11th Annual Clinical Trials Summit 2020

"A critical guide for successfully conducting clinical trials"

#VIct

28th May 2020,
Kohinoor Continental Hotel,
Mumbai, India

AGENDA AT A GLANCE

Key Speakers Include

BANOTH VENKATESWARLU
Assistant Drugs Inspector, Central Drug Standard Control Organization (CDSCO)

CHIRAG TRIVEDI
Director & Head of Clinical Study Unit
Sanofi-Aventis

REBU NINAN
Director - Strategic Marketing & Commercial Operations – Biologics, Dr. Reddy's Laboratories

PRASANNA GANAPATHI
Associate Vice President – Global Clinical Sciences
Mylan Laboratories

SHUBHANGI DESAI
Director - Global Clinical Trial Management
Abbott (Singapore)

YASMIN SHENOY
Director-Regulatory Affairs
Sanofi-aventis

SHREEKANT SAPATNEKAR
Director - Clinical Research
Lilavati Hospital & Research Centre

SANDESH SAWANT
Director and Head Clinical Trials
Cipla

MURTUZA BUGHEDIWALA
Associate Director – GCO
Johnson & Johnson

RAJENDRA JANI
Senior Subject Expert & Advisor
Clinical Research Consultant

MURUGANANTHAN KRISHNAN
Country Monitoring Head - Global Development Operations, Global Drug Development, Novartis

RANJIT BARSHIKAR
CEO - QbD International, United Nations Adviser, Member Editorial Board Journal of Generic Medicines, England

SRIRUPA DAS
Director - Medical Affairs
Abbott

SUTAPA BANDYOPADHYAY NEOGI
Professor, International Institute of Health Management Research (IIHMR)

ANANT PATIL
Asst Professor Department of Pharmacology
Dr DY Patil Medical College

PRATIKSHA PALAHE
Head NFB
National facility for Biopharmaceuticals

ARUN GUPTA
Head Medical Affairs & Clinical Research
Dabur Research & Development Centre

JYOTSNA PATWARDHAN
Head Development QA
Novartis

VAIBHAV SALVI
Head - Project Management and Strategic Initiatives, Clinical Study Unit, Sanofi

KARAN THAKKAR
Regional Clinical Site Lead
Pfizer

PRASHANT A. PANDYA
DGM-Global Strategic Sourcing - Scientific Affairs, Mylan Laboratories

PRANJAL BORDOLOI
Vice President – Clinical, Medical Affairs & Pharmacovigilance, Veeda Clinical Research

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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

PRASHANT BODHE
Director
CliniSearch

SAKHARAM GARALE
Head South-East Asia Operations ACMA & Managing Partner, RENOVARE Healthcare Solutions

SUJAY KULKARNI
Business Partner/ Medical Expert
Novartis

SANDEEP JAGTAP
Assist. General Manager - Clinical R & D
Mylan Laboratories

WHO ATTENDS?

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

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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)

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AGENDA AT A GLANCE

CONFERENCE INTRODUCTION

We are glad to announce the **11th Annual Clinical Trials Summit 2020 to be held in Mumbai, India during 28th May 2020.** The global Contract Research Organization (CRO) market size was estimated at US$ 34.5 billion in 2018 and is projected to reach US$ 55.3 billion by 2024, growing at a CAGR of 8.2% during 2019 to 2024. Indian clinical trials market size is expected to reach US$ 3.15 billion by 2025. It is projected to register a CAGR of 8.7% over the forecast period.

Increasing cost of drug development is expected to drive the growth. Drug maker and sponsor companies are under pressure to replace the revenue loss caused by generics, increasing patent expiry, number of partnerships to identify biologics, and growing R&D costs, which has made drug development more expensive and complex. In addition, growing pressure on market players to follow stringent timelines has increased the demand for outsourcing of research activities.

This Conference brings together 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

The **11th Annual Clinical Trials Summit 2020** will provide opportunities for everyone to learn, gain insight and new skills, and also, there will be many opportunities to network and meet new peoples from industry and patient's clinical organizations, **11th Annual Clinical Trials Summit 2020** hope to lead to new successful collaborations in the future. It is definitely our aim and ambition for every participant to return home somehow enriched, both professionally and on a personal level.

KEY THEMES DISCUSSED

- Current key changes and challenges for trials in India.
- Challenges while growing your research development.
- Discuss the various principles and methods for implementing the project life cycle at each important phase.
- Setting up the best position to sustain an agile procedure for your study design
- Addressing biomarker integration into a protocol while remaining agile.
- Planning and managing an adaptive clinical trials – Challenges and the best practices to achieve
- Discussing on the flexibility to redesign clinical trials at intermediate stage.
- Current evolution of clinical trials: Addressing challenges for the future?
- Discussing the major challenges with global trials —How can they be overcome?
- Discussion and development of functional processes in living organisms
- Provide clinical research and construct foundations for biomedical research and forms of study.
- Required advancement of clinical trials and new medicines
- Discussing the pharmaceutical industry's financed portion.
- Discussing future – Current challenges and overview to look out for while collaborating with the CROs and Sponsorships company
- Establishing an effective and quality collaboration between Sponsors and CROs and if it fails, what are the costs and negative results of a failed partnership?
- Clinical studies and patients assessment
- Identification of study participants and evaluation of physiological or health outcomes.
- New drugs and clinical trial rules to prepare for regulatory inspection and to improve the quality and lifespan of patients
- Be part of a major networking opportunity

WHY SHOULD YOU ATTEND?

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 SHOULD ATTEND AND WHO YOU'LL 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

AGENDA AT A GLANCE

DAY ONE - 28th May 2020

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

09:20 Chairperson opening remarks

RANJIT BARSHIKAR
CEO - QbD International, United Nations Adviser
Member Editorial Board Journal of Generic Medicines, England

MARKET OVERVIEW & ANALYSIS

09:30 – Challenges while growing your research development.

- Discuss the various principles and methods for implementing the project life cycle at each important phase.
- Discuss key factors affecting income from operations.
- Key factors that can make profit margins or break them.
- Analytics to help monitor critical measures of development.

10:00 – Topic TBC

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

10:30 – Morning Coffee/Tea & Discussion

CHALLENGES & OPPORTUNITIES

10:50 – DISCUSSION WITH EXPERTS: Planning and managing an adaptive clinical trial – Challenges and the best practices to achieve

- Discussing on the flexibility to redesign clinical trials at intermediate stage.
- With cross-over research, how adaptive designs can work.
- Understanding the logistical barriers that must be over come in order to use adaptive designs within existing trial frameworks.
- Addressing the review attempts to clarify the variations between several common types of adaptive designs proposed.
- What are the main sources of the funding and how regulatory agencies are solving these limitations.
- How do you handle the contracting? What are the extra costs?
- What advice would you have on to persuading people that the implementation and designs does not pose a risk?
- Adaptive clinical study designs in global trials

Moderator:

RANJIT BARSHIKAR
CEO - QbD International, United Nations Adviser
Member Editorial Board Journal of Generic Medicines, England

Panellists:

RAJENDRA JANI
Senior Subject Expert & Advisor
Clinical Research Consultant

SHREEKANT SAPATNEKAR
Director - Clinical Research
Lilavati Hospital & Research Centre

SANDESH SAWANT
Director and Head Clinical Trials
Cipla

ARUN GUPTA
Head Medical Affairs & Clinical Research
Dabur Research & Development Centre

SANDEEP JAGTAP
Assist. General Manager - Clinical R & D
Mylan Laboratories

ANANT PATIL
Asst. Professor Department of Pharmacology
Dr DY Patil Medical College

11:30 – DISCUSSION WITH EXPERTS: Current evolution of clinical trials: Addressing challenges for the future?

- Discussing the major challenges with global trials — How can they be overcome?
- What are the main challenges faced in the field of clinical trials and how tackle those issues.
- Challenges associated with balancing the desire for external validity, pragmatic trials, precision medicine, operational complexity and the expense of clinical trials
- Addressing the complexities of future clinical trials to be more practical, applicable, reliable and the collection of more meaningful data.

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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 - 28th May 2020

- Enhanced visibility of clinical trials and improving portunity for the future usefulness of trial results and the efficiency of their conduct
- Collaborative efforts to drive in the right direction

Moderator:

PRANJAL BORDOLOI
Vice President – Clinical, Medical Affairs & Pharmacovigilance Veeda Clinical Research

Panellists:

PRASANNA GANAPATHI
Associate Vice President – Global Clinical Sciences
Mylan Laboratories

MURTUZA BUGHEDIWALA
Associate Director – GCO
Johnson & Johnson

SUJAY KULKARNI
Business Partner/ Medical Expert
Novartis

KARAN THAKKAR
Regional Clinical Site Lead
Pfizer

SUTAPA BANDYOPADHYAY NEOGI
Professor, International Institute of Health Management Research (IIHMR)

12:10 – Discussion and development of functional processes in living organisms

- Provide clinical research and construct foundations for biomedical research and forms of study.
- Pre-clinical testing and medical treatment evaluation.
- Select applicants based on admission into clinical studies.
- Required data for preclinical studies

12:40 - Networking luncheon

Afternoon Chair Person

13:50 – Required advancement of clinical trials and new medicines approach

- Discussing the pharmaceutical industry's financed portion.
- Understanding the essential issues of morality and safety.
- Controlling excessively clinical research results.
- Questions frequently asked about commonly per formed scholastic clinical research.

14:20 – DISCUSSION WITH EXPERTS: Discussing future – Current challenges and overview to look out for while collaborating with the CROs and Sponsorships company

- Establishing an effective and quality collaboration between Sponsors and CROs and if it fails, what are the costs and negative results of a failed partnership?
- Failing partnerships between a pharma company and its CROs - What is the reason? Is it financial or the research development time? How can we avoid those situations?
- How to build a success partnership between pharmaceutical companies and CROs in order to per form clinical trials effectively. What is the right effort to shape a positive relationship from both the sponsor and CRO.
- What are some of the obstacles that often occur in partnerships with sponsors and CRO? How to ensure that your team is able to handle these situations effectively?
- What are the needs of different sponsors and how CRO must appreciate and approach?
- What to keep in mind while strategic partnership is a balancing act between the sponsor's need for flexibility and the CRO's need for standardization.

Moderator:

PRASHANT BODHE
Director
CliniSearch

Panellists:

SHUBHANGI DESAI
Director - Global Clinical Trial Management
Abbott (Singapore)

MURUGANANTHAN KRISHNAN
Country Monitoring Head - Global Development Operations, Global Drug Development, Novartis

REBU NINAN
Director - Strategic Marketing & Commercial Operations – Biologics, Dr. Reddy's Laboratories

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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

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AGENDA AT A GLANCE

DAY ONE - 28th May 2020

PRASHANT A. PANDYA
DGM-Global Strategic Sourcing - Scientific Affairs
Mylan Laboratories

SAKHARAM GARALE
Head South-East Asia Operations ACMA & Managing Partner, RENOVARE Healthcare Solutions

VAIBHAV SALVI
Head - Project Management and Strategic Initiatives Clinical Study Unit, Sanofi

PRATIKSHA PALAHE
Head, NFB
National facility for Biopharmaceuticals

BANOTH VENKATESWARLU
Assistant Drugs Inspector
Drug Standard Control Organization (CDSCO)

YASMIN SHENOY
Director-Regulatory Affairs
Sanofi-aventis

SRIRUPA DAS
Director - Medical Affairs
Abbott

JYOTSNA PATWARDHAN
Head Development QA
Novartis

15:10 – Afternoon Tea/Coffee

15:30 – Clinical studies and patients assessment

- Identification of study participants and evaluation of physiological or health outcomes.
- Diagnosing the therapeutic given to the patients.
- Helping the investigator to assign participants to a particular intervention / treatment.
- Discussing strategies that are not invasive, such as diet and exercise.

16:00 – DISCUSSION WITH EXPERTS: New drugs and clinical trial rules – Being ready for regulatory inspections

- Current key changes and challenges for trials in India
- What are the current challenges that the researchers must know before conducting a clinical trials in India? In the current scenario, how to solve these challenges?
- Current Scenario - protocol and testing procedure for authorizing a new drug before it is used on a patient?
- How to be prepared on inspections and documentations during the inspections
- Discussing about the validity of clinical trial permission to initiate a clinical trial?
- Staying on top of recent regulatory updates

Moderator:

Panellists:

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

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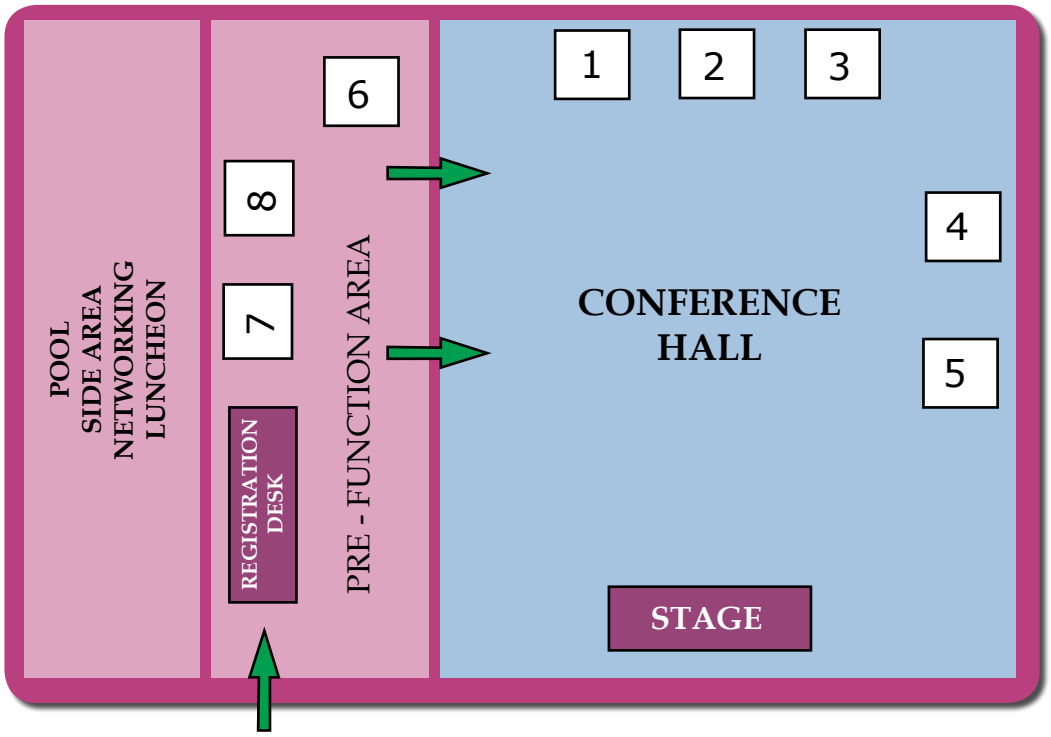
"Since Pharama companies have ventured into Biologicals/ Biosimilars business, the conference could have focused on discussing case stdies in Biosimilars Clinical trails, challenges in CTS in New Biologicals& Vaccines."

Regulatory Affairs Biologicals-Cipla New Ventures, Cipla

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



1 4 7

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3 6

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

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AGENDA AT A GLANCE

REGISTER ONLINE :

Link : https://www.bookmytrainings.com/catalogue/event/75086-11th-annual-clinical-trials-summit-2020

For Multiple Bookings - Photocopy this form and send it to **bookings@virtueinsight.com**

REGISTRATION FORM

RESERVATION PRICING:

Early Bird Discount Price

Cost per delegate (Valid till 14th April 2020) -
Fee: INR 10,000 + GST(18%)

Standard Rate

Cost per delegate (Valid From 15th April 2020)-
Fee: INR 15,000 + GST(18%)

Discounted Rate for Bulk Booking of More Than 5 Delegates

Please email us at **bookings@virtueinsight.com**

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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.

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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.

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General Information Venue:
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Mumbai 400059 - India
Tel: 91 22 66919000 / 91 22 28209999

TERMS AND CONDITIONS:

Payment terms: Virtue Insight requires the full amount to be paid before the conference. We may refuse entry to delegates who have not paid their invoice in full.
W
Cancellations: Delegates and vendors are subject to the following charges and refunds upon withdrawal or cancellation between 2-3 month's prior 75% cancellation fee/ 25% refund. Less than 2 months prior to the event Full cancellation fee / No refund.

Administration Fee: If you cancel your participation (once confirmed) and haven't paid the attendance fee you will be liable to pay an administration fee of INR 5,000

Substitutions/Name Change: If you are unable to attend you may nominate, in writing, another delegate to take your place at any time prior to the start of the event. This can be done at no extra cost.

Presentation: If you cannot attend the conference, you can still purchase the presentations for INR 5,000 + Tax

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 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.

VENUE

Kohinoor Continental Hotel

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MAP & DIRECTIONS

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