KEY SPEAKERS INCLUDE:-

K. Bangaru Rajan, Dy. Drugs Controller (I) CDSCO, **DCGI**
Arun Bhatt, President, **Clininvent Research**
Bhaswat S. Chakraborty, Senior VP, R&D, **Cadila**
Richard Young, Vice President, EMEA, **Medidata (UK)**
Amit Arora, Head Medical Affairs, **Merck Serono**
Ashwani Pandita, Head Quality Management and Training, Global Clinical Research Operations, **Glenmark**
Kedar Suvarnapatrak, Head - Regulatory Affairs, **Boehringer Ingelheim**
Chirag Trivedi, Director & Head of Clinical Study Unit, **Sanofi Aventis**
Babita Kirodian, Head of Country Pharmacovigilance, **Bristol Myers Squibb**
Sunit Maity, AVP Product Development, **Theramyt Novobiologics**
Pratik Shah, Head- Clinical, Medical & Regulatory Affairs, PV and QA, **Astellas Pharma**
Jyotsna Patwardhan, Head Development QA, **Novartis**
Piyush Gupta, Associate Director, **GNH India**
Mazhar Maruf, Regional Head of Pharmacovigilance- Asia Pacific, **Glenmark**
Sujay Salvi, Head, Clinical Trial Supplies Management, **SIRO Clinpharm**
Chitra Bargaje, Consultant, **ADAMAS Consulting**
V.K. Sharma, Associate Vice President, **Unichem Laboratories**
Milind Antani, Head - Pharma LifeSciences, **Nishith Desai Associates**
Deepti Sanghavi, Senior Medical Writer-Medical Writing, **SIRO Clinpharm**
Vandana Jolad Shivangi, Director, **VIaTAL Pharma Consulting**

Plus Many More...
CONFERENCE INTRODUCTION:-

The International Registry of Clinical trials, the data bank maintained by the NIH in U.S. (clinical.trials.gov), has around 203,394 trials being carried out worldwide. As per this registry, the number of trials carried out in India is only 3043, which is <1.5 % of global trials. The Indian registry set up under the aegis of WHO and the Indian Council of Medical Research (ICMR) in 2008 which made registration of all trials mandatory from June 15th of 2009 also corroborates this number. Understandably > 40 % of all global trials are carried out in the U.S. China has registered 17198 trials (> 8%), substantially higher than India. The fear that there is an avalanche of trials moving out to India, risking our population to trial drugs is thus unfounded. As of now India is by no means a preferred hub for clinical trials, but the the potential to become one, in view of many favourable factors, such as state-of-the-art skills of investigators, level of quality healthcare institutions, the availability of patient populations with diverse genetic pools, language advantage and information technology based analytical tools.

The events of the last two years which severely affected the clinical trial scenario in India may have even consolidated and tightened the system to bring in more transparency and quality assurance which will enhance the credibility of Indian efforts in the area. What is required is a systematic, time bound regulatory evaluation and approval system for all phases of trials and better and transparent communication between the stake holders and the regulatory agency. Without new drugs discovery, much of the disease problems of the world will remain unattended and neglected. The new government, in one of its early policy statements had emphasized the need to encourage properly conducted clinical trials in India with appropriate regulatory controls. It is fervently hoped that realising the importance of this segment in New Drug Discovery Research, the concerned authorities will take a pragmatic view and through time bound and more diligent approval processes encourage clinical research.

6th annual clinical trials summit 2015 will examine the current issues faced in clinical trials operations, addressing the risks, timeline and budget stipulations, while effectively tackling key challenges in overcoming trials agreement and site contract arbitration problems. This summit will discuss the operational element of trial site management, strategic partnership with CROs and SMOs, patient, talent &investigators management in order to improve & optimize the overall drug development effectiveness and ROI. This conference will be shared by leading industrial practitioners across the region to promote practical discussions; especially on the know-how to manage needs, variability of different countries and institutions to enhance clinical operational excellence and vigilance. Attendees will have the chance to learn, network and benchmark against the global top pharma and local industry leaders on the best practices in talent, site, budget and performance management in clinical trials. The conference aims to provide a detailed analysis of what it takes to conduct clinical trials from a biopharmaceuticals and vaccines perspective in India and also addressing risk/benefit balance, anecdotal experiences of the multinational pharmaceutical industry in India and other parts of Asia, selection and role of CROs, logistics of operations, clinical trials management, government policies and pharmacovigilance. 6th annual clinical trials summit 2015 will provide you with the data that you need to recognize this complex and rapidly expanding sector. Knowing the future market, and what impacts will that has on future business opportunities? This is your opportunity to stay ahead by learning the latest trends and networking with the trendsetters.

It gives us immense pleasure in welcoming you to the 6th Annual Clinical Trials Summit 2015. I wish and pray that all our efforts will be beneficial to our industries and to our country at large.

KEY THEMES DISCUSSED AT THIS SUMMIT:-

Update yourself with respect to terms of legislation, policies, systems, technology, communication strategies and best practices

Determining the steps and strategies for enhancing quality in healthcare

Discovering the new trends in global clinical trials and their role in India

Technologies that drive efficiencies in global clinical trials

Strategies to conduct successful interventional oncology trials in India

Quality by design

Monitoring, managing and leading clinical trials: An integrated approach for better trial success

Maintaining proper balance in relationships: Sponsor – Site – CRO & Patients

Margin of safety: Identifying ideal clinical sites and strategizing patient recruitment and clinical sites management in India to develop appropriate clinical studies

Effectively incorporating GCP & GCPs – Knowing what TO-DO and what NOT TO-DO

Re-Thinking patient recruitment and patient experience

Finding the ideal partner in outsourcing your logistics operations in India how to identify smart packaging solutions to balance quality and costs

Identifying the decision criteria for partnering with the right vendors in Asia

How to manage risks in clinical trials effectively and how to successfully incorporate risk sharing models in clinical trials

Avoiding mistakes in data collection and ensuring profitability and to understand the long term operation strategies for managing clinical trials.

Overcoming challenges faced in regulatory approval processes – obtaining drug/ clinical supplies import and export licenses in Asia

Regulatory review at the drugs controller general of India (DCGI) and central drugs standard control organization (CDSCO): science, quality, and speed

Margin of safety: Identifying ideal clinical sites and strategizing patient recruitment and clinical sites management in India to develop appropriate clinical studies

Targeting the right patients in clinical trials

Effectively addressing risk/benefit balance

Next generation of clinical trials – How big will the market be?

Be part of a major networking opportunity

TARGET AUDIENCE-INDUSTRY:-

Pharmaceutical organisations, Generic pharmaceutical companies, Contract research organisations, Patient recruitment companies, Government- Department of health, Non-profit organisations/ Association, Consultants

WHO SHOULD ATTEND:-

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:-

6th Annual Clinical Trials Summit 2015 - “A critical guide for successfully conducting clinical trials” - 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 drinks time, meet the leading international vendors expand your knowledge of the latest business models and strategies in the high-level conference. Show casing the products of tomorrow in the co-located exhibition.
08:30 – Coffee and registration – An opportunity to meet and to network with your conference colleagues.

09:30 – Chairperson opening remarks

V.K. Sharma, Associate Vice President, Unichem Laboratories (https://www.linkedin.com/pub/v-k-sharma/23/ba/197)

09:40 – Indian Clinical Trials: Current challenges and future focus
- Evolving Indian Regulatory scenario
- Challenges to India’s potential in clinical research
- Focussing the future on fundamentals


10:10 – Clinical trial outsourcing: Concerns and guidelines
- Status of India in current global clinical research market
- Conducting clinical trials in India
- Latest guidelines & scrutinizing for investigators
- Possible remedies for Indian market to match regulatory guidelines
- How to improve quality assurance in Indian clinical research industry

10:40 – Morning Coffee/Tea & Discussion

11:00 – Keynote Panel Discussion: Challenges and Opportunities for now and future
- What are the current problems faced in today’s market and how to successfully overcome them in this highly competitive market?
- Which emerging markets are hottest today?
- Offshoring – Balancing the right opportunities and risks
- What makes each market unique and how do markets compare?
- Successful budget development & analysis - How do sponsors develop study budgets? How do sites price their services?
- Recruitment and retention of patients

Moderator:

V.K. Sharma, Associate Vice President, Unichem Laboratories (https://www.linkedin.com/pub/v-k-sharma/23/ba/197)

Panellists:

Bhaswat S. Chakraborty, Senior VP, R&D, Cadila (https://www.linkedin.com/pub/bhaswat-chakraborty/18/34/27)


Richard Young, Vice President, EMEA, Medidata (UK) (https://www.linkedin.com/pub/richard-young/4/29a/960)

11:40 – Risk based approach
- Onsite and remote monitoring approaches
- Recurrent risks and mitigation through monitoring
- Quality-by-design
- Risk management and risk minimization
- Risk minimization effectiveness measurement

Richard Young, Vice President, EMEA, Medidata (UK) (https://www.linkedin.com/pub/richard-young/4/29a/960)

12:10 – Busting Myths - Comparator sourcing from India
- Common myths, Common assumptions
- How sourcing mistakes escalate sourcing costs and delay trials
- Regulatory Facts for innovator registrations in India
- Take an informed decision - Based on facts
- Role of Specialized Comparator suppliers

Piyush Gupta, Associate Director, GNH India

12:40 - Networking luncheon - Take your discussions further & build new relationships in a relaxed & informal setting...

14:00 - Afternoon Keynote Panel Discussion - Maintaining proper balance in relationships: Sponsor – Site – CRO & Patients
- Four-way relationship between sponsors, sites, CROs & patients - Realistic expectations, clear communications, shared understandings, practical policies, and efficient problem resolution
- Quantitative analysis reveals rapid changes in the industry and trends for the future. How can sponsors, sites and CROs meet the challenges?
- Choosing a partner who can take necessary steps to rectify the situation when things go wrong
- Understanding sponsors principle for selecting the local clinical research organization
- Identifying the anticipated advantages of a collaborative clinical trial alliance for greater efficiency and cost reduction
- What are the current perspectives on the future of outsourcing in Asia?

Moderator:

Vandana Jolad Shivangi, Director, VIaTAL Pharma Consulting

Panellists:

Amit Arora, Head Medical Affairs, Merck Serono (https://www.linkedin.com/in/arora007)


Sujay Salvi, Head, Clinical Trial Supplies Management, SIRO Clinpharm (https://www.linkedin.com/pub/sujay-salvi/5/73b/82a)
15:20 – Afternoon Tea/Coffee

15:40 – Monitoring, managing and leading clinical trials: An integrated approach for better trial success

- Clinical research staff should understand the difference between tactile execution and strategic execution in clinical operations
- It is important to gain new insights into an integrated role which addresses many unmet needs of a clinical trial
- The ‘Next Generation Clinical Research Professionals’ should adapt to their new role by looking inside to face the outside
- Clinical trial success depends greatly on creating and nourishing a collaborative and learning culture in this new role

Moderator:

Deepthi Sanghavi, Senior Medical Writer-Medical Writing, SIRO Clinpharm (https://www.linkedin.com/pub/dr-deepthi-sanghavi/5/591/b76)

Chirag Trivedi, Director & Head of Clinical Study Unit, Sanofi Aventis (https://www.linkedin.com/pub/dr-chirag-trivedi/21/b0/344)

Pratik Shah, Head- Clinical, Medical & Regulatory Affairs, PV and QA, Astellas Pharma (https://www.linkedin.com/in/drpratikshah)

Jyotsna Patwardhan, Head Development QA, Novartis

Chitra Bargaje, Consultant, ADAMAS Consulting (https://www.linkedin.com/in/chitrabargaje)

16:10 – Panel Discussion: The developing regulatory framework in advanced and developing markets – for Today & Tomorrow

- Adapting to India’s transformed regulatory landscapes to conduct clinical trials
- A brief recap of recent regulatory developments. Ensuring you comply with market requirements
- What is to be learnt on how Indian companies can work in harmony with the RoW legal frameworks
- Effectively incorporating GCP & GCPs – Knowing what TO-DO and what NOT TO-DO

Moderator:

Milind Antani, Head - Pharma LifeSciences, Nishith Desai Associates (https://www.linkedin.com/in/milindantani)

K. Bangaru Rajan, Dy. Drugs Controller (I) CDSCO, DCGI

Mazhar Maruf, Regional Head of Pharmacovigilance- Asia Pacific, Glenmark (https://www.linkedin.com/pub/dr-mazhar-maruf/b/303/2b5)

Kedar Suvarnapathaki, Head - Regulatory Affairs, Boehringer Ingelheim (https://www.linkedin.com/in/kedar-suvarnapathaki/4/954/765)

Babita Kirodian, Head of Country Pharmacovigilance, Bristol Myers Squibb (https://www.linkedin.com/profile/view?id=37647503)
A 2020 Vision for Clinical Research In India

Led By: Workshop Leaders From Medidata Solutions, Cadila and more..

Timings: 09:00 - 10:00 Coffee & Registration
10:00 - 16:00 Workshop
Timing Includes Lunch and Refreshment Breaks

DAY 2 - 29th MAY 2015

Workshop Topics -

- An Indian Regulatory Update
- Interactive Medidata Demo - Medidata Platform
- RBM - Improving quality whilst reducing cost!
- Interactive Medidata Demo RBM

Workshop Leaders -

Kyle Davids, Regional Account Manager, Medidata Solutions (https://www.linkedin.com/pub/kyle-davids/6/83a/231)

Bhaswat S. Chakraborty, Senior VP, R&D, Cadila (https://www.linkedin.com/pub/bhaswat-chakraborty/18/34/27)

Andrew Gebbie, Senior Solution Specialist, Medidata Solutions (https://www.linkedin.com/pub/andrew-gebbie/33/a25/904)

Christopher Burke

ABOUT MEDIDATA -

We provide innovative clinical development solutions that safely and efficiently improve quality of life. We provide our customers with a competitive advantage by facilitating operational excellence in their clinical research processes:

- Eliminating redundant and error-prone processes,
- Fostering collaboration via dynamic information flow between traditional trial design, planning, execution and analysis silos
- Increasing study execution agility through insightful decision-making
- Maximizing value to sites and sponsors by supporting a best-in-class solution approach.

For more Information, visit: http://www.mdsol.com/

ABOUT VIRTUE INSIGHT -

Virtue Insight equips business professionals around the world with the latest in-depth industry knowledge and provides networking opportunities in the telecom, infrastructure and pharmaceutical industry. Our aim is to provide a platform to share knowledge and insight and provide our event attendees to network effectively and deliver maximum ROI by making 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 ROI by making new business alliances.

For more Information, visit: http://www.virtueinsight.com/

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6th Annual Clinical Trials Summit 2015

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3. Networking Luncheon
4. Conference Hall 3
5. Conference Hall 2
6. Conference Hall 1
7. Registration Desk

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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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Tel: 91 22 66919000 / 91 22 28209999

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