10th Annual Clinical Trials Summit 2019

"A critical guide for successfully conducting clinical trials"

28th May 2019,
Kohinoor Continental Hotel,
Mumbai, India

#VIct

AGENDA AT A GLANCE

Key Speakers Include

K. BANGARURAJAN
Joint Drugs Controller (INDIA)
CDSCO (HQ)

RAVI SEKHAR KASIBHATTA
Senior Vice President, Clinical Research
Lupin

KAMLESH PATEL
Director - Strategy, Insignia Communication & Founder - Synaegis Healthcare

ARUN BHATT
Consultant – Clinical Research & Development

YASMIN SHENOY
Director-Regulatory Affairs
Sanofi-aventis

LALIT LAKHWANI
Associate Director and Head of Clinical strategy
Dr. Reddy's Laboratories

AMMAR RAZA
Country Medical Director & Chief Medical Office
Allergan

AGAM SHAH
Head Clinical Operations
Wockhardt

AMEY MANE
General Manager - Medical Affairs
Janssen India (Pharmaceutical companies of Johnson & Johnson)

PRAVIN GHADGE
Head of Clinical Research Services
Reliance Life Sciences

JYOTSNA PATWARDHAN
Head Development QA
Novartis

PRANJAL BORDOLOI
AVP - Medical Affairs and Pharmacovigilance
Veeda Clinical Research

ASHWANI PANDITA
General Manager Quality Management & Training, Global Clinical Research Operations
Glenmark Pharmaceuticals

ROSHAN PAWAR
Senior Medical Advisor
Alkem Laboratories

RANJIT BARSHIKAR
QbD / CGMP Consulting
Member Editorial Board Journal of Generic Medicines England

PRASHANT BODHE
Director
CliniSearch

RENUKA NEOGI
Clinical Research Operations Manager
Sanofi

SUJAY KULKARNI
Senior Manager, Clinical Research and Pharmacovigilance
Glaxo Smith Kline (GSK)

Plus many more COMING SOON.....

WHO ATTENDS?

- **30+** Speakers
- **70%** Pharma / Biotech
- **3+** Hours of Networking
- **1** Day
- **1** Golden Opportunity

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Plot No – 07 – 2nd Floor
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"The sessions was informative on products and the discussions was fantastic. It has given a better idea on where the industry is heading. To start a new era of clinical trials, this seems to be a promising start for the industry. The second innings for the clinical trials seems promising technically as well as operationally"

Sr. Manager – Global RA, Abbott

AGENDA AT A GLANCE

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"Very well structured summit. Adequate knowledge on the topic of clinical research, regulations, guidelines, amendments, etc are well discussed"

ICRI (Institute of Clinical Research, India)

28th May 2019,
Kohinoor Continental Hotel,
Mumbai, India

AGENDA AT A GLANCE

CONFERENCE INTRODUCTION:-

We are glad to announce the 10th Annual Clinical Trials Summit 2019 to be held in Mumbai, India during 23rd May 2019. This Conference brings together Academicians, Researchers, Doctors, Principle Investigators, Clinical research sites, CROs, CMOs, Investors, and senior executives from Biopharma, Medical devices and Pharmaceutical industries around the globe to discuss, reflect on and develop their ideas. It offers many opportunities for professional contact and development

10th Annual Clinical Trials Summit 2019 is inspiring keynote presentations, plenary talks and panel discussions. This will discuss most recent techniques, developments, novel strategies and various disciplines involved in drug discovery, clinical research, patient centricity, clinical site & supply management, medical imaging, data management and outsourcing in clinical trials. It will educate healthcare and clinical researcher professionals about design, operation, organizing, research computing, regulatory aspects and reporting of clinical trials. It also promotes better understanding by the general public about the importance of clinical trials in prevention, diagnosis and treatment of diseases.

We have been delivering the conference through close collaboration with the industry for nearly a decade. For the 2019 edition, the agenda includes a host of new and exciting features

Take a chance and make it count in your Professional life. Attend the 10th Annual Clinical Trials Summit 2019 Conference to network with your peers, exchange expertise and experiences, and arm yourself with the latest information to take your department to the next level.

We look forward to see you personally at our esteemed event.

KEY THEMES DISCUSSED IN THIS CONFERENCE:-

- Accomplish effective patient recruitment and retention in clinical trials by impacting innovations & digitisation in clinical research
- Bettering the grade of the international health clinical research
- Strategies for globalization in clinical trials
- Connecting the developed and the developing nations
- Leveraging new technologies to improve clinical trials efficiency in Asia
- Transforming your trials procedure by implementing artificial intelligence
- Investigating how trial sponsors and service providers can cooperate to better carry out the trial timelines while sustaining quality
- Why pharma and biotech industries are specified for new and smarter ways to conduct clinical research
- Operative patient recruitment and retention in clinical trials
- What will persuade and impact the patient?
- Successfully operate challenges in early phase clinical development
- Overcoming the key challenges within early phase clinical trials
- Developing risk-based monitoring implementation: Deduction in technology, Role progress and Business process
- Concentrating on the lessons learned and best practices resulting from 5 years of RBM implementation
- Clinical trial – A regulated procedure and plan of action
- Data safety and efficacy of the newly developed drug. What are the mandatory for further approval of the drug to bring it into the market
- Understanding the current framework of clinical trial regulations in India
- Brief information for preparing for regulatory inspection
- Be part of a major networking opportunity

AN EVENT TO VOW

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 time, meet the leading international vendors showcasing the products of tomorrow in the co-located exhibition. Expand your knowledge of the latest business models and strategies in the high-level conference.

WHY EXHIBIT?

Make Sales
Debut new products
Profile your brand
Meet new business partners
Develop key relationships
Educate pharma and biotech companies

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

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Conference was very informative and the positive of the conference is Mr. Bangarurajan sir. Regulatory perspectives were very much good and clarified. Very much happy for the conference

Research Associate, The Himalaya Drug Company

28th May 2019,
Kohinoor Continental Hotel,
Mumbai, India

AGENDA AT A GLANCE

DAY ONE - 28th May 2019

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

09:20 Chairperson opening remarks

RANJIT BARSHIKAR
QbD / CGMP Consulting
Member Editorial Board Journal of Generic Medicines, England

MARKET OVERVIEW & ANALYSIS

09:30 Topic TBC

LALIT LAKHWANI
Associate Director and Head of Clinical strategy
Dr. Reddy's Laboratories

10:00 Strategies for globalization in clinical trials

- Connecting the developed and the developing nations
- Dealing with differences owing to culture and ethnicity
- Role of CROs and third party stakeholders
- Increasing the number of clinical trials sites in areas such as Asia Pacific, Europe, Latin America, and the Middle East

10:30 – **Morning Coffee/Tea & Discussion**

CHALLENGES & OPPORTUNITIES

10:50 DISCUSSION WITH EXPERTS: Leveraging new technologies to improve clinical trials efficiency in Asia

- Transforming your trials procedure by implementing artificial intelligence
- Addressing the methods which will have the most impact on trials in five years, adaptive trials and risk-based strategies
- Giving an opportunity to render transformation in clinical trial methodology
- Discussing on using advanced analytics to monitor patients in their own home outside of the hospital environment
- View point from an industry: The future of investing technology in clinical trials. An overview at the impact of data collection and analysis methods, current challenges, and patient centricity.
- Being certain that FDA filing is successful and the drug or treatment in query is approved for mass distribution
- Key considerations for achieving digital trial success

Moderator:

AMEY MANE
General Manager- Medical Affairs
Janssen India (Pharmaceutical companies of Johnson & Johnson)

Panellists:

PRAVIN GHADGE
Head of Clinical Research Services
Reliance Life Sciences

KAMLESH PATEL
Director - Strategy, Insignia Communication & **Founder -** Synaegis Healthcare

AGAM SHAH
Head Clinical Operations
Wockhardt

SUJAY KULKARNI
Senior Manager, Clinical Research and Pharmacovigilance
GSK

11:30 DISCUSSION WITH EXPERTS: Investigating how trial sponsors and service providers can cooperate to better carry out the trial timelines while sustaining quality

- Why pharma and biotech industries are specified for new and smarter ways to conduct clinical research
- Initiating what the quality 'touch points' should be for the continuance of the trial so you can measure the success of your partnership
- Questioning what tools can be used to determine quality throughout the trial to assure you have an precise picture of how the service provider is acting on key deliverables
- Addressing best practices for developing well - defined SOPs to ensure service providers are better equipped to accomplish the clinical trial to a high standard
- Building progressive training schemes for service providers to be certain that information is reaching all employees undiluted
- Highlighting the requirement to have a grooming strategy in place to assure data quality is maintained at every stage

Moderator:

RANJIT BARSHIKAR
QbD / CGMP Consulting
Member Editorial Board Journal of Generic Medicines, England

Panellists:

ARUN BHATT
Consultant – Clinical Research & Development

PRASHANT BODHE
Director
CliniSearch

ROSHAN PAWAR
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Alkem Laboratories

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Senior Business Analyst, HCL Technologies

AGENDA AT A GLANCE

DAY ONE - 28th May 2019

12:10 Operative patient recruitment and retention in clinical trials

- What will persuade and impact the patient?
- Is there anything pharma can supply for a trial member that will alter the value of participation?
- The aim of patient-driven clinical trials and the burden of participation
- Utilize fitting procedures and techniques to limit dropouts without, in any capacity, constraining a patient to remain in the study

12:40 - Networking luncheon

Afternoon Chair Person

13:50 Patient Centricity in Clinical Trials

- Role of patients in CTs … going beyond the current paradigm
- What does patient centricity mean?
- Why do we need patient centricity in CTs?
- Evolution of patient centricity
- Challenges and regulatory issues in a patient centric approach
- Global status & some examples of putting patient centricity in practice

AMMAR RAZA
Country Medical Director & Chief Medical Office
Allergan

14:20 DISCUSSION WITH EXPERTS: Developing risk-based monitoring implementation: Deduction in technology, Role progress and Business process

- Concentrating on the lessons learned and best practices resulting from 5 years of RBM implementation
- Partnership between business and technology - Illustrating how innovation in one area causes the other
- Discussing CRA role including the development of new skill sets to address the evolved expectations, and the creation of new roles to support RBM
- Implications for implementation – Suggestion from sites about RBM, as well as audit results
- Discussing critical thinking — the need for people to have the skills to be able to assess the information they are seeing in doing centralized monitoring
- An adaptive approach that interact both on-site and centralized monitoring along with real-time access to data

Moderator:

Panellists:

RAVI SEKHAR KASIBHATTA
Senior Vice President, Clinical Research
Lupin

AMMAR RAZA
Country Medical Director & Chief Medical Office
Allergan

JYOTSNA PATWARDHAN
Head Development QA
Novartis

15:10 – Afternoon Tea/Coffee

REGULATORY

15:30 Clinical trial – A regulated procedure and plan of action.

- Data safety and efficacy of the newly developed drug. What are the mandatory for further approval of the drug to bring it into the market
- Increasing demand for CROs to conduct clinical trials and market growth for globalizing your trials
- Determining compound that conducts experiments to gather information on how it is absorbed, distributed, metabolized, and eliminate.
- Clinical Quality Assurance, Data Management, Biostatistics and Regulatory Affairs to ensure that the data and info needed is delivered so they can decide if a trial has been successful

16:00 DISCUSSION WITH EXPERTS: Understanding the current framework of clinical trial regulations in India

- Understand the current framework of clinical trial regulations in India
- Brief information for preparing for regulatory inspection
- Improving the quality and lifespan of patients - The value of drug trials in promoting health services, new drugs and therapies
- Recently adapted regulatory guidelines in terms of serious adverse events (SAEs) reporting, informed consent, compensation in case of injury or death in clinical trials.
- Discussing on Investigator initiated studies and the funding support from the pharmaceutical industries
- Abstracting the necessary information on researchers planning to perform a clinical trial in India.

Moderator:

Moderator TBC
Nishith Desai Associates

Panellists:

K. BANGARURAJAN
Vice President Medical Affairs
CDSCO (HQ)

YASMIN SHENOY
Director-Regulatory Affairs
Sanofi-aventis

PRANJAL BORDOLOI
AVP - Medical Affairs and Pharmacovigilance
Veeda Clinical Research

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

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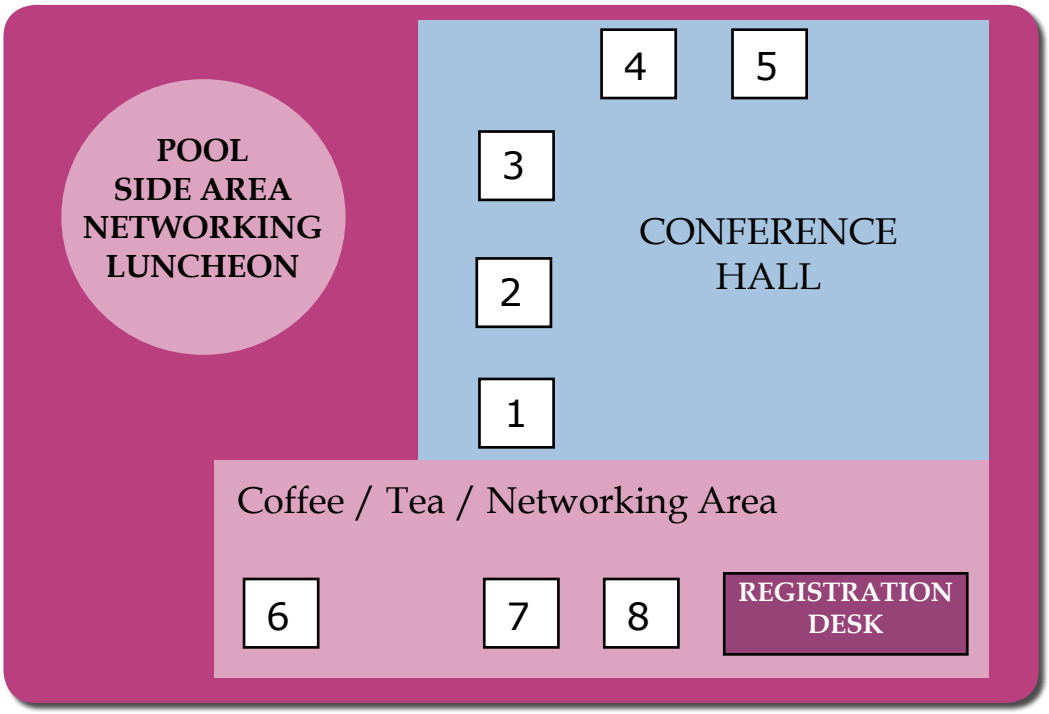
"Since Pharama companies have ventured into Biologicals/ Biosimilars business, the conference could have focused on discussing case stdies in Biosimilars Clinical trails, challenges in CTS in New Biologicals& Vaccines."

Regulatory Affairs Biologicals-Cipla New Ventures, Cipla

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



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Note :- The floorplan is subject to change at the discretion of the organisers.

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"Topic was very good huge on current seminar, Location is very good to Aelequase, Speaking was good to deliver current situation, Very on panel discussion and due and Answer session"

Sr. CRA, Lambda Therapeutic Research

AGENDA AT A GLANCE

REGISTRATION FORM

RESERVATION PRICING:

Early Bird Discount Rate Till 08th April 2019

1 day conference per delegate - Fee: INR 10,000 + GST(18%)

Standard Rate (09th April 2019 Onwards)

1 day conference per delegate - Fee: INR 15,000 + GST(18%)

For Bulk Booking of More Than 5 Delegates

Please email us at bookings@virtueinsight.com

Registration Form Details:

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

Job Title .....

Company .....

GST No (If Applicable) .....

Official Contact Number .....

Address .....

.....

Country .....Postcode.....

Phone .....Fax .....

Email .....

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

Signature .....

Methods of Payments:

By Cheque - Complete and return the above registration form via post or email, together with your cheque payable to Virtue Insight.

By Bank Transfer:

Account Name	- Virtue Insight
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Account Number	- 915020031763553
Bank Name	- Axis Bank
Bank Address	- 2/8 LAMBERT NAGAR, 1st cross street, Virugambakkam, Chennai - 600 092
Branch Name	- Virugambakkam, Chennai
Swift Code	- AXISINBB211
NEFT / IFSC Code	- UTIB0000211
Micro Code	- 600211010

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

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UK Office: Tel: +44 - 2036120886

General Information Venue:
Kohinoor Continental Hotel
Andheri Kurla Road
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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 ☐

VENUE

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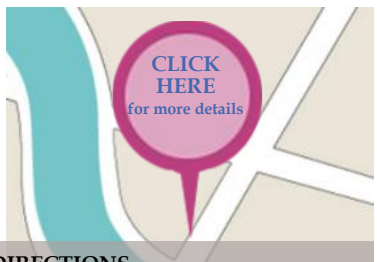
Phone: 91 22 66919000 / 91 22 28209999



MAP & DIRECTIONS

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"This is a really well managed, informative, interactive and learning event also allowing us to network together and its absolute a value for money. I wish them the "All is The Best". Keep up the "GOOD SHOW"

General Manager, Accutest Research

UPCOMING CONFERENCES

UK

• (Pharma)	Pharma Blockchain 2019	05th & 06th March 2019, London, UK
• (Pharma)	13th Biosimilars Congregation 2019	11th & 12th June 2019, London, UK
• (Pharma)	2nd Annual Pharma AI & IoT 2019	10th & 11th July 2019, London, UK
• (Pharma)	8th Annual Pharma AntiCounterfeiting & Serialisation 2019	16th & 17th July 2019, London, UK

USA

• (Pharma)	19th Pharmacovigilance 2019	09th & 10th October 2019, Chicago, USA
• (Pharma)	3rd Annual Pharma Pricing, Reimbursement & Market Access 2019	16th & 17th October 2019, Chicago, USA

INDIA

• (Pharma)	2nd Annual Pharma Regulatory Summit 2019	14th March 2019, Mumbai, India
• (Tech)	Blockchain 2019	11th April 2019, Bangalore, India
• (Pharma)	10th Annual Clinical Trials Summit 2019	28th May 2019, Mumbai, India
• (Tech)	6th Annual IoT & AI Summit 2019	3rd July 2019, Bangalore, India
• (Pharma)	2nd Annual Pharma Packaging, Labelling, Serialisation, Track and Trace 2019	19th September 2019, Mumbai, India
• (Pharma)	20th Pharmacovigilance 2019	07th November 2019, Mumbai, India
• (Pharma)	14th Biosimilars Congregation 2019	12th December 2019, Mumbai, India

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

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Phone - (UK) - + 44 - 2036120886 Email - (UK) - info.uk@virtueinsight.com

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.

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