13th Annual Clinical Trials Summit 2022

#VIct

"A critical guide for successfully conducting clinical trials"

19th May 2022, Kohinoor Continental Hotel, Mumbai, India

AGENDA AT A GLANCE

Key Speakers Include

KAMAL K HALDER
ADCI
CDSCO (WZ)

MUKESH KUMAR
Senior Vice President & Head, Clinical R&D
Cipla

SADHNA JOGLEKAR
Senior Vice President, Global Medical Affairs
Sun Pharma

PRATIK SHAH
Vice President Medical Affairs
Bharat Serums and Vaccines

RAVI SEKHAR KASIBHATTA
Senior Vice President, Clinical Research
Lupin

MANISH SHAH
Associate Vice President
Wockhardt

SANDESH SAWANT
Senior Director, Medical Services Head - Clinical Trials, Cipla

RAGHURAM JANAPAREDDY
Partner & Managing Director – India
Tenthpin

DIVAKAR KOLLI
Associate Director and Head - Clinical & Non-Clinical QA, Cipla

TUSHAR SAKPAL
Director - Clinical Data Standards & Automation, Novartis

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

YASMIN SHENOY
Director-Regulatory Affairs
Sanofi

ANIKET JOSHI
Associate Global Portfolio Delivery Director
Novartis

RISHI JAIN
Medical Director
AbbVie

DILIP PAWAR
Head - Medical Affairs and Pharmacovigilance
Unichem Laboratories

CHIRAG TRIVEDI
Clinical Study Unit Cluster Head
Sanofi

KEDAR NAYAK
Head - Clinical Development
GSK

ARUN BHATT
Consultant – Clinical Research & Development

AMITA BHAVE
Head Regulatory Affairs GDD
Novartis

HARSHAD KOTHAWADE
Head-Regulatory Management & Trade Compliance, Merck

Conceptualised By

Plot No - 07 - 2nd Floor Ekambaram Industrial Estate, Alapakkam, Porur Chennai - 600 116, India
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info@virtueinsight.com

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SADANAND KULKARNI
Head-Medical, Regulatory, Vigilance, Quality
Fresenius Kabi

VAIBHAV SALVI
Head – Medical Information, Asia
Sanofi

INDRANIL PURKAIT
Sr. General Manager and Head Medical Affairs
Ipca Laboratories

ASHWANI PANDITA
General Manager Quality Management & TrainingGlobal Clinical Research Operations,
Glenmark

VALLABH DESHPANDE
HOD PV Operations
Glenmark

VISHWAS SOVANI
Founder Director
Pharmawisdom

GANESH KADHE
Senior Leadership Team Member, Scientific & Medical Affairs, Abbott Nutrition

ROSHAN PAWAR
Associate General Manager
Alkem Laboratories

SAKHARAM GARALE
Founder & CEO
Renovare Healthcare Solutions

Plus more COMING SOON.....

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Sponsorship Enquires - info@virtueinsight.com

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 - info@virtueinsight.com

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Event Partners

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your drug development arm

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CONFERENCE INTRODUCTION : -

The global clinical trials market size is expected to reach USD 69.3 billion by 2028. The market is expected to expand at a CAGR of 5.7% from 2021 to 2028. An increase in the volume and complexity of clinical trials has been witnessed lately, which plays an important role in the R&D of new drugs and other products.

India CRO Market has grown at a CAGR of 5.51%, in value terms, and is valued at USD 956.8 million in 2020. The market is further expected to reach USD 1,883.0 million by 2027 with a CAGR of 10.75% during the forecast period. Among the factors contributing to the growth of the India CRO market are the rapidly growing oncology studies field, the booming pharmaceutical industry, and efforts from the Indian government.

13th Annual Clinical Trials Summit 2022 will provide a platform to discuss on the futuristic advancements in clinical trials and clinical research. This multidisciplinary program involves broad participation of people from clinical trials community from around the globe who are focused on learning more about clinical research, clinical trials planning and management.

This conference intends to focus on the global health and clinical trials around the world. Bioethics, regulations, patient recruitment, site selection, real-world data, data integration & Strategy, outsourcing, vendor management, quality (QbD) in Trial Conduct, risk-based monitoring, clinical auditing & financial planning and other significant topics that play a key role in clinical trials will be addressed along with innovative sessions on new technologies, effective and quality collaborations.

It gives us immense pleasure in welcoming you to the **13th Annual Clinical Trials Summit 2022.** I wish and pray that all our efforts will be beneficial to our industries and to our country at large

KEY THEMES DISCUSSED

- The growth of hybrid trial and virtual trials in India – Where we are?
- Better patient recruitment and retention – Can be achieved by DCT?
- Digital transformation and AI in clinical trials
- What are key challenges in patient safety? Ways to overcome and better alternatives
- Risk-based monitoring (RBM) – Is ensuring patient safety?
- Clinical trial design and implementation – How technology makes an easier way?
- Wearable devices, remote monitoring and virtual trials – Risk and benefits
- Key market trends and challenges driving opportunities and outsourcing
- End-to-end strategic partnership and managing the communications gap in CROs
- How can sponsors successfully manage the EU CTR change?
- Technology accelerates new age clinical research
- Are the regulations sufficient in clinical trials and what needs to be done?
- Remote clinical research – Risks and chances
- How RWE is transforming clinical trials?
- How do we deal with privacy concerns around RWD?
- Ensuring and maintaining compliance with the rules and regulations.
- Be part of a major networking opportunity

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

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.

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AGENDA AT A GLANCE

DAY ONE - 19th May 2022

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

09:20 – Chairperson opening remarks

PRATIK SHAH
Vice President Medical Affairs
Bharat Serums and Vaccines

CHALLENGES & OPPORTUNITIES

09:30 - Getting Future Ready – Standards Driven Automations – Possibility & Opportunities

- CRF concepts and submission concepts
- Third part data and data cleaning
- How standards (global + company) can drive automations?
- SDTM/ADaM concepts and TFL concepts

TUSHAR SAKPAL
Director - Clinical Data Standards & Automation
Novartis

10:00 – DISCUSSION WITH EXPERTS: Key changes and visible trends in clinical trials

- Challenges and lessons learned from Covid-19 trials
- What can we anticipate for clinical development post pandemic? Barriers in adoption of new normal
- Opportunities and challenges of collecting wearable data in decentralized trials
- The growth of hybrid trial & virtual trials in India.
- Prioritizing study risks and learning from past experiences
- Digital transformation and AI in clinical trials
- Planning for better clinical trials globally.
- Clinical trials in Nutraceuticals: The new frontier?

Moderator:

DILIP PAWAR
Head - Medical Affairs and Pharmacovigilance
Unichem Laboratories

Panellist:

SANDESH SAWANT
Senior Director, Medical Services Head - Clinical Trials
Cipla

ANIKET JOSHI
Associate Global Portfolio Delivery Director
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Clinical Study Unit Cluster Head
Sanofi

KEDAR NAYAK
Head - Clinical Development
GSK

GANESH KADHE
Senior Leadership Team Member, Scientific & Medical Affairs, Abbott Nutrition

ARUN BHATT
Consultant – Clinical Research & Development

10:50 – Morning Coffee/Tea & Discussion

PATIENT SAFETY

11:10 – DISCUSSION WITH EXPERTS: Ensuring the patient safety and centricity in clinical trials.

- What are key challenges in patient safety? Ways to overcome and better alternatives.
- Enhancing patient-site centricity and clinical innovation through technology
- What can we do better to improve patient recruitment?
- Impact of technology in field of clinical trials - where are we heading with these developments and what's next?
- Role of DCT methods in the process of patient enrolment and safety.
- How much data is used and what information is shared with the patient?
- Risk-based monitoring (RBM) – Is ensuring patient safety?

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DAY ONE - 19th May 2022

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RAGHURAM JANAPAREDDY
Partner & Managing Director – India
Tenthpin

Panellist:

MUKESH KUMAR
Senior Vice President & Head, Clinical R&D
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RISHI JAIN
Medical Director
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VALLABH DESHPANDE
HOD PV Operations
Glenmark

INDRANIL PURKAIT
Sr. General Manager and Head Medical Affairs
Ipca Laboratories

ROSHAN PAWAR
Associate General Manager
Alkem Laboratories

12:00 – Advantages, challenges and limitations of technology in clinical trials

- Integrating e-technologies into clinical trial design, implementation and dissemination
- Lack of previous experience with trial conduct and digital platforms
- Potential uses of artificial intelligence and machine learning in clinical trials
- Leveraging AI to accelerate clinical research
- New technologies such as wearable devices, remote monitoring and virtual trials – Challenges.

12:30 – Networking luncheon

CRO RESPONABILITIES

13:40 – DISCUSSION WITH EXPERTS: Risk identification and quality management in sponsorship

- What are the key market trends and challenges driving opportunities and outsourcing?
- Recognizing the challenges of navigating multiple stakeholders.
- Focusing on the relationship between CROs and sponsors – What are the distractions?
- Discussing the current industrial trends globally and in India as well.
- End-to-end strategic partnership and managing the communications gap
- Ensuring that high quality data is collected as part of CRO collaboration
- How can sponsors successfully manage the EU CTR change?

Moderator:

VISHWAS SOVANI
Founder Director
Pharmawisdom

Panellist:

PRATIK SHAH
Vice President Medical Affairs
Bharat Serums and Vaccines

RAVI SEKHAR KASIBHATTA
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ASHWANI PANDITA
General Manager Quality Management & Training Global Clinical Research Operations, Glenmark

SAKHARAM GARALE
Founder & CEO
Renovare Healthcare Solutions

14:30 – Challenges and risks for launching decentralized trials

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DAY ONE - 19th May 2022

- Better patient recruitment and retention – Can be achieved by DCT?
- Barriers in drug distribution, management and data system
- Importance of patient convenience – What has to be done?
- Regulatory compliance & patient-investigator experience in DCT
- Ensuring each DCT remains transparent, accessible and patient-centric

15:00 – Afternoon Tea/Coffee

15:20 – Early phase development: Is India ready?

SADHNA JOGLEKAR
Senior Vice President, Global Medical Affairs
Sun Pharma

REGULATORY

15:50 – DISCUSSION WITH EXPERTS: Recent changes in regulatory aspect of clinical trials in India

- Ensuring and maintaining compliance with the rules and regulations.
- Following the pandemic, what are the regulatory challenges for the CRO industry?
- Delays in approval from regulatory agencies. What needs to be done?
- Protecting safety: Standardizing and streamlining the regulatory process

Moderator:

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

Panellist:

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Merck

SADANAND KULKARNI
Head-Medical, Regulatory, Vigilance, Quality
Fresenius Kabi

16:40 - Chairperson's closing remarks and end of conference

PRATIK SHAH
Vice President Medical Affairs
Bharat Serums and Vaccines

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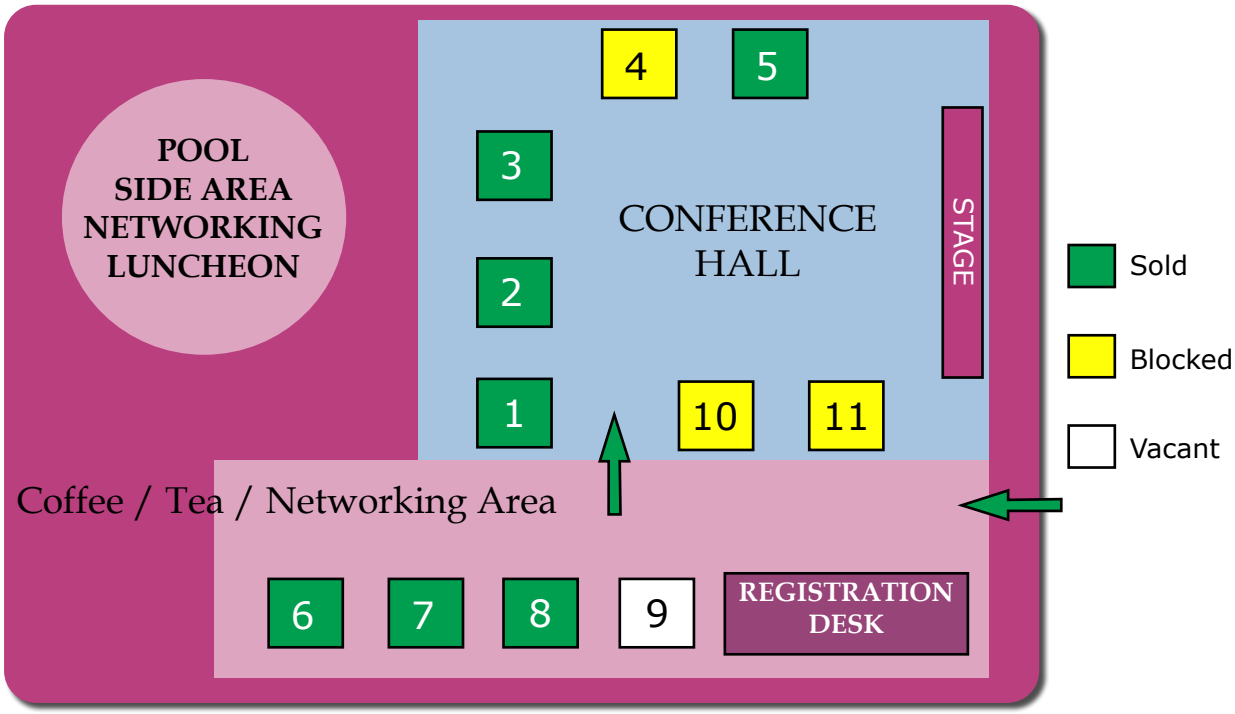
FLOOR PLAN - Book your stalls now before they run out !!!



1	CLINEVO Technologies	5	Pro Relix Research your drug development arm	9	
2	TENTHPIN	6	OntimeGlobe Quality, Service & Trust	10	
3	ADVITY	7	INNVOCEPT SOLUTIONS	11	
4		8	Target Institute of Medical Education & Research (TIMER)		

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

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REGISTER ONLINE :

Link : https://www.townscript.com/e/13th-annual-clinical-trials-summit-2022-301012

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

REGISTRATION FORM

RESERVATION PRICING:

Standard Price

Cost per delegate

Fee: INR 15,000 + GST(18%)

Discounted Rate 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) ☐

Please keep my contact details confidential. Not to be shared to the other attendees - (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 Name	- Virtue Insight
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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Web: http://www.virtueinsight.com
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UK Office: Tel: +44-20 3509 3779

General Information Venue:
Kohinoor Continental Hotel
Andheri Kurla Road
Andheri (E)
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.

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 (Subject to availability) - Please email to bookings@virtueinsight.com

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.

Covid Situation – In the case where the government of Maharashtra decide to go into a lockdown or restrictions on social and business gatherings during the dates of the conference, the event will be postponed to a new date. Registered clients can choose to join the conference on the new date or decide to take a credit note for their payment so that they can decide to participate for any of our future events within the timeframe of next one year from the time we start hosting live events as soon as the lockdown restrictions are lifted by the government.

VENUE

Kohinoor Continental Hotel

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

MAP & DIRECTIONS

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