CLINICAL RESEARCH NETWORK INDIA
A Make in India CRO

Presents

14th Annual Clinical Trials Summit 2023

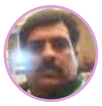
#VIct

"A critical guide for successfully conducting Clinical Trials"

23rd – 24th May 2023, Kohinoor Continental Hotel, Mumbai - India

AGENDA AT A GLANCE

Key Speakers Include



GOURI SHANKAR
Assistant Drugs Controller
CDSCO

MUKESH KUMAR
Senior VP & Head, Clinical R&D
Cipla

PRATIK SHAH
VP - Medical Affairs
Bharat Serums and Vaccines

SADHNA JOGLEKAR
Head, Global Drug Development India
Novartis

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

RAHUL GUPTA
Senior Vice President, Regulatory Affairs
USV

SANDESH SAWANT
VP Medical Affairs & Head - Clinical Trials
Cipla

MANISH SHAH
Associate Vice President
Wockhardt

YASMIN SHENOY
Director-Regulatory Affairs
Sanofi

VIPIN SETHI
Asst Vice President
Cadila

MURTUZA BUGHEDIWALA
Global Trial Program Head
Novartis

NIDHI SINGH
Director-Clinical Operations
Clinical Research Network India

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

AMITA BHAVE
Head Regulatory Affairs
Novartis

VAIBHAV SALVI
Director and Head – Clinical Study Unit, India and South East Asia, Sanofi

SEEMA PAI
Director Clinical Site Operations – India Cluster, Pfizer

RISHI JAIN
Director Medical Affairs & Pharmacovigilance
AbbVie

PRABHAT SINHA
Director Government & Public Affairs
Boehringer Ingelheim

PANKAJ GUPTA
Chief Scientific Officer
Novartis

SANTOSH TAUR
Director Medical Affairs - Vaccines & Digital
Pfizer

SHIRAZ KANDAWALLA
Associate Director Regulatory Affairs
Ferring Pharmaceuticals

LESTTER CRUZ SERRANO
Head of Medical Affairs & Global Site Engagement Lead
Cognizant SIP

HIREN THAKKAR
Managing Director
Octalsoft

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

Conceptualised By

Virtue Insight

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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Key Speakers Include

MUKESH GORI
Associate Director - ESP Management PV Strategy & Operations, Novartis

QAYUM MUKADDAM
Head of MACR
Tech Observer

TARANNUM KASHMIRI
Founder and CEO
ClinPro Research

HITENDRA NATH PANDEY
Associate Director – Statistics
Eli Lilly

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

KEDAR NAYAK
Head - Clinical Development
GSK

JYOTSNA PATWARDHAN
Cluster Head Clinical / PV Country Quality Middle East / Africa / Turkey / India
Novartis

KAMLESH PATEL
Head -Medical Affairs & Health Tech
Lupin

SANKET NEWALE
Head Medical Affairs
Emcure Pharmaceuticals

KAVITA LAMROR
Expert, Real World Investigator & RWD Product Owner, Sanofi

GANESH KADHE
Country Lead & SLT Member, Scientific & Medical Affairs, Abbott

ANIKET JOSHI
Associate Global Portfolio Delivery Director
Novartis

HARSHAD KOTHAWADE
Head of Regulatory Management & Trade Compliance, Merck Group

MAYUR MAYBHATE
Head Medical Affairs
Alkem Laboratories

VAIBHAV AGARWAL
GM, Global Head- Digital
Shalina Healthcare

PRITI THAKOR
Head of Medical Affairs - Southern Asia
Johnson & Johnson

INDRANIL PURKAIT
Senior General Manager - Medical Affairs
Ipca Laboratories

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

RAJ KHIRASARIA
Medical & Diagnostics Lead, Rare diseases
Sanofi

SEERA DILEEP RAJU
Senior Manager - ML & AI
MSD

VISHWAS SOVANI
Founder Director
Pharmawisdom

PRASHANT BODHE
Director
CliniSearch

SAKHARAM GARALE
Founder & CEO
RENOVARE Healthcare

Plus more coming soon...

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PRINCIPAL PARTNER

CLINICAL RESEARCH NETWORK INDIA
A Make in India CRO

SILVER PARTNERS

cognizant | CLINPRO RESEARCH EMPOWERING SOLUTIONS

TechObserver | Octalsoft TECHNOLOGY SIMPLIFIED

EXHIBITORS

CLINEVO Technologies | MEDCLINICA Accelerating Clinical Trials | ancillarie passion for research

paradigmIT Clinical Trial Services | CRYOPDP a cryoport company | ClinChoice

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KEY THEMES

- Why Decentralisation is the future of Clinical Trials?
- Challenges and risks for launching decentralized trials
- How to manage a Pandemic/Crisis Management in the Future?
- Lessons from Covid-19 pandemic on conducting global Clinical Trials
- Advantages, challenges, and limitations of technology in Clinical Trials
- Current status, challenges and future outlook of RWE and RWD
- Collaborations between CROs and the Pharmaceutical Industry
- Enhancing Patient centricity and patient safety
- Designing quality into Clinical Trials to optimise patient recruitment
- Impact of digital transformation - Digitizing Clinical Trials
- Data Integrity and Data Management
- Creating Effective Outsourcing Partnerships
- Remote clinical research – Risks and chances
- End-to-end strategic partnership & managing communication gap in CROs
- Are the regulations sufficient in Clinical Trials ? What needs to be done?
- Regulatory updates for bettering Clinical Trials
- 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 predicted to hit USD 84.43 bn by 2030 with a registered CAGR of 5.7% during the forecast period 2022 to 2030. 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. However, the market growth was hindered in 2020 due to the COVID-19 pandemic. Nevertheless, the future seems promising for the market owing to factors such as globalization and decentralisation of Clinical Trials, rapid technological evolution, and augmenting demand for CROs to conduct research activities.

14th Annual Clinical Trials Summit 2023 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 **14th Annual Clinical Trials Summit 2023**. I wish and pray that all our efforts will be beneficial to our industries and to our country at large

WHO SHOULD ATTEND

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 - 23rd May 2023

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

09:20 – Welcome Address

CHALLENGES & OPPORTUNITIES

09:30 – Challenges and risks for launching decentralized trials

- 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

SADHNA JOGLEKAR
Head, Global Drug Development India
Novartis

DECENTRALISATION

10:00 – DISCUSSION WITH EXPERTS: Why Decentralisation is the future of Clinical Trials ?

- Adapt and succeed in a decentralised landscape and its benefits
- What are the key considerations for a successful decentralised trial
- Changing what's possible today for a future for patients tomorrow
- Future proofing Clinical Trials using Decentralized Approaches
- Taking small steps along the way toward implementing decentralized approaches
- Opportunities and challenges of collecting wearable data in decentralized trials
- Role of stakeholders in shaping the ecosystem and making decentralized approach successful

Moderator:

VIPIN SETHI
Asst Vice President
Cadila

Panellists:

MANISH SHAH
Associate Vice President
Wockhardt

PANKAJ GUPTA
Chief Scientific Officer
Novartis

KEDAR NAYAK
Head - Clinical Development
GSK

TARANNUM KASHMIRI
Founder and CEO
ClinPro Research

11:00 – Morning Coffee / Tea & Discussion

RWE & RWD

11:30 – Current status, challenges and future outlook of RWE and RWD

- How RWE is transforming Clinical Trials?
- Use of real-world evidence among regulators
- How do we deal with privacy concerns around RWD?
- Risk of combining RWE in the regulatory decision-making process.
- Real world evidence / Non interventional studies and its implications for healthcare improvement
- More and better RWD

KAVITA LAMROR
Expert, Real World Investigator & RWD Product Owner
Sanofi

12:00 – TOPIC TBC

Speaker TBC

12:30 – Networking luncheon

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DAY ONE - 23rd May 2023

BRIDGING - PHARMA & CRO

13:30 – DISCUSSION WITH EXPERTS: Collaborations between CROs and the Pharmaceutical Industry

- Organization and preparedness
- How the Integration of DCT components can improve patient experience and promote greater investigator site engagement?
- Moving to another level of site collaboration
- Ensuring the right infrastructure to support today's complex clinical trial designs
- What is an effective long-term Partnership?
- Building quality into clinical trials
- When to engage with patient advocacy organisations and the value they can bring?
- How CROs can benefit from continual improvement analysis and benchmarking

Moderator:

PRASHANT BODHE
Director
CliniSearch

Panellists:

VAIBHAV SALVI
Director and Head – Clinical Study Unit, India and South East Asia, Sanofi

JYOTSNA PATWARDHAN
Cluster Head Clinical / PV Country Quality Middle East / Africa / Turkey / India
Novartis

SEEMA PAI
Director Clinical Site Operations – India Cluster
Pfizer

QAYUM MUKADDAM
Head of MACR
Tech Observer

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

14:20 –Transforming the perceptions and approaches in clinical research

- What are the trends impacting clinical R&D and outsourcing?
- Technology accelerates new age clinical research
- The current scene for clinical research in India and globally.
- Are the regulations sufficient in Clinical Trials and what needs to be done?
- Remote clinical research – Risks and chances

14:50 – Afternoon Tea / Coffee

PATIENT SAFETY

15:10 – DISCUSSION WITH EXPERTS: Enhancing Patient centricity and patient safety

- Prioritising patients – Always placing patients first
- Leading the industry by engaging patients in every possible steps
- Meeting new patient expectations and building the expected personalized trial experience
- Educating stakeholders via patient stories
- Engagement with patients that emphasizes the value of trial participation
- How can positive patient engagement be optimized throughout the clinical development process?
- Bringing it all together to enhance the patient experience

Moderator:

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

Panellists:

PRATIK SHAH
VP - Medical Affairs
Bharat Serums and Vaccines

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

PRABHAT SINHA
Director Government & Public Affairs
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Head Medical Affairs
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DAY ONE - 23rd May 2023

INDRANIL PURKAIT
Senior General Manager - Medical Affairs
Ipca Laboratories

REGULATORY

16:00 – DISCUSSION WITH EXPERTS: Areas where regulatory changes would help in betterment of Clinical Trials in India

- Regulatory changes especially during covid, Is it better than the old system? What else can be done for improvisation
- Are the regulations sufficient towards Decentralisation and what needs to be done?
- Is the system reluctant to embrace Decentralisation?
- Delays in approval from regulatory agencies. What needs to be done?
- Protecting patients: Standardizing and streamlining the regulatory process

Moderator:

MILIND ANTANI
Leader, Pharma and Healthcare
Nishith Desai Associates

Panellists:

GOURI SHANKAR
Assistant Drugs Controller
CDSCO

RAHUL GUPTA
Senior Vice President, Regulatory Affairs
USV

YASMIN SHENOY
Director-Regulatory Affairs
Sanofi

SHIRAZ KANDAWALLA
Associate Director Regulatory Affairs
Ferring Pharmaceuticals

AMITA BHAVE
Head Regulatory Affairs
Novartis

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

17:00 - End of conference Day 01

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DAY TWO - 24th May 2023

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

09:30 – Clinical Research Environment in India: Challenges & Proposed Solutions-CRNI

- Challenges during clinical trials in India
- Infrastructure for conducting clinical trials in India-CRNI
- Proposed Solutions and Regulatory reforms

NIDHI SINGH
Director-Clinical Operations
Clinical Research Network India

OUTSOURCING / PARTNERSHIPS

10:10 – DISCUSSION WITH EXPERTS: Creating Effective Outsourcing Partnerships

- Creating value through innovative partnerships
- How good collaborations enable faster and more patient-centric trials?
- Learn how a smooth collaboration and data exchange ensures data-driven decisions
- R&D outsourcing – Key points to look out for
- Study planning, RFP management, strategic partner governance and category sourcing
- Learn how to strengthen vendor oversight (classic, remote, and decentralized)
- Reduce the overall cost of outsourcing execution – Steps to achieve the same

Moderator:

MUKESH KUMAR
Senior VP & Head, Clinical R&D
Cipla

Panellists:

HITENDRA NATH PANDEY
Associate Director – Statistics
Eli Lilly

MUKESH GORI
Associate Director - ESP Management PV Strategy & Operations
Novartis

GANESH KADHE
Country Lead & SLT Member, Scientific & Medical Affairs
Abbott

11:10 – Morning Coffee / Tea & Discussion

11:30 – Designing quality into Clinical Trials to optimise patient recruitment

- Challenges of the changing regulatory environment vs protocol and study design
- Capturing the patient perspective
- Lower risk of regulatory delay or rejection

12:00 – Solution Provider Presentation

For sponsorship opportunities please contact
info@virtueinsight.com

12:30 – Networking luncheon

IMPACT OF TECHNOLOGY

13:40 – DISCUSSION WITH EXPERTS: Impact of Digital Transformation - Digitizing Clinical Trials

- What are the key market trends and challenges driving opportunities
- Impact of COVID-19 on Clinical Trials – Role of technology
- COVID-19 as a catalyst for Digital Transformation
- Need for companies to adapt to digitalisation
- Some examples of transformational technologies put to use
- How should CT look like in the future?

Moderator:

KAMLESH PATEL
Head -Medical Affairs & Health Tech
Lupin

Panellists:

SANTOSH TAUR
Director Medical Affairs - Vaccines & Digital
Pfizer

ANIKET JOSHI
Associate Global Portfolio Delivery Director
Novartis

VAIBHAV AGARWAL
GM, Global Head- Digital
Shalina Healthcare

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DAY TWO - 24th May 2023

LESTTER CRUZ SERRANO
Head of Medical Affairs & Global Site Engagement Lead
Cognizant SIP

HIREN THAKKAR
Managing Director
Octalsoft

PRITI THAKOR
Head of Medical Affairs - Southern Asia
Johnson & Johnson

SEERA DILEEP RAJU
Senior Manager - ML & AI
MSD

14:30 – Challenges and opportunities in Rare disease registries in India – From a Medical affairs perspective

- Genesis of Rare Disease Registry in India
- Role of different stakeholders in rare disease registries
- Challenges in implementation of rare disease registries
- Maintaining rare disease registries over the long term
- Power of rare disease registries

RAJ KHIRASARIA
Medical & Diagnostics Lead, Rare diseases
Sanofi

LESSONS FROM COVID

15:00 – Lessons learnt from Covid-19 pandemic on conducting global Clinical Trials – Focusing on safety aspects

- The most impactful Clinical Trial changes that were put into place due to the pandemic?
- Which of these changes will/must outlast the pandemic? What regulatory changes are needed to ensure this happens?
- How does RWE and RWD facilitate clinical development
- Collection and use of public/patient data
- Have investigators/trial site personnel had sufficient input into these changes, if not, what needs to be done to help sites?
- Adapting risk mitigation strategies
- Medical evaluation of adverse events

Moderator:

VISHWAS SOVANI
Founder Director
Pharmawisdom

Panellists:

SANDESH SAWANT
VP Medical Affairs & Head - Clinical Trials
Cipla

MURTUZA BUGHEDIWALA
Global Trial Program Head
Novartis

HARSHAD KOTHAWADE
Head of Regulatory Management & Trade Compliance
Merck Group

SANKET NEWALE
Head Medical Affairs
Emcure Pharmaceuticals

SAKHARAM GARALE
Founder & CEO
RENOVARE Healthcare

16:00 – Afternoon Tea / Coffee and End of conference

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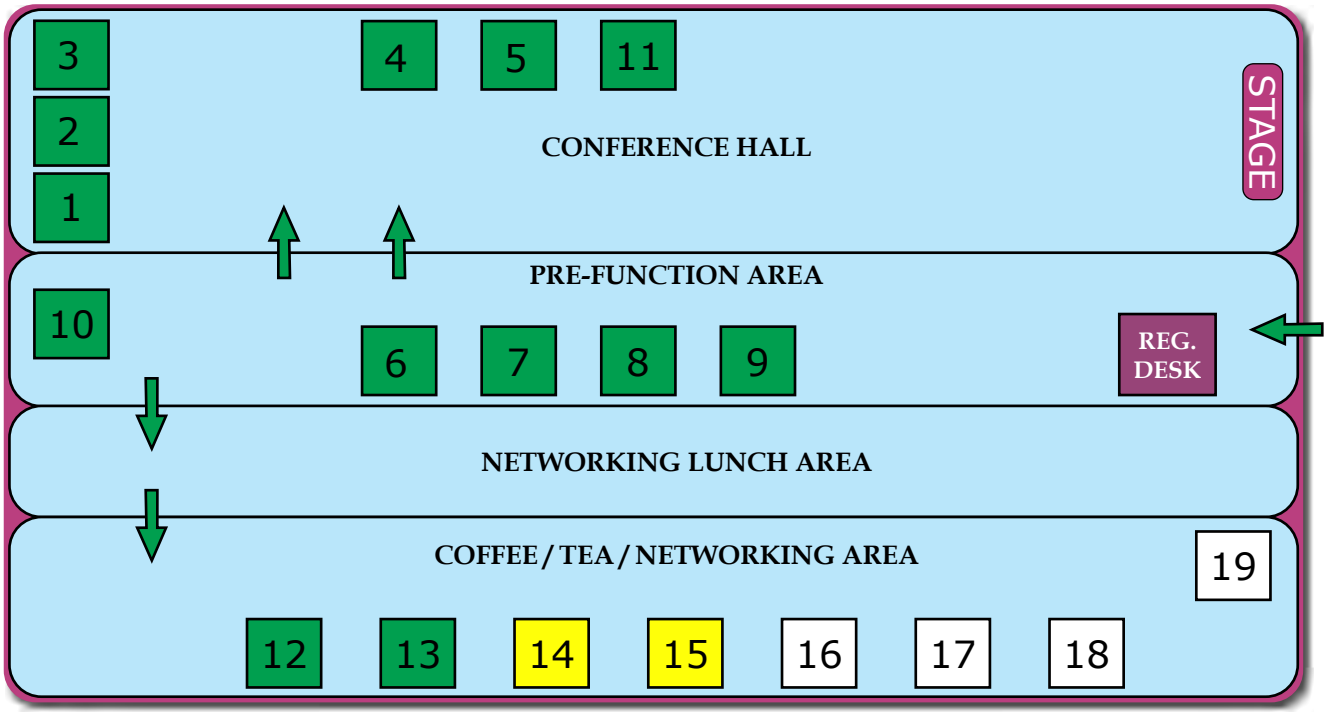
FLOOR PLAN - Book your stalls now before they run out !!!

Sold Blocked Vacant



1	cognizant	7	paradigmIT Clinical Trial Services	13	Neuberg Diagnostics
2	CLINPRO RESEARCH	8	ClinChoice	14	
3	CLINEVO Technologies	9	Clinion	15	
4	ancillarie	10	CRYOPDP a cryoport company	16	
5	TechObserver	11	CLINICAL RESEARCH NETWORK INDIA	17	
6	MEDCLINICA Accelerating Clinical Trials	12	Octalsoft	18	
				19	

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AGENDA AT A GLANCE

REGISTER ONLINE :

Link : https://www.townscript.com/e/14th-annual-clinical-trials-summit-2023-143130

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

REGISTRATION FORM

RESERVATION PRICING:

Early Bird Price (Valid Till 04th May 2023)

Cost per delegate - Fee: INR 15,000 + GST(18%)

Standard Price

Cost per delegate - Fee: INR 18,000 + 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:

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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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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.

VENUE

Kohinoor Continental Hotel

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

MAP & DIRECTIONS

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