

15th Annual Clinical Trials Summit 2024

#Vlct

"A critical guide for successfully conducting Clinical Trials"

29th & 30th May 2024, Kohinoor Continental Hotel, Mumbai, India

AGENDA AT A GLANCE

Key Speakers
Conference Info
Day One
Day Two
Floor Plan
Booking Details

Key Speakers Include



MAYUR PARMAR
Drugs Inspector (Deputy Collector, Gujarat Government), **FDA**



MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates



SUYOG MEHTA
VP & Head - Medical Affairs & Clinical Research, India & Emerging Markets
Sun Pharma



ANITHA K
Global Head Operations, GDO Data Operations
Novartis



ANIL KUKREJA
VP - Medical Affairs & Regulatory
AstraZeneca



YASMIN SHENOY
Director-Regulatory Affairs
Sanofi



SANDESH SAWANT
VP Medical Affairs & Head - Clinical Trials
Cipla



ANUP PINGLE
Medical Director - Global Health Access
GSK



RAMESH JAGANNATHAN
Vice President, Medical Affairs
Bharat Serums and Vaccines



MUKESH GORI
Director ESP Engagement PV & PS
Novartis



SHALINI MENON
Country Medical Director, South Asia
Sanofi



DIVAKAR KOLLI
Director - Development Quality Assurance
Cipla



ANIRBAN ROY CHOWDHURY
AVP & Head-Global CoE for Clinical Data Management Biostatistics & Clinical Operations, **Sun Pharma**



SUCHITA MORE
Associate Director Medical Affairs
MSD



VAIBHAV SALVI
Director & Head - Clinical Study Unit, India & South East Asia, **Sanofi**



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



RASHMI HEGDE
VP Medical Affairs
GSK



VIVEK GUPTA
Associate Director - Strategic Engagements & Vendor Management - Clinical & Medical Affairs, **Organon**



SHIRAZ KANDAWALLA
Associate Director Regulatory Affairs
Ferring Pharmaceuticals



SAKSHI SHRIVASTAVA DESAI
Associate Director International PV Strategy Realization, **Johnson & Johnson**



VIPIN SETHI
Asst Vice President
Cadila



DILIP PAWAR
Director & Head Clinical Development and Medical Affairs, **Unichem Laboratories**



CHIRAG TRIVEDI
Global Head, Clinical Study Units (CSU) Early Operational Strategy, **Sanofi**



KAMLESH PATEL
Head - Medical Regulatory Clinical Research & Health Tech, **Lupin**

Conceptualised By



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ROSHAN PAWAR
Head Medical Affairs
Alkem Laboratories



KEDAR NAYAK
Head - Clinical Development
GSK



INDU NAMBIAR
Head PV, Local Patient Safety Lead
Boehringer Ingelheim



SADANAND KULKARNI
Head - Medical, Regulatory, Vigilance &
Quality (South Asia), Fresenius Kabi



DEVEN BABRE
Former Director Analytics & Benchmarking
GSK



RENUKA NEOGI
Head & Deputy General Manager - Global
Clinical Quality Management, Sun Pharma



PRIYA CHATTERJEE
Head Regulatory Affairs - South Asia
Bayer Pharmaceuticals



VISHVAJIT M. KARANDIKAR
Business Unit (BU) Head -Parenteral Nutrition
Fresenius Kabi



NISHITH VYAS
Associate Director, R&D Strategic Sourcing and
Vendor Management, Organon



GOPINATH MADHU
Senior Client Partner, Digital & Technology
Pfizer



SANKET NEWALE
Head Medical Affairs & Business Compliance
Wockhardt



MAYUR MAYBHATE
Head Medical Affairs
Alkem Laboratories



GODHULI CHATTERJEE
Senior Medical Advisor, India-South East Asia
Sanofi



INDRANIL PURKAIT
Senior GM - Medical Affairs
Ipca Laboratories



KAVITA LAMROR
Partner, RWE & Digital Transformation
Maxis Clinical



SHRADDHA BHANGE
Senior Medical Safety Lead
Sandoz



PRAVIN GHADGE
AVP and Head - India clinical research
Sun Pharma Laboratories



SEERA DILEEP RAJU
Senior Manager - ML & AI
MSD



KUSHAL SARDA
GM & Head, Medical Affairs, Clinical Research
& PV, Shalina Healthcare



VISHWAS SOVANI
Founder Director
Pharmawisdom



VANDAN TRIPATHI
Sr Brand Manager (Digital)
Cipla

Plus More Coming Soon...

EXHIBITOR



CLINICAL RESEARCH
NETWORK INDIA
Contract Research
Organization

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KEY THEMES

- Clinical Trials – Market Analysis: Opportunities & Challenges
- Why Decentralisation is the future of Clinical Trials?
- Decentralisation - Sustaining DCT adoption in a challenging economic environment
- Challenges and risks for launching decentralized trials
- Prioritising patients – Always placing patients first
- Improving collaboration & transparency: The need for strong sponsor-vendor relationships
- Clinical Trial Supply - What's the new way forward?
- Innovative methods for Clinical trial design
- Inspection readiness - What to expect when you're inspected?
- Rising opportunities & challenges for a successful clinical trial management
- How RWE / RWD is transforming Clinical Trials? Challenges & Opportunities?
- Technology & Innovation – Impacts & Improvements on Patient Experience
- Explore the Impact of DCT on clinical development & the evolution of audits
- Creating an effective clinical trial site management
- Outsourcing in clinical trials: How to build successful partnerships?
- Collaborations between CROs and the Pharmaceutical Industry
- Data Integrity and Data Management
- End-to-end strategic partnership & managing communication gap in CROs
- Ratification - New Drugs and Clinical Trial Rules 2023
- What regulatory changes & developments can help in advancement of Clinical Trials in India
- Be part of a major networking opportunity

CONFERENCE INTRODUCTION

The global clinical trials market size was valued at USD 53.87 billion in 2022 and is expected to grow at a CAGR (Compound annual growth) of 5.7% over the forecast period and expected to reach USD 65.2 billion by 2025. The growth in this market is primarily driven by factors such as globalization of clinical trials, development of new treatments, evolution in technology, and increasing demand for CROs to conduct clinical trials.

Globalization of clinical trial has led to increase in investment in new product development in emerging countries thereby, having a positive impact on overall market. The availability of the vast array of services from drug discovery to post-marketing surveillance has further simplified the life for mid-size and small-scale pharmaceutical and biotechnological organizations by providing them the option to outsource what they think is beyond their core expertise.

15th Annual Clinical Trials Summit 2024 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 who are focused on learning more about clinical research, Clinical Trials planning & management. This event opens discussion of timely topics of mutual theoretical and practical interest for clinical trial investigators who are developing new drugs and biologics. This groundbreaking platform continues the conversation between business, academics, patient advocacy, and regulatory agencies to discuss new methods and solutions to statistical challenges relevant to the design and analysis of Clinical Trials collaboratively in the real world. It is high time that we look into innovative strategies, new technologies, effective and quality collaborations to address these issues, which can cater to the needs of the patient and the industry.

It gives us immense pleasure in welcoming you to the **15th Annual Clinical Trials Summit 2024**. I wish and pray that all our efforts will be beneficial to our industries and to our country at large

WHO SHOULD ATTEND AND WHO YOU'LL MEET

CIOs, CEOs, CDOs, Vice Presidents, Presidents, Heads, Directors and Team Leaders from the following areas:
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 System

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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DAY ONE - 29th May 2024

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

09:10 – Welcome Address

EXCELLENCE IN CLINICAL RESEARCH

09:20 – Effective CAPA management, continuous improvement and operational excellence in clinical research

- Why clinical research CAPA is not as effective as GMP CAPA and what are the gaps
- In most of the cases retraining is the CAPA action, is it effective?
- How effective CAPA management can lead to operational excellence
- How TIMELY and effective CAPA can prevent data quality issues
- Case studies for achieving operational excellence through continuous improvement

DIVAKAR KOLLI

Director - Development Quality Assurance
Cipla

CLINICAL TRIAL MANAGEMENT

10:00 – Evaluating the new opportunities & challenges in rising to the expectations and demands of a post-pandemic clinical trial management

- The most impactful clinical trial management changes that were put into place due to the pandemic? Lessons learnt from that which will carry on for betterment
- What are the core fundamentals we need to have in place to achieve excellence in clinical trial management?
- How are we adapting to the new normal and excelling?
- How does RWE and RWD facilitate clinical trial management?
- What are the challenges and future outlook of RWE and RWD?
- Data collection & management: Enhancing compliance, efficiency, and speed to market through effective data integration and management

Moderator:

VIPIN SETHI

Asst Vice President
Cadila

Panellists:

SANDESH SAWANT

VP Medical Affairs & Head - Clinical Trials
Cipla

RAMESH JAGANNATHAN

Vice President, Medical Affairs
Bharat Serums and Vaccines

ANUP PINGLE

Medical Director - Global Health Access
GSK

SUCHITA MORE

Associate Director Medical Affairs
MSD

ROSHAN PAWAR

Head Medical Affairs
Alkem Laboratories

KAVITA LAMROR

Partner, RWE & Digital Transformation
Maxis Clinical

10:50 – Morning Coffee / Tea & Discussion

11:20 – Topic TBC

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PATIENT CTRICITY

11:40 – DISCUSSION WITH EXPERTS: Prioritising Patients
– Always placing patients first

- Patient involvement & engagement - Is it a conversation or an obligation?
- Importance of engaging patients in every possible ways
- Meeting new patient expectations and building the expected personalized trial experience
- How should we view patient involvement?
- How will patient involvement change as the clinical trial landscape advances with questions around data and virtual trials etc.
- Understanding what works and what doesn't from a patient perspective – How is this relayed to regulators?
- Educating stakeholders via patient stories
- Bringing it all together to enhance the patient experience

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Moderator:

VISHWAS SOVANI
Founder Director
Pharmawisdom

Panellists:

CHIRAG TRIVEDI
Global Head, Clinical Study Units (CSU) Early Operational
Strategy, **Sanofi**

INDU NAMBIAR
Head PV, Local Patient Safety Lead
Boehringer Ingelheim

INDRANIL PURKAIT
Senior GM -Medical Affairs
Ipca Laboratories

MAYUR MAYBHATE
Head Medical Affairs
Alkem Laboratories

.....

12:30 - Networking luncheon

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SPONSOR - SITE - CRO - PATIENTS

13:40 - DISCUSSION WITH EXPERTS: Improving collaboration & transparency: Disruptions have increased the need for strong sponsor-vendor relationships.

- How must collaboration and transparency across the supply chain continue to evolve to meet the rising demand?
- Delivering greater collaboration & transparency in sponsor - vendor relationships to drive future success
- Structural changes that sponsors need to implement to allow them to have more effective relationships with their vendors
- How CROs can benefit from continual improvement analysis and benchmarking?
- How are we moving beyond the world of good intentions and making transparency tangible?
- Organization & preparedness - Moving to another level of site collaboration
- Positive learnings that we can embed to achieve greater success?

Moderator:

VISHWAS SOVANI
Founder Director
Pharmawisdom

Panellists:

MUKESH GORI
Director ESP Engagement PV & PS
Novartis

ASHWANI PANDITA
GM Quality Management & Training, Global Clinical
Research Operations, **Glenmark Pharmaceuticals**

VIVEK GUPTA
Associate Director - Strategic Engagements & Vendor
Management - Clinical & Medical Affairs, **Organon**

SANKET NEWALE
Head Medical Affairs & Business Compliance
Wockhardt

KUSHAL SARDA
GM & Head, Medical Affairs, Clinical Research & PV
Shalina Healthcare

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14:30 - Differentiated medicomarketing initiatives for KOL engagements along with evidence generation

- Real world evidence generation
- Re-emphasis and Opinions on developed guidelines
- NCEs and their journey in India

SANKET NEWALE
Head Medical Affairs & Business Compliance
Wockhardt

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15:00 - Afternoon Tea / Coffee

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15:30 - Innovative methods for Clinical trial design

- Contemporary strategies to improve clinical trial design
- Setting up the best position to sustain an agile procedure for your study design
- The flexibility to redesign clinical trials at an intermediate stage

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DAY ONE - 29th May 2024

- How does AI transform key steps of clinical trial design from study preparation to execution towards improving trial success rates?
- Effective trial design and improved compliance

PRIYA CHATTERJEE

Head Regulatory Affairs - South Asia
Bayer Pharmaceuticals

17:00 - End of conference Day 01

REGULATORY

16:00 - Keynote Panel Discussion: What regulatory changes & developments can help in advancement of Clinical Trials in India

- How are we tracking the evolving regulatory landscape changes and ensuring we stay compliant?
- New drugs and clinical trial rules to prepare for regulatory inspection
- Ratification - New Drugs and Clinical Trial Rules 2023
- New CDSCO Regulatory Document Submission Process
- How should operators and regulators work together to build a regulatory framework that fosters innovation whilst protecting standards?
- Are the regulations sufficient towards Decentralisation and what needs to be done?
- Delays in approval from regulatory agencies. What needs to be done?
- Standardizing and streamlining the regulatory process

Moderator:

MILIND ANTANI

Leader, Pharma and Healthcare
Nishith Desai Associates

Panellists:

MAYUR PARMAR

Drugs Inspector (Deputy Collector, Gujarat Government)
FDA

ANIL KUKREJA

VP - Medical Affairs & Regulatory
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08:30 - Coffee & Registration - An opportunity to meet and to network with your conference colleagues.

Moderator:

DILIP PAWAR

Director & Head Clinical Development and Medical Affairs
Unichem Laboratories

Panellists:

VAIBHAV SALVI

Director & Head - Clinical Study Unit, India & South East Asia, Sanofi

NISHITH VYAS

Associate Director, R&D Strategic Sourcing and Vendor Management, Organon

KEDAR NAYAK

Head - Clinical Development
GSK

PRAVIN GHADGE

AVP and Head - India clinical research
Sun Pharma Laboratories

KAMLESH PATEL

Head - Medical Regulatory Clinical Research & Health Tech, Lupin

RWE & RWD

09:30 - How is RWE / RWD is transforming Clinical Trials? Challenges & Opportunities?

- How does RWE aids stakeholders to support decision-making and improve safety and effectiveness, and ultimately, patient outcomes.
- How can RWD be applied to gain insight in clinical development? How does it improves clinical trial outcomes?
- Getting real: Who is leading the real-world data charge with clinical trials?
- Decentralisation meets real-world data
- Barriers to adoption of RWD in Clinical Trials and the possible solutions
- Use of real-world evidence among regulators
- Dealing with privacy concerns

SUYOG MEHTA

VP & Head - Medical Affairs & Clinical Research, India & Emerging Markets, Sun Pharma

DECENTRALISATION

10:00 - Keynote Panel Discussion: Decentralisation - Sustaining DCT adoption in a challenging economic environment

- Decentralized Trials: Ensuring the best blend of decentralized & in-person elements for your trial
- Current key changes & challenges for trials in India
- DCT model as part of protocol design to support organizations to find the right balance operationally and to makes the patients' lives easier
- Wide range of factors that need to be considered when determining the risk vs the benefit to a study
- Patient-centric sample collection - An essential gateway into the future of DCT
- Impact of allowing people to participate in clinical trials in new ways which enable better access and data for treatments and care management in the future
- Opportunities and challenges of collecting wearable data in decentralized trials
- Role of stakeholders in shaping the ecosystem and making decentralized approach successful

10:50 - Morning Coffee / Tea & Discussion

11:20 - Topic TBC

For sponsorship opportunities please contact
info@virtueinsight.com

INSPECTION READINESS

11:50 - What to expect when you're inspected?

- Key Learnings from recent inspections to smoothen your inspection readiness plan
- Different approaches to inspection readiness and how these vary across companies and regulatory updates?
- Authorities interactions and how inspections have been conducted pre- and post-pandemic?
- Building a readiness framework that takes into account new technologies and disruptors such as legislative changes, gene therapies, digital health and DCTs.

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RENUKA NEOGI

Head & Deputy General Manager - Global Clinical Quality Management, **Sun Pharma**

12:20 - Topic TBC

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info@virtueinsight.com

12:40 - Networking luncheon

OUTSOURCING / PARTNERSHIPS

13:50 - DISCUSSION WITH EXPERTS: Outsourcing in clinical trials: How to build successful partnerships?

- How to choose the right one for our trial?
- What considerations include while choosing your outsourcing model?
- Harmonizing Outsourcing to keep clinical Trials on Track - Charting a course / Strategic alignment / Metrics that drive excellence
- The Synergy of collaboration: Creating a success story
- R&D outsourcing - Key points to look out for
- What is an effective long-term Partnership?
- When to engage with patient advocacy organisations and the value they can bring?
- Benchmarking success in overcoming key operation & strategic barriers
- Discuss alternative site models and benchmark best practice for understanding the relationships between different stakeholders

Moderator:

SUYOG MEHTA

VP & Head - Medical Affairs & Clinical Research, India & Emerging Markets, **Sun Pharma**

Panellists:

ANIRBAN ROY CHOWDHURY

AVP & Head-Global CoE for Clinical Data Management Biostatistics & Clinical Operations, **Sun Pharma**

ANITHA K

Global Head Operations, GDO Data Operations
Novartis

SHALINI MENON

Country Medical Director, South Asia
Sanofi

SHRADDHA BHANGE

Senior Medical Safety Lead
Sandoz

14:40 - Explore the Impact of DCT on clinical development & the evolution of audits

- Investigate how the creation of new data sources is bringing new challenges in data integrity, security and privacy, while offering opportunities for real-time monitoring
- Discover strategies for adapting existing clinical audit processes to ensure they are effective in evaluating and improving the quality of clinical research in the digital age
- Practical solutions including procedural changes, education, and upskilling of auditors for high quality audit standards and alignment with evolving regulations

15:10 - Afternoon Tea / Coffee

OBSERVATIONAL STUDIES

15:30 - Observational Studies: Pros & Cons

- Importance of observational studies in Indian scenario
- What should we expect and not expect from observational studies
- Regulatory scenario as regards observational studies

SADANAND KULKARNI

Head - Medical, Regulatory, Vigilance & Quality (South Asia), **Fresenius Kabi**

IMPACT OF TECHNOLOGY

16:00 - Keynote Panel Discussion: Technology & Innovation - Impacts & Improvements on Patient Experience

- Impact of Digital Transformation - Digitizing Clinical Trials
- What are the key market trends and challenges driving opportunities

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- Trying to define what AI actually means in Clinical Trials
- Need for companies to adapt to digitalisation
- Patient Recruitment: Leveraging digital and mobile technologies to increase patient recruitment
- In what ways can we improve our capacity to anticipate and mitigate disruptive events and how are technological innovations supporting this?
- Does the new technology answer the key needs of ALL the stakeholders and not just for the sponsors/ tech companies

Moderator:

VISHVAJIT M. KARANDIKAR

Business Unit (BU) Head -Parenteral Nutrition
Fresenius Kabi

Panellists:

RASHMI HEGDE

VP Medical Affairs
GSK

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Senior Manager - ML & AI
MSD

GOPINATH MADHU

Senior Client Partner, Digital & Technology
Pfizer

VANDAN TRIPATHI

Sr Brand Manager (Digital)
Cipla

.....
17:00 - Closing remarks and End of conference
.....

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/ news letter about the event and advertise the event via different forms of media.

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



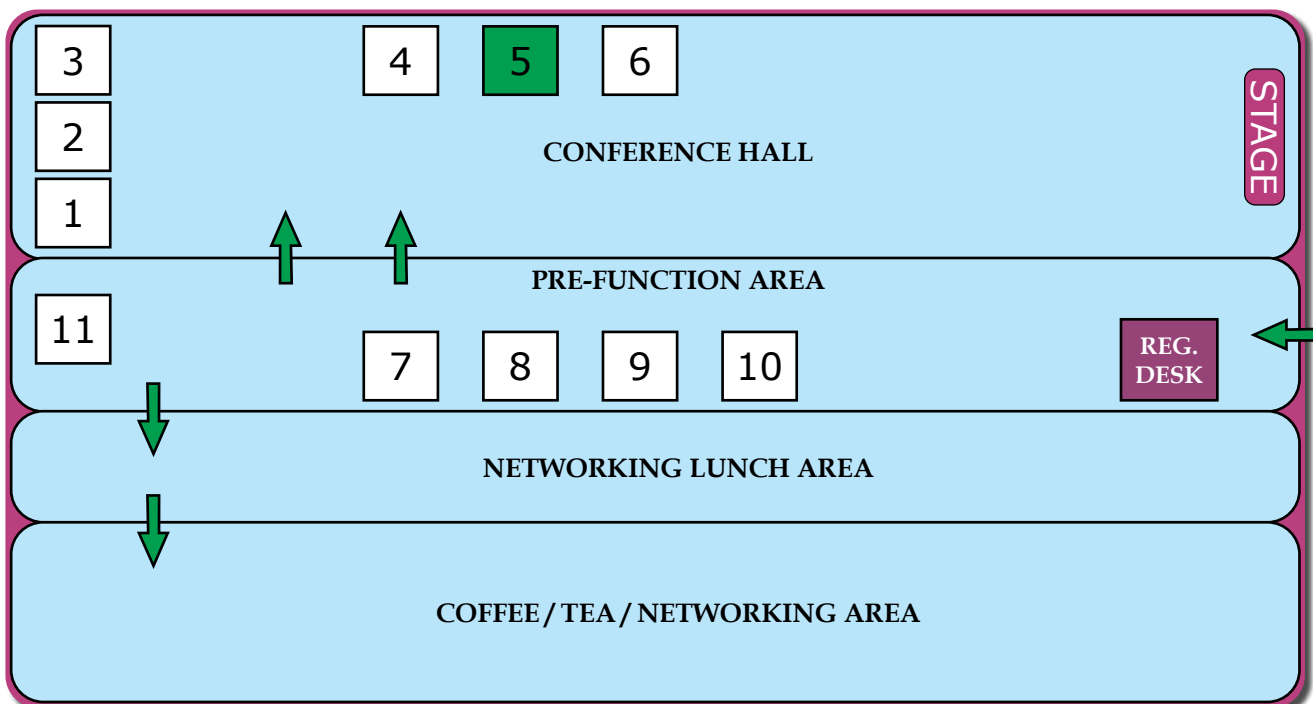
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Note :- The floorplan is subject to change at the discretion of the organisers.

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REGISTER ONLINE :

Link : <https://www.townscript.com/e/15th-annual-clinical-trials-summit-2024-023203>

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

REGISTRATION FORM

RESERVATION PRICING:

Super Early Bird Price (Valid Till 03rd April 2024)

Cost per delegate - Fee: INR 14,000 + GST(18%)

Standard Price

Cost per delegate - Fee: INR 19,000 + GST(18%)

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
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: <https://virtueinsight.com/>

India Office: Tel: +91 44 42108101

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, Natural Calamity, National Security: 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.

Conceptualised By



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info@virtueinsight.com