedin.com/pub/dr-mazhar-maruf/b/303/2b5>)

Kedar Suvarnapathaki, Head - Regulatory Affairs, Boehringer Ingelheim (<https://www.linkedin.com/pub/kedar-suvarnapathaki/4/954/765>)

Babita Kirodian, Head of Country Pharmacovigilance, Bristol Myers Squibb (<https://www.linkedin.com/profile/view?id=37647503>)

16:50 - Chairperson's closing remarks and end of conference

17:00 -18:00 - Networking Drinks - Take your discussions further & build new relationships in a relaxed & informal setting...





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A 2020 Vision for Clinical Research In India

Led By: Workshop Leaders From
Medidata Solutions, Cadila and more..

Timings: 09:00 - 10:00 Coffee & Registration

10:00 - 16:00 Workshop

Timing Includes Lunch and Refreshment Breaks

DAY 2 - 29th MAY 2015

Workshop Topics -

- An Indian Regulatory Update
- Interactive Medidata Demo - Medidata Platform
- RBM - Improving quality whilst reducing cost!
- Interactive Medidata Demo RBM

Workshop Leaders -

Kyle Davids, Regional Account Manager, Medidata Solutions
(<https://www.linkedin.com/pub/kyle-davids/6/83a/231>)

Bhaswat S. Chakraborty, Senior VP, R&D, Cadila
(<https://www.linkedin.com/pub/bhaswat-chakraborty/18/34/27>)

Andrew Gebbie, Senior Solution Specialist, Medidata Solutions
(<https://www.linkedin.com/pub/andrew-gebbie/33/a25/904>)

Christopher Burke

ABOUT MEDIDATA -

We provide innovative clinical development solutions that safely and efficiently improve quality of life. We provide our customers with a competitive advantage by facilitating operational excellence in their clinical research processes:

- Eliminating redundant and error-prone processes,
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For more Information, visit: <http://www.mdsol.com/>

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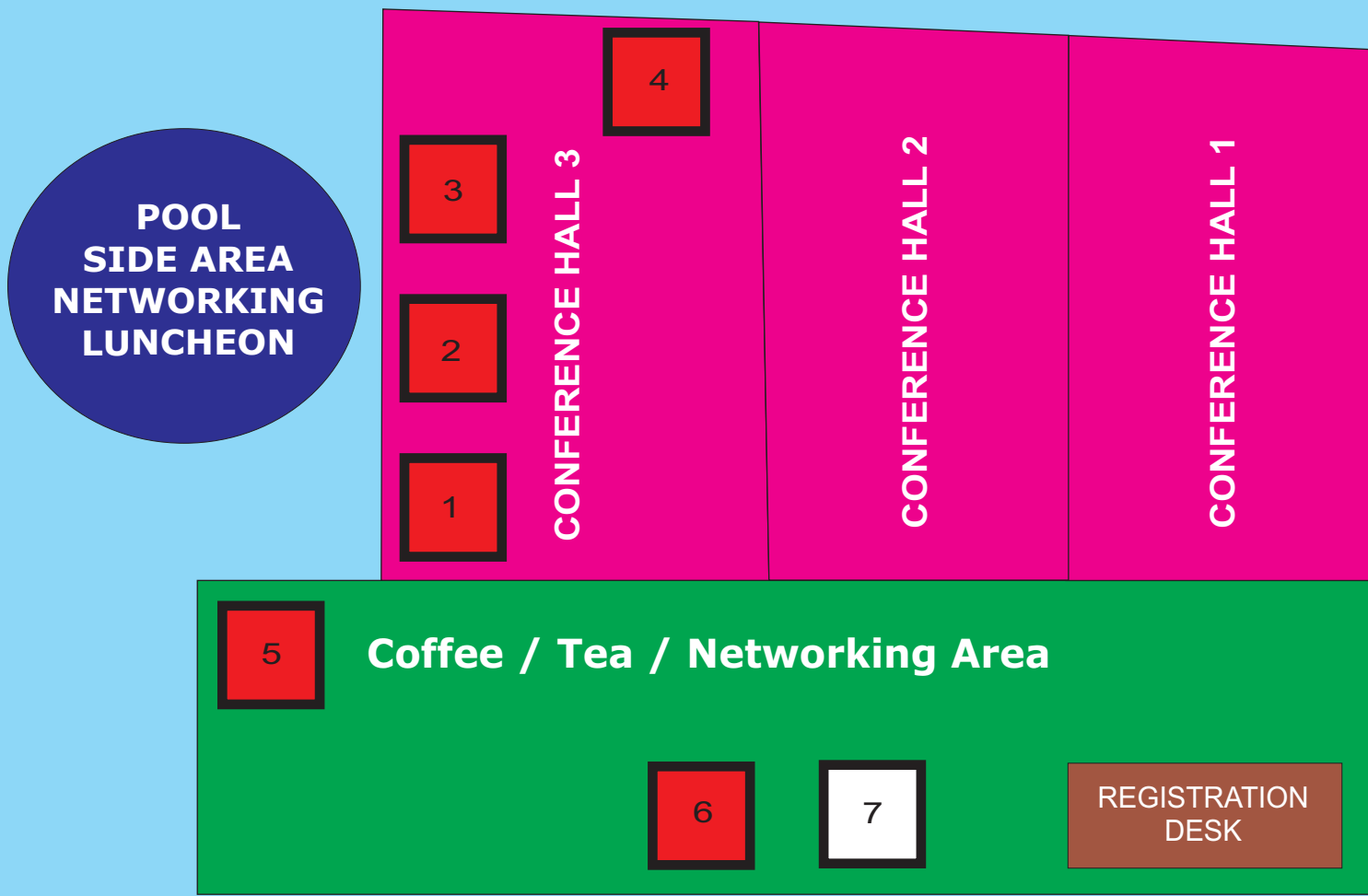
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Attendees from our previous Clinical Trials Conference

Abbott	MS Clinical Research	Bayer	Medidata Solutions
Abbott Nutrition R & D	Newtronic	Beroe Consulting India	Metropolis Healthcare
Acceliant	Nishith Desai Associates	Bilcare	Metropolis Healthcare
Accutest	Novartis	Biocon Foundation	MJ Biopharm
ACG Associated Capsules	Novartis Healthcare- Vaccines Division	BioSpectrum	MMSH Clinical Research
Alcon - Global Clinical Site Management	Ocasa Logistic Solutions	Biotechnology Industry Research Assistance Council	MS Clinical Research
Alkem Laboratories	OmniActive Health Technologies	Boehringer Ingelheim	Mylan Laboratories
Allergan Healthcare	Oncquest Laboratories	Bristol-Myers Squibb	Natco Pharma
Antara	Oviya MedSafe	Business Vibes	National Institute of Health, U.S. Embassy
Apotex	Panacea Biotec	C.L.A.I.M.S	Newtronic
Astellas Pharma	ParadigmIT	Cadila	Nishith Desai Associates
AstraZeneca	Percipenz	Cambridge Research & Instrumentation	Novartis
Atharva Lifesciences Consulting	Pharma Bio World	CanBiotech	Ocasa Logistic Solutions
Bangalore Diabetes Hospital	Pharma Mirror	CCRT	OmniActive Health Technologies
Bayer	PharmaLeaf	Cipla	Oncquest Laboratories
Beroe Consulting India	PharmaVOICE	City X Ray & Scan Clinic	Oracle Health Science
BioSpectrum	Pharmcast	Clinical Diagnostic Centre	Oviya MedSafe
Biotechnology Industry Research Assistance Council	Piramal Life Sciences	Clinigene	Panacea Biotec
Boehringer Ingelheim	PRA International	Cliniminds	ParadigmIT
Bristol-Myers Squibb	Provenance Research	Clininvent Research	PDP Couriers
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CCRT	Reliance Life Sciences	Coffee Day	Pharmaphorum
Cipla	Rubicon Research	Cognizant Technologies	PharmaVOICE
Clinical Diagnostic Centre	Ruby Hall Clinic	Crescent Scientific	Pharmcast
Clinigene	S P Software Technologies	CSC	Physis Learning Academy
Cliniminds	Sanofi Pasteur	Cygnus Business onsulting & research	Piramal Life Sciences
Clininvent Research	Sanofi Pasteur	Cytespace Research	Pirmal Healthcare
CliniSearch	Sanofi-Aventis	Dabur India	PRA International
Clinitrials Research	SanceCR	DBMS Consulting	Provenance Research
Clinnex	Serum Institute of India	DCGI	Quad One Technologies
ClinOma Healthcare	SGD S.A Glass	DiagnoSearch LifeSciences	Quartesian
ClinTrials Research	SIRO Clinpharm	Dr. Reddy's Laboratories	Quest Diagnostics
Coffee Day	Solonist Business Solutions	ECCRO India Services	Quintiles
Cognizant Technologies	SP Software Technologies	Ecron Acunova	Ranbaxy Laboratories
CSC	SRL	Eli Lilly	RegPak BioPharma Consulting
Cygnus Business onsulting & research	SRL Diagnostics	EMC Corporation	Reliance Life Sciences
Dabur India	Stempeutics Research	Etyka Clinical Solutions	Rubicon Research
DBMS Consulting	Strides	Expire Health Research	Ruby Hall Clinic
DCGI	TCS	Express Pharma	S P Software Technologies
DiagnoSearch LifeSciences	Tech Observer	Famy Care	Sahajanand Medical Technologies
Dr. Reddy's Laboratories	Tech Tree	Forte Research Systems	Salzer Technologies Limited
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Ecron Acunova	Templegate	Fresenius Kabi	Sanofi India
Eli Lilly	The Pharma World	G7 SYNERGON	Sanofi Pasteur
Express Pharma	Torrent Research Centre	Generic Licensing	Sanofi
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Forte Research Systems	Unilever	Glenmark Pharmaceuticals	SenceCR
Fortis Clinical Research	Unithink	Global Data	Serum Institute of India
Fresenius Kabi	Until Roi	Global Health	SFS Pharma Logistics
G7 SYNERGON	VAC3 ClinicalService	Going To Meet	SGD S.A Glass
Generic Licensing	Vanthys	Government of Victoria, Australia \ India office	Shantha A Sanofi Company
GlaxoSmithKline	Veeda Clincial Research	GSK	SIRO Clinpharm
Glenmark	VerGo Pharma Research	GVK Bio	Solonist Business Solutions
Global Data	Voisin Consulting	HCL Technologies	SP Software Technologies
Global Health	Voisin Life Sciences	Heart Care Associates	Spectrum Oncology
Going To Meet	VPH	Hinduja Hospital	SRL Diagnostics
GVK Bio	Watson Pharma	Hindustan Times	Stempeutics Research
HCL Technologies	Western Institutional Review Board	Hospira Healthcare	Strides
Heart Care Associates	Witness	ICRI	Sun Pharma Advanced Research Company
Hinduja Hospital	Wockhardt	Image Core Lab	Tata Memorial Hospital
Hindustan Times	World Pharma Today	Inbiopro Solutions	TCS
Hospira Healthcare	YCLIN	Indian Academy of Clinical Research	Tech Observer
ICRI	Zydus Cadila Healthcare	Indus Biotech	Tech Tree
Image Core Lab	A.Menarini	Interven laboratories	Tech-Observer
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Indian Academy of Clinical Research	Abbott Nutrition R & D	ITS-DCHRC	Templegate
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Johnson and Johnson	Alkem Laboratories	Karmic Lifesciences	VAC3 ClinicalService
Jubilant Clinsys	Allergan Healthcare	Lambda Therapeutic Research	Vanthys
Karmic Lifesciences	Antara	Linköping University	Veeda Clincial Research
Lambda Research	Apotex	Lupin Bioresearch Center	VerGo Pharma Research
Linköping University	Astellas Pharma	Marken	Voisin Consulting
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Marken	Atharva Lifesciences Consulting	Medanta Duke Research Institute	VPH
Medi Stats Lab	Auriga Research	Medi Stats Lab	Watson Pharma
Metropolis Healthcare	Aurigene Discovery Technologies		Western Institutional Review Board
MMSH Clinical Research	Azidus Laboratories		Witness
	Bangalore Diabetes Hospital		Wockhardt
	Baxter		

Registration Form

28th & 29th May 2015, Kohinoor Continental Hotel, Mumbai, India

RESERVATION PRICING:

Standard Rate:- (Please Tick)

Conference & Workshop for 1 or 2 delegates /D- Fee: INR 07,000 + Tax (12.36%)
Conference only for 1 or 2 delegates /D - Fee: INR 06,000 + Tax (12.36%)

Group Bookings:- (Please Tick)

Conference & Workshop-3 & above delegates/D- Fee: INR 06,000 + Tax (12.36%)
Conference Only - 3 & above delegates /D - Fee: INR 05,000 + Tax (12.36%)

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2 Days conference & Workshop /D - Fee: INR 08,000 + Tax (12.36%)

REGISTRATION FORM DETAILS:

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I confirm that I have read & agree to the terms and conditions of booking..... (Please Tick)

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Chennai 600 087, Tiruvallur district, Tamil Nadu, India

Queries:

Should you have any questions on bookings, Please feel free to contact us.

Email: info@virtueinsight.com
Web: <http://www.virtueinsight.com>
India Office: Tel: +91 044 6453 6444

General information Venue:

Kohinoor Continental Hotel
Andheri Kurla Road
Andheri (E)
Mumbai 400059 - India
Tel: 91 22 66919000 / 91 22 28209999

Payment terms:

Virtue Insight requires the full amount to be paid before the conference. Virtue Insight may refuse entry to delegates who have not paid their invoice in full.

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