# 9th Annual Clinical Trials Summit 2018

"A critical guide for successfully conducting clinical trials"

**22nd May 2018,**
**Kohinoor Continental Hotel,**
**Mumbai, India**

#VIct

## AGENDA AT A GLANCE



## Key Speakers Include

**OMPRAKASH S. SADHWANI**
Joint Commissioner (Nashik Division)
Food and Drugs Administration (M.S.)

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

**NILIMA A. KSHIRSAGAR**
National Chair Clinical Pharmacology
ICMR Govt. of India

**MUZAFFAR AHMAD**
Member Strategic Advisory Board on Health Millenium Alliance (Govt of India) and Member Council of India

**JAMILA JOSEPH**
Senior Vice President and Head Clinical Research Services
Reliance Life Sciences

**DEVEN V PARMAR**
Vice President & Head Clinical R&D
Cadila Healthcare

**ARUN BHATT**
Consultant – Clinical Research & Development

**SANDESH SAWANT**
Director and Head Clinical Trials
Cipla

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

**DILIP PAWAR**
Independent Clinical Consultant

**SHIRAZ KANDAWALLA**
Associate Director - Regulatory Affairs
Abbott

**BINDU AJIT**
Program Director
Biocon Academy

**AMMAR RAZA**
Country Medical Director & Chief Medical Office
Allergan

**KEDAR SUVARNAPATHAKI**
Head - Regulatory Affairs & IP
Boehringer Ingelheim

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

**SIDDHARTH DESHPANDE**
Assistant Professor Department of Clinical Pharmacology
KEM Hospital

**AGAM SHAH**
Head Clinical Operations
Wockhardt

**JYOTSNA PATWARDHAN**
Head Development QA
Novartis

**CHIRAG TELI**
Head of Medical Services
Alkem Laboratories

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

**SUJAY SURESH KULKARNI**
Senior Manager - Medical and Regulatory Afairs
GSK

**RANJIT BARSHIKAR**
Member of the Editorial Board
Journal of Generic Medicines - England

**PRANJAL BORDOLOI**
AVP - Medical Affairs and Pharmacovigilance
Veeda Clinical Research

**PRASHANT BODHE**
Director
CliniSearch

**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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*"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**

## AGENDA AT A GLANCE



## CONFERENCE INTRODUCTION:-

With four-out-of-five clinical trials failing to meet original recruitment targets, new approaches are needed. Patients with chronic conditions or life-threatening diseases are often looking for a solution, a treatment that may help improve their quality of life or extend their life. Delays in clinical trials can cause significant problems for patients. We need to better understand the barriers and myths that deter both physicians from discussing clinical trials and patients from participating in them.

Virtue Insight welcomes you to attend the 9th Annual Clinical Trials Summit 2018, which is going to be held in Mumbai on 22nd May 2018. We cordially invite all the participants who are interested in sharing their knowledge and research in the arena of Clinical Trials.

9th Annual Clinical Trials Summit 2018 anticipates participants around the globe with thought provoking Keynote lectures, Oral Presentations and Poster Presentations. This is an excellent opportunity for the delegates from Universities and Institutes to interact with the world class Scientists. The main theme of the conference is to positively learn and educate about clinical trials is essential, if only to counter more negative perceptions.

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 9th Annual Clinical Trials Summit 2018. I wish and pray that all our efforts will be beneficial to our industries and to our country at large

## KEY THEMES DISCUSSED IN THIS CONFERENCE:-

- Current challenges and regulations for clinical trials in India
- Having a positive impact on overall market to globalize trials and growth in new product development in emerging countries
- Formulating a risk-based inspection plan for advanced clinical trials
- New tools and technologies for data capture for clinical trials
- Developing effective partnerships and vendor relationships
- Dealing with the evolve business frameworks that allows third-party vendors, CROs, and sponsors to formulate traditional contracts for contemporary trials
- Efficient administration for outsourced site contract negotiation
- Necessary strategies to implement the maximize value of the collaboration.
- Patient and clinical site centricity: Optimising the end users, patients and the clinical sites
- Understanding the needs of both patients and the clinical site that should be considered
- Encouraging data analytics for next-generation clinical trials
- Leveraging advanced data analytics and m-health for next-gen trials
- EHR (Electronic Health Records) for clinical research facility
- Recent guidelines issued by FDA on the use of EHR data
- Major roles of clinical pharmacology in drug discovery and development
- Exhibiting and simulating the overall drug development process
- New clinical trials rules and its impact
- Current requirements of Indian Clinical Trial Application (CTA) and how this will change with the new clinical trial regulation
- Regulatory considerations in India and south-east Asia
- 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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*"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"*

**Senior Business Analyst, HCL Technologies**

## AGENDA AT A GLANCE



## DAY ONE - 22nd May 2018

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

**09:20 Chairperson opening remarks**

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

### MARKET OVERVIEW & ANALYSIS

**09:30 Topic TBC**

OMPRAKASH S. SADHWANI
**Joint Commissioner (Nashik Division)**
Food and Drugs Administration (M.S.)

**10:00 Encouraging data analytics for next-generation clinical trials**

- Constructing data analytics platform and common analytics shapes that can be employed to many types of clinical trials
- Risk-based observation and quality to cooperate and contribute innovations based on big data and advanced analytics to clinical trials operations
- How changing this approach using advanced data analytics and m-Health solutions can identify areas of risk much faster and more accurately
- New and innovative way to run clinical trials by gaining more traction through remote trials

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

### CHALLENGES & OPPORTUNITIES

**10:50 DISCUSSION WITH EXPERTS: Formulating a risk-based inspection plan for advanced clinical trials**

- Conventional auditing approaches and efficiency
- Strategies on changing regulations, intricated clinical trial structures and outsourcing
- New tools and technologies for data capture for clinical trials
- Auditing and necessity on risk-based approach to trials
- Best practices and methods for developing a risk-based audit program with insight from various members of a clinical trial team.
- Implementing RBM internally and externally, what are challenges face in major and common barriers?
- Strategies and key concerns that need to be addressed for successful RBM

**Moderator:**

RANJIT BARSHIKAR
**Member of the Editorial Board**
Journal of Generic Medicines - England

**Panellists:**

SANDESH SAWANT
**Director and Head Clinical Trials**
Cipla

SIDDHARTH DESHPANDE
**Assistant Professor Department of Clinical Pharmacology**
KEM Hospital

ARUN BHATT
**Consultant – Clinical Research & Development**

**11:30 DISCUSSION WITH EXPERTS: Developing effective partnerships and vendor relationships**

- Establishing a team atmosphere for creative problem solving
- Plan of success, drug development projects and a series of problems and solutions
- Constructing an effective model early on for a successful partnership with CROs and site payment vendors
- Investigate site payments and a view on simple line item and cost within CRO and vendor contracts
- Dealing with the evolve business frameworks that allows third-party vendors, CROs, and sponsors to formulate traditional contracts for contemporary trials
- Insuring efficient management and governance - appointing clear roles and obligations among sponsor and CRO to prevent duplicative attempts and set practical expectations

**Moderator:**

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

**Panellists:**

DEVEN PARMAR
**Vice President & Head Clinical R&D**
Cadila Healthcare

AGAM SHAH
**Head Clinical Operations**
Wockhardt

PRANJAL BORDOLOI
**AVP - Medical Affairs and Pharmacovigilance**
Veeda Clinical Research

**12:10 Efficient administration for outsourced site contract negotiation**

- Efficient site contract negotiation to critically support important clinical operation milestones around site activation
- Outsourcing model to provide increased flexibility and access to industry expertise
- Necessary strategies to implement the maximize value of the collaboration.
- Detailed strategic views to enhance the efficiency and potency of outsourcing site contract negotiation

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*"This conference was informative. There was good exchange of information. It provided current and actual seminar in india regarding Clinical Trials would like to attend this conference in future"*

Clinical Research Associate, Lambda Therapeutic Research

## AGENDA AT A GLANCE



## DAY ONE - 22nd May 2018

**12:40 - Networking luncheon**

**Afternoon Chair Person**

PRASHANT BODHE
**Director**
CliniSearch

**13:50 Creating workforce for the future - Biocon Academy a case study**

BINDU AJIT
**Program Director**
Biocon Academy

**14:10 DISCUSSION WITH EXPERTS: Key strategies to globalizing clinical trials into emerging markets**

- Encouraging requirement for CROs to perform clinical trials and improve treatments on personalized medicine, augmenting evolution in technology
- Having a positive impact on overall market to globalize trials and growth in new product development in emerging countries
- Drug discovery to post-marketing surveillance
- Increase product portfolio and drive innovation to point and further improve capabilities in clinical trial designing
- Integrating predictive analytics that can help thrust R&D plot and perform clear ties for long-run financial impacts
- Leveraging advanced data analytics and m-health for next-gen trials

**Moderator:**

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

**Panellists:**

JAMILA JOSEPH
**Senior Vice President and Head, Clinical Research Services**
Reliance Life Sciences

DILIP PAWAR
**Independent Clinical Consultant**

AMMAR RAZA
**Country Medical Director & Chief Medical Office**
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CHIRAG TELI
**Head of Medical Services**
Alkem Laboratories

JYOTSNA PATWARDHAN
**Head Development QA**
Novartis

SUJAY SURESH KULKARNI
**Senior Manager, Medical and Regulatory Affairs**
GSK

**14:50 EHR (Electronic Health Records) for clinical research facility**

- Significance of evaluating sites EHR systems when used as a point in clinical trials
- Recent guidelines issued by FDA on the use of EHR data
- Challenges & opportunities for sponsors while evaluating these systems fundamental and elements of data quality
- Thoughts to support sponsors in the assessment of EHR systems

**15:20 Clinical Development of Biologics- Unique Challenges and Opportunities**

- Recombinant DNA technology - changed the way medicines are discovered and developed
- Biologics are Different
- Biologics vs. Non biologics - Development costs and timelines
- Opportunities and Challenges with Biologics
- Clinical Development of Biologics – how is it different? Differences in clinical pharmacology / Development challenges etc.

AMMAR RAZA
**Country Medical Director & Chief Medical Office**
Allergan

**15:50 – Afternoon Tea/Coffee**

**REGULATORY**

**16:20 DISCUSSION WITH EXPERTS: New clinical trials rules and its impact**

- Current requirements of Indian Clinical Trial Application (CTA) and how this will change with the new clinical trial regulation
- Substantial amendments and non-substantial amendments
- Ethical considerations for clinical trials performed in children guideline compared with adults
- Influencing the best strategy for the different regulations across India and globally
- Key development for sponsors and investigators to insure if they meet regulatory necessities when performing multi-coun try clinical trials
- Conducting direct-to-patient trials using technologies, such as apps and wearables to report data and analyse current strategies and relevant regulations
- Assuring the efficacy and success of clinical trials – What is a best practice for working with regulatory agencies?

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*"1. Very useful to network with sponsors and CRO.*
*2. Good place to know the progress of competition"*

**Manager - eclinical, DDi**

## AGENDA AT A GLANCE



## DAY ONE - 22nd May 2018

**Moderator:**

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

**Panellists:**

**K. BANGARURAJAN**
**Joint Drugs Controller**
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**Abbott**

**KEDAR SUVARNAPATHAKI**
**Head - Regulatory Affairs & IP**
**Boehringer Ingelheim**

**PRASHANT BODHE**
**Director**
**CliniSearch**

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

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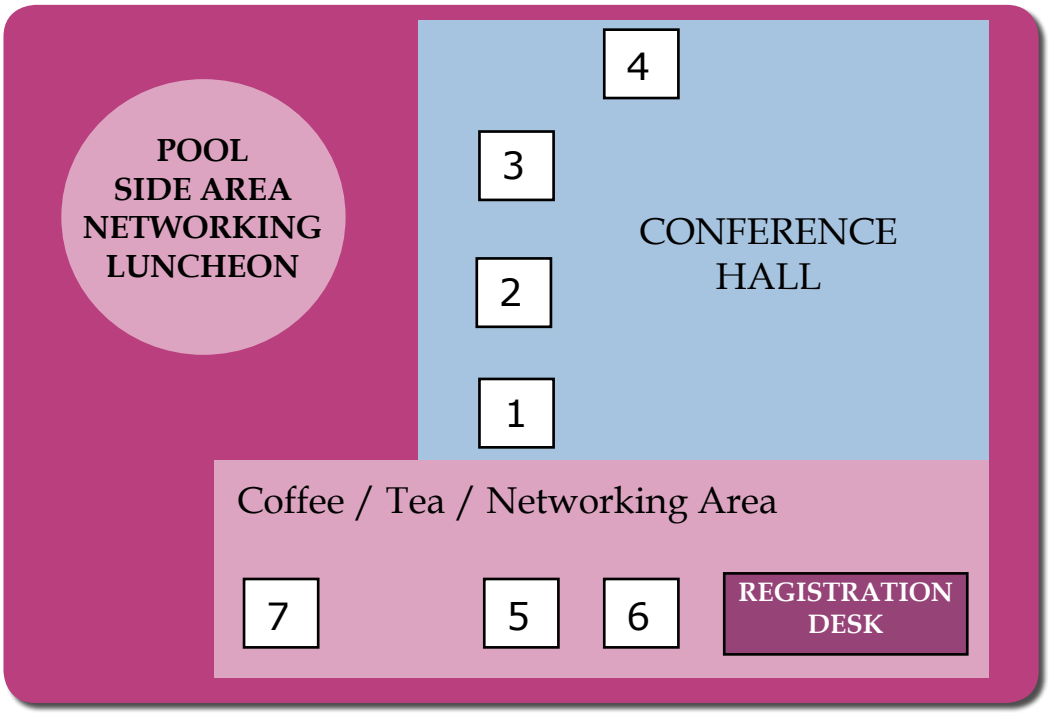
*"Its a good conference and the approach of new ideas get a merge in single pool without any barriers"*

**Research Associate, Lupin Bioresearch Center**

## AGENDA AT A GLANCE



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




1 4 7

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


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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**

## AGENDA AT A GLANCE



## REGISTRATION FORM

### RESERVATION PRICING:

**Early Bird Discount Rate Till 4th April 2018**

1 day conference per delegate - Fee: INR 6,000 + GST(18%)

**Standard Rate (5th April 2018 Onwards)**

1 or 2 delegates - per delegate - Fee: INR 7,000 + GST(18%)

**Group Discounts**

3 or 4 delegates - per delegate - Fee: INR 6,500 + GST(18%)

**Group Discounts**

For 5 & above delegates - per delegate - Fee: INR 6,000 + GST(18%)

**Spot Registration:-**

1 day conference per delegate - Fee: INR 8,000 + GST(18%)

**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:**

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|---|---|
| Account Type | - Current |
| 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.

**Email:** info@virtueinsight.com
**Web:** http://www.virtueinsight.com
**India Office: Tel: +91 44 42108101**

**General Information Venue:**
Kohinoor Continental Hotel
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Andheri ( E )
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**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

**Kohinoor Continental Hotel**

**Address: Andheri Kurla Road, Andheri ( E ), Mumbai - 400059, India.**

**Phone: 91 22 66919000 / 91 22 28209999**


**MAP & DIRECTIONS**

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*"Great administration of entire programme session by session, pleasant surprise is that 95% of speakers as planned turned up"*

**Director Operations, GSS HR Solutions**



## UPCOMING CONFERENCES

- (Pharma) - 9th Annual Clinical Trials Summit 2018 - 22nd May 2018, Mumbai, India
- (Tech) - 5th IoT & AI Summit 2018 - 05th July 2018, Bangalore, India
- (Pharma) - Pharma AI & IoT 2018 - 11th - 12th July 2018, London, UK
- (Pharma) - 7th Annual Pharma AntiCounterfeiting & Serialisation 2018 - 12th - 13th September 2018, London, UK
- (Pharma) - Pharma Packaging and Labelling 2018 - 19th September 2018, Mumbai, India
- (Pharma) - 16th Pharmacovigilance 2018 - 02nd - 04th October 2018, Cambridge, Massachusetts (USA)
- (Pharma) - 17th Pharmacovigilance 2018 - 15th November 2018, Mumbai, India
- (Tech) - 11th Annual Cloud & Big Data Analytics 2018 - 29th November 2018, Bangalore, India
- (Pharma) - 13th Biosimilars Congregation 2018 - 13th December 2018, Mumbai, India

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

Phone - (India) - + 91 44 42108101
Phone - (UK) - + 44 - 2036120886

Email - (India) - info@virtueinsight.com
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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