8th Annual Clinical Trials Summit 2017

"A critical guide for successfully conducting clinical trials"

24th May 2017, Kohinoor Continental Hotel, Mumbai, India

Key Speakers Include

MANMOHAN SINGH, Pfizer,
APAC Regional Medical Director

RAJENDRA H. JANI, Zydus Cadila,
Advisor/ Independent Subject Expert

SUMIT MUNJAL, Takeda Pharmaceuticals (UK),
Medical Director Lead, Global Medical Safety, Head of Mature Established products

YASMIN SHENOY, Sanofi-aventis,
Director-Regulatory Affairs

SRIRUPA DAS, Abbott,
Associate Director - Medical Affairs

CHIRAG TRIVEDI, Sanofi-aventis,
Director & Head of Clinical Study Unit

TAPANKUMAR M. SHAH, AstraZeneca,
Country Head – Site Management & Monitoring

MUKESH KUMAR, Dr. Reddy's Laboratories,
Global Head - Clinical Management

SHILPA RAUT, Novartis,
Regional Training Head - Asia, Middle East and Africa Cluster

NARESH TONDARE, Glenmark Pharmaceuticals,
Head – India and Nepal Regulatory Affairs

MILIND ANTANI, Nishith Desai Associates,
Partner In-Charge - Pharma LifeSciences

JYOTSNA PATWARDHAN, Novartis,
Head Development QA

ABHAY PHANSALKAR, Cipla,
Head Clinical Trials

PRAVIN GHADGE, Reliance Life Sciences,
Head - Medical Writing & Pharmacovigilance

Plus many more COMING SOON .....

Special Reasons To Attend

- Achieving a successful and sustainable clinical trails strategy in 2017
- Outsourcing early stage manufacturing
- Tracking returns, Reconciliation & Destruction to manage costs
- Benefits and challenges - local and international vendors
- Develop trial design and elaborate patient access
- Span all phases of clinical and observational research
- Real world trials and population health in the east India
- Insights, Implications, Impact and Implementation of risk management in trial conduct
- Strategic partnerships between Sponsor – CRO – Site - Patients
- DATA – Collection, Design, Storage, Execute and Manage clinical trials
- Transforming data into quantifiable knowledge and growth in the quantity of clinical data collected
- Impact of technology - Setting up big data with the power of sophisticated analytics
- Human factors trial design and management
- New e-clinical technologies to improve data quality and optimise clinical outcomes
- Current status – Regulatory
- Updates on development for safety reporting in Indian clinical trial regulation
- Next generations of clinical trials – How big will the market be?
- Be part of a major networking opportunity

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FOR DELEGATE REGISTRATIONS:-

Our potent conference agenda delivering the latest information and the world class leaders as speakers attract delegates to attend from around the world. We aim for our attendees to be equipped with knowledge of latest developments & enable them to network with the industry key personnel.

Delegate Registration - delegate@virtueinsight.com

FOR SPONSORSHIP OPPORTUNITIES:-

Sponsorship or exhibition is the best way to speed network with decision makers. The world leader speakers in our conferences attract niche delegates from all over the world. This would be a wonderful opportunity to reach the right audience and save money and time on all your other advertising gimmicks. To give you an advertising edge we constantly update the industry pioneers via emails/newsletters about the event and advertise the event via different forms of media.

Sponsorship Enquires - sponsor@virtueinsight.com

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CONFERENCE INTRODUCTION:-

Virtue Insight's 8th Annual Clinical Trials Summit will bring together leaders from across pharma, biotech and academia to share case studies and best practices on effective clinical trial management and vendor oversight. The 2017 program focuses on key issues and opportunities in the clinical trial industry, including Patient Recruitment, Site Selection, Data Integration, Existing Data Sources, Mobile Tech, Project Management, Outsourcing, Vendor Management, Risk-Based Monitoring, Clinical Auditing, Regulatory Authorities, pharmaceutical industries, contract research organizations, patient associations, and academic groups are represented. This conference is known to facilitate the interaction between all stakeholders, speakers and participants, thus encouraging lively Q&A sessions without cultural barriers. In addition, as usual, this Conference represents a great opportunity to network with all players involved in drug and device development.

The fast change of our working environment - be it regulatory or scientific - requires an accurate update for those with accumulated experience wanting to gain new competencies, but in particular also for the young stakeholders who will contribute to the development of the next generation of drugs and devices.

Virtue Insight also offers comprehensive sponsorship packages, which includes presentation opportunities, exhibit space, branding and networking with specific prospects. Sponsorship allows you to achieve your objectives before, during, and long after the event. Any sponsorship can be customized to meet your company's needs and budget. Signing on early will allow you to maximize exposure to qualified decision-makers.

It gives us immense pleasure in welcoming you to the 8th Annual Clinical Trials Summit 2017. 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 CONFERENCE:-

- Key drivers behind achieving a successful and sustainable clinical trails strategy in 2017
- Develop faster, more effective strategies by setting up big data with the power of sophisticated analytics
- Outsourcing early stage manufacturing
- Benefits and challenges with using local and international vendors
- Develop trial design and elaborate patient access
- Span all phases of clinical and observational research
- How we use mobile in clinical trials nowadays? What is the present barrier?
- Integrated approaches to using digital as a clinical Tool: Real world trials and population health in the east India
- The Impact of in-life unjust information on clinical trials execution
- Observing operational progress and efficiency of a study or an asset in critical for drug development success
- Strategic partnerships between Sponsor-CRO and how the industry has evolved in the past 5 years
- DATA – Collection, Design, Storage, Execute and Manage clinical trials - an architect's perspective
- Possibilities for transforming data into quantifiable knowledge and growth in the quantity of clinical data collected
- Human factors trial design and management
- Understanding new e-clinical technologies to improve data quality and optimise clinical outcomes
- What are the expectations of regulatory authorities and what type of regulatory structure does India currently have?
- Updates on development for safety reporting in Indian clinical trial regulation
- Next generations of clinical trials – How big will the market be?
- Be part of a major networking opportunity

WHO WILL YOU MEET:-

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?

8th Annual Clinical Trials Summit 2017 - "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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08:30 – Coffee and registration – An opportunity to meet and to network with your conference colleagues.

09:20 – Chairperson opening remarks

MARKET OVERVIEW & ANALYSIS

09:30 – What are the key drivers behind achieving a successful and sustainable clinical trails strategy in 2017?

- Empathize what sites and patients require from clinical trials and how current technologies can help bring forward
- Develop quality of data and save time by altering and streamlining processes for sites
- Improve patient engagement and retention with new technologies that reduce the burden
- Develop faster, more effective strategies by setting up big data with the power of sophisticated analytics

OUTSOURCING

10:00 – Outsourcing early stage manufacturing

- Logistics of using contract manufacturing organizations for early stage products
- Pilot scale manufacturing requirements
- GMP-grade and non-GMP grade manufacturing
- Benefits and challenges with using local and international vendors

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10:30 – Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

10:50 – DISCUSSION WITH EXPERTS: Develop trial design and elaborate patient access

- Span all phases of clinical and observational research
- Expand and influence on physician therapeutic decisions
- Databases and clinical records, which can improve patient recruitment for clinical and observational research
- Patients with longitudinal clinical records, which can be used for real-world evidence studies that deliver clinical, financial, and humanistic outcomes
- Clinical trial environment where patient-specific clinical information can be easily transferred and shared within a payer system
- Improved patient access to coverage and reimbursement for new healthcare technologies
- Integrate value-focus across the product lifecycle
- Identify market trends that are causing a move to a value based reimbursement and decision model
- Explain the value of gaining payer input into clinical trial design

Moderator:

CHIRAG TRIVEDI, Director & Head of Clinical Study Unit, **Sanofi-aventis**

Panellists:

SHILPA RAUT, Regional Training Head - Asia, Middle East and Africa Cluster, **Novartis**

RAJENDRA JANI, Advisor/ Independent Subject Expert, **Zydus Cadila**

MUKESH KUMAR, Global Head- Clinical Management, **Dr. Reddy's Laboratories**

IMPACT OF TECHNOLOGY

11:40 – How we use technology in clinical trials nowadays? What is the present barrier?

- How to enrich patient occurrence; experiences, BYOD, travel, etc.
- How to improve data capture
- Technical barrier - Is the technology ready?
- Regulatory obstacle, do officials limit adoption?
- Discuss the disconnect among hype and evidence

12:10 – Integrated approaches to using digital as a clinical tool: Real world trials and population health in the east India

- Public-private pre-competitive partnerships
- Need to approach data analysis differently
- Share the load, work together
- What does this new model look like?

12:40 – Networking luncheon

Afternoon chair person

14:00 – DISCUSSION WITH EXPERTS: Strategic partnerships between Sponsor-CRO and how the industry has evolved in the past 5 years

- How is the partnership model trending? Are collaborating arrangements still increasing in number and/or scope, or is the model in decline? What are the key reasons behind current trends?
- How well do Sponsor and CRO expectations of these relationships align? Do we still see the gaps we observed in 2012? Have expectations increased or decreased due to the experiences of the past 5 years?

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- Have partnerships delivered on the prospective benefits of enhancing R&D productivity and/or efficiency? What is preventing us from accelerating progress?
- To what extent do Sponsor/CRO relationships impact prevailing topics in clinical development such as enhanced patient engagement, leveraging big data, novel approaches to protocol design, and utilization of quality management systems?
- What does the future hold for Sponsor/Provider relationships? Do we expect measured, incremental change, or are there disruptive paradigms that could alter the landscape?

Moderator:

Panellists:

MANMOHAN SINGH, APAC Regional Medical Director, **Pfizer**

TAPANKUMAR M. SHAH, Country Head – Site Management & Monitoring, **AstraZeneca**

SUMIT MUNJAL, Medical Director Lead, Global Medical Safety, Head of Mature Established products, **Takeda Pharmaceuticals (UK)**

DATA MANAGEMENT

14:50 – DATA – Collection, Design, Storage, Execute and Manage clinical trials - an architect's perspective

- Era of big data
- Speed of data movement, accessibility of current data sources and emergence of new technology frameworks
- Opportunities on which trials can be designed and executed faster, better and much more economically
- Discussing used cases, accessible technologies & programs based on big data that can applied in the environment of modern clinical trials.
- Possibilities for transforming data into quantifiable knowledge and growth in the quantity of clinical data collected
- Clinical trial data sharing and data privacy

15:20 – Afternoon Tea/Coffee

15:40 – Differentiated clinical trial designs for a branded genetics portfolio

SRIRUPA DAS, Associate Director - Medical Affairs, **Abbott**

REGULATORY

16:10 – DISCUSSION WITH EXPERTS: Clinical trial regulatory challenges

- Challenges faced by Sponsors and CROs
- Updates on development for safety reporting in Indian clinical trial regulation
- Overview of the regulation on risk-adapted trials and key factors
- IMA regulations and policies - how are patients and ethics committees impacted and do the regulations meet their needs?
- Regulatory challenges and constraints when evaluating vaccine clinical trials
- Present situations in the regulation of vaccines and how they are being addressed
- Improve patient safety, reporting timeliness of critical adverse events including deaths during clinical trials, and the payment of compensation to patients
- Trial design and applicable regulatory guidance strategies to overcome
- Regulatory considerations for a trial being run across different regions

Moderator:

MILIND ANTANI, Partner In-Charge - Pharma LifeSciences, **Nishith Desai Associates**

Panellists:

SRIRUPA DAS, Associate Director - Medical Affairs, **Abbott**

NARESH TONDARE, Head– India and Nepal Regulatory Affairs, **Glenmark Pharmaceuticals**

JYOTSNA PATWARDHAN, Head Development QA, **Novartis**

ABHAY PHANSALKAR, Head Clinical Trials, **Cipla**

YASMIN SHENOY, Director-Regulatory Affairs, **Sanofi-aventis**

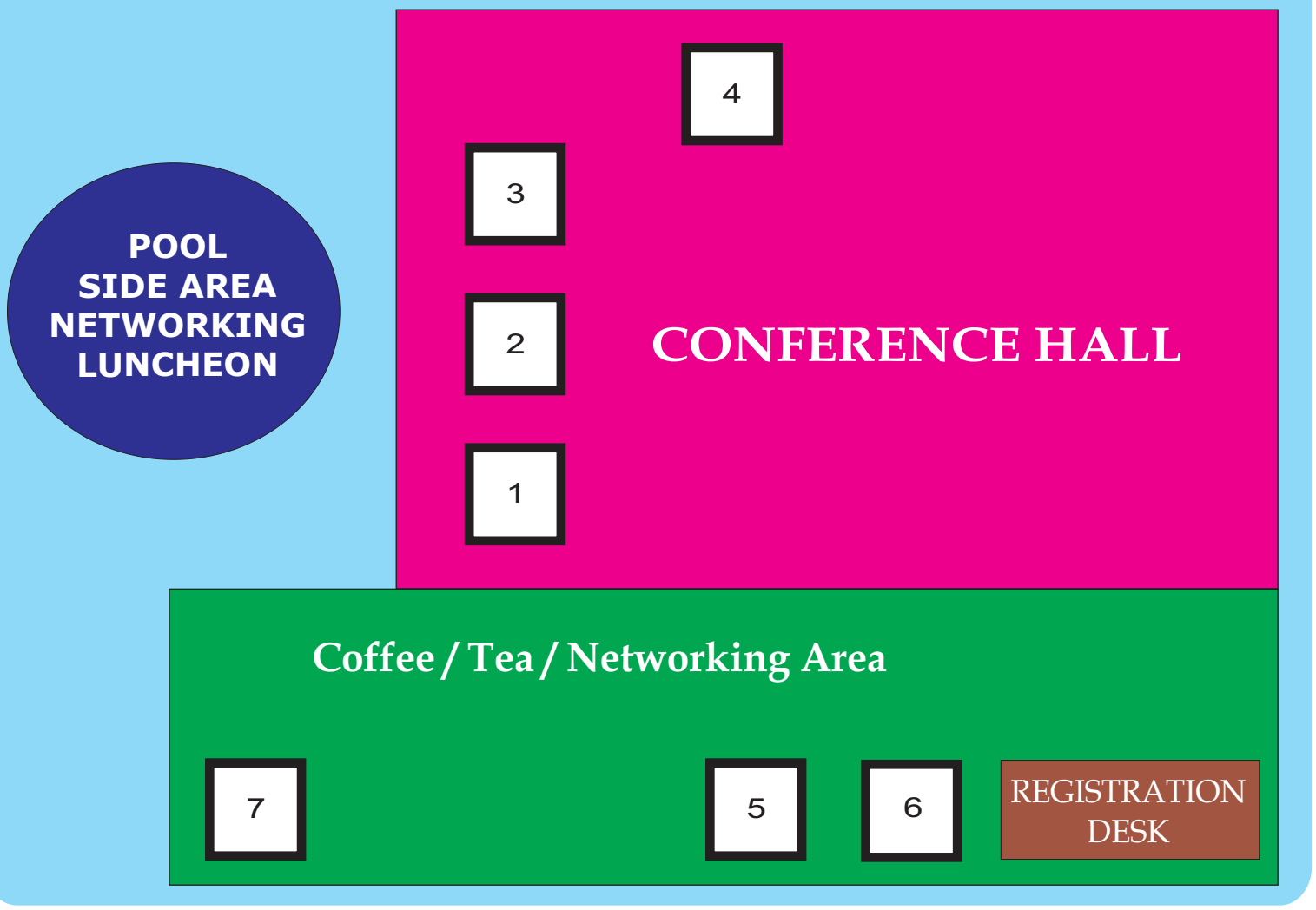
PRAVIN GHADGE, Head - Medical Writing & Pharmacovigilance, **Reliance Life Sciences**

17:00 – Chairperson's closing remarks and end of conference

17:10 - 18:10 - Networking Drinks - Take your discussions further & build new relationships in a relaxed & informal setting

8th Annual Clinical Trials Summit 2017

FLOOR PLAN - Book your stalls now before they run out !!!



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Partial list of attendees from our previous Clinical Trials Conference

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Abbott
Abbott Healthcare
Abbott Nutrition R & D
Acceliant
Accutest
ACG Associated Capsules
ACG Pharmapack
ACM Global Central Laboratory
ADAMAS Consulting
AET Laboratories
Alcon - Global Clinical Site Management
Alkem Laboratories
Allergan Healthcare
Almac
AlphaMD LifeSciences
Amneal Pharmaceuticals
Ancillarie
Antara
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ArisGlobal
Astellas Pharma
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Auriga Research
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Clininvent Research
Clinion IT Services
CliniSearch
Clinitrials Research
Clinnex CRO
ClinOma Healthcare
Clinsoft Clinical Research
Clintech India
ClinTrials Research
Coffee Day
Cognizant Technologies
Consultant – Clinical Research & Development
Crescent Scientific
CRIMSON
CSC
Cygnus Business onsulting & research
Cytel Statistical Software and Services
Cytespace Research
D2L Clinical Solutions
Dabur India
Daewoong Pharmaceutical
Daiichi Sankyo
DBMS Consulting
DCGI
DiagnoSearch LifeSciences
Dr Lal Path Labs
Dr. Reddy's Laboratories
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ECCRO India Services
Ecron Acunova
Eli Lilly
EMC Corporation
Ephicacy Lifesciences Analytics
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Expire Health Research
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GlaxoSmithKline
Glenmark
Global Data
Global Health
GNH India
Going To Meet
Government of Victoria, Australia \ India office
GSK
GVFL
GVK Bio
HCL Technologies
Heart Care Associates
Hinduja Hospital
Hindustan Times
Hospira Healthcare
ICRI
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INC Research
India Law
Indian Academy of Clinical Research
Indian Council for Research on International Economic Relations
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Invent Bio Med
Ipca Laboratories
ISBEC
ITS-DCHRC
JAIC Asia Holdings
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JH Bio
Johnson & Johnson
JSS medical research India
Jubilant Clinsys
KAP Computer Solutions
Karmic Lifesciences
Keosys Medical Imaging
Kinapse
Lambda Therapeutic Research
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MakroCare
Marken
Mascot Spincontrol
MD Pharmacology
Medanta Duke Research Institute (MDRI)
Medi Stats Lab
Mediception Science
Medidata Solutions
Metropolis Healthcare
Micro Labs
Micro Therapeutic Research Labs
MJ Biopharm
MMSH Clinical Research
MS Clinical Research
Mylan Laboratories
Natco Pharma
National Institute of Health, U.S. Embassy
Neurogen Brain and Spine Institute
Newtronic
Nishith Desai Associates
Norwich Clinical Services
Novartis Healthcare
Novartis Healthcare- Vaccines Division
Ocasa Logistic Solutions
OmniActive Health Technologies
Oncquest Laboratories
Oracle Health Science
Oviya MedSafe
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PDP Couriers
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Pharma Bio World
Pharma Mirror
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PharmaVOICE
Pharmcast
PhaseON Clinical Research
Physis Learning Academy
Piramal Enterprises
Piramal Healthcare
Piramal Life Sciences
PPCE
PRA Internationl
Pristine Hospital and Research centre
Provenance Research
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Ruby Hall Clinic
S P Software Technologies
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Solonist Business Solutions
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Spectrum Oncology
SRL Diagnostics
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Tech Tree
TechPharmic Consulting
Techsol
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The George Institute for Global Health
The Himalaya Drug Company
The Pharma World
Theramyt Novobiologics
Thermo Fisher Scientific
Torrent Pharmaceuticals
Torrent Research Centre
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REGISTRATION FORM

RESERVATION PRICING:

Early Bird Discount Rate Till 10th April 2017

1 day conference per delegate - Fee: INR 6,000 + Tax ☐

Standard Pricing (11th April 2017 Onwards)

1 or 2 delegates - per delegate - Fee: INR 8,000 + Tax ☐

Group Discounts

3 or 4 delegates - per delegate - Fee: INR 7,000 + Tax ☐

Group Discounts

For 5 and above delegates - per delegate - Fee: INR 6,000 + Tax ☐

Spot Registration:-

1 day conference per delegate - Fee: INR 9,000 + Tax ☐

Registration Form Details:

Forename .....Surname .....

Job Title .....Company .....

Official Contact Number .....

Address .....

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

Signature .....

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Bank Address - 2/8 LAMBERT NAGAR, 1st cross street, Virugambakkam, Chennai - 600 092
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Swift Code - AXISINBB211
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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 44 64536444

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.

Substitutions/name changes or cancellations:
There is a 50% liability on all bookings once made, whether by post, fax, or email. There is a no refund policy for cancellations received on or after one month before the start of the event. Should you decide to cancel after this date, the full invoice must be paid. Conference notes will then be sent to you. Unfortunately, we are unable to transfer places between conferences and executive briefings. However, if you cannot attend the conference, you may make a substitution/name change at any time, as long as we are informed in writing by email, fax or post. Name changes and substitutions must be from the same company or organization and are not transferable between countries.

Indemnity:
Virtue Insight reserves the right to make alterations to the conference/executive briefing content, timing, speakers or venue without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of Virtue Insight. If such a situation arises, we will refund your registration fee and we will try to reschedule the event.

Fee:
The conference fee includes lunch, refreshments and conference papers provided on the day. This fee does not include travel or hotel accommodation.

How we will contact you:
Virtue Insight's preferred method of communication is by email and phone. Please ensure that you complete the registration form in full so that we can contact you.

News Updates:

Please tick if you do not wish to receive email updates in the future ☐

UPCOMING CONFERENCES:

- **12th Pharmacovigilance 2017 - 22nd - 23rd February 2017, London, UK**
- **3rd IoT Summit 2017 - 08th March 2017, Mumbai, India**
- **10th Annual Cloud Computing & Big Data Analytics 2017 - 22nd March 2017, Bangalore, India**
- **10th Biosimilars Congregation 2017 - 09th - 10th May 2017, London, UK**
- **8th Annual Clinical Trials Summit 2017 - 24th May 2017, Mumbai, India**
- **4th IoT Summit 2017 - 27th July 2017, Bangalore, India**
- **11th Biosimilars Congregation 2017 - 07th September 2017, Mumbai, India**
- **6th Annual Pharma AntiCounterfeiting & Serialisation 2017 - 13th - 14th September 2017, London, UK**
- **13th Pharmacovigilance 2017 - 27th - 28th September 2017, Chicago, USA**
- **14th Pharmacovigilance 2017 - 09th November 2017, Mumbai, India**
- **3rd Annual Pharma Pricing, Reimbursement & Market Access 2017 - 15th - 16th November 2017, London, UK**

For more info on these summits - Kindly contact us at -

Phone - (India) - + 91 44 64536444
Phone - (UK) - + 44 - 2036120886

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Virtue Insight:-

Virtue Insight equips business professionals around the world with the latest indepth industry knowledge and provides networking opportunities in the telecom, infrastructure and pharmaceutical industry. Our aim is to provide a platform to share knowledge and insights and provide our event attendees to network effectively and deliver maximum ROI by make new business alliances. We strive to produce high quality conferences which include the latest topics which are delivered by world class leaders of the industry.

Our motto is to offer our customers the expertise and connections for a profitable business. Our events encompass an optimum chance to gain maximum value in terms of networking and an opportunity to sponsor and exhibit to attract new business alliances.