2nd INDIAN CANCER CONGRESS

8th – 12th November, 2017 I Clarks Convention Centre, Bengaluru, India

INSIGHT INNOVATION INTEGRATION

Hall 21 | Senate -II | 09 Nov 2017		
Duration	**Topic**	**Panelists/Speakers**
9:15am to 9:20 am	**Opening Remarks**	
First Session **ICH GCP (R2): AND ITS IMPACT ON HOW TRIALS WILL BE RUN NOW ON**		
9:20am to 9:35 am	Presentation on Overview and Objective of the Session: **Biggest Change in 20 years- ICH GCP E6 (R2) ITS IMPACT ON STAKEHOLDERS**	Ms. Mala Srivastava - Co-founder & Managing Partner, Nextvel Consulting LLP
9:35 am to 10:25 am	**PANEL DISCUSSION** How will R2 impact Global clinical trials Risk Based Monitoring Pros & Cons Auditor's Perspective	Moderator: Mala Srivastava • ***Dr. V G Somani-Joint Drugs Controller India, CDSCO*** • Dr. Harsha Doddihal-Medical Monitor Quintiles IMS • Dr. Sudheer Balaraju Head Clinical Operations India, Navitas Life Sciences Ltd. • Mr. Abby Abraham Co-founder & VP Clinical Solutions Algorics • Ms. Chandrika Arora CEO Qmatra • Mr. Krishnamurthy Rao COO BIOCAD
10:25 am to 10:35 am	Wrap-up and Key Takeaways from the Session	Dr. Sudheer Balaraju
10:35 AM 10:50 AM	**RECENT REGULATORY CHANGES TO BOOST CLINICAL RESEARCH IN INDIA**	**DR. VG SOMANI JT DCG(I) CDSCO INDIA**
Second Session **CHANGING LANDSCAPE OF CLINICAL RESEARCH REGULATIONS FROM 2009 to NOW**		
10:50 am to 11:10 am	Presentation: Overview of Changes in Indian Regulations governing Clinical Research in India from 2009 to now • ICF & AV Consenting • CT Inspections • Export and Import Biological Materials • SAE Reporting and Compensation for Clinical Trial related injury • Guidelines for Biosimilar • Role of Subject Expert Committees • Online Submissions • Handbook for Applicants and Reviewers Issued by ICMR & CDSCO	Dr. Saral Thangam- CEO & Managing Director Norwich Clinical Services, Bangalore
11:10 am to 11:55 am	**PANEL DISCUSSION** Compliance to Changing Regulations in Indian Clinical Regulations from 2009 onwards Which are aspects that have changed and how to ensure compliance	Moderator: Dr. Saral Thangam • ***Dr. V G Somani-Joint Drugs Controller India, CDSCO*** • Dr. Raju Chacko Oncologist, CMC Vellore • Dr. Kamal Saini, Medical Director Oncology – Covance, Belgium • Dr. Shenaz Khaleeli, Technical Director, PharmaLeaf

Conference Secretariat

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		• Dr. Jayasheel BG, Head - Pharmacovigilance & Regulatory Affairs at Alcon • Dr. Gaurav Mathur- Director Regulatory, QuintilesIMS
11:55 am to 12:05 pm	Wrap-up and Key Takeaways from the Session	Dr. Jayasheel BG
12:05 pm to 1:30pm ORATION- No parallel sessions		
LUNCH 1:30pm to 2:30pm		
Third Session **CHANGING REGULATION & RESEARCH ETHICS COMMITTEE OBLIGATIONS**		
2:30 pm to 2:45 pm	Presentation: Changing Regulation & Research Ethics Committee Obligations • Registration with CDSCO • Accreditation of ECs • Re-registration of ECs • Academic Clinical Trials • Inspections of Ethics Committees	Dr. Sandhya Ravi Consultant Clinical Research
2:45 pm to 3:00 pm	ICMR revised ethical guidelines to be issued highlights and changes	Dr. Roli Mathur, Scientist E, ICMR, Delhi
3:00 pm to 3:45 pm	**PANEL DISCUSSION** CR Regulations What Ethics Committee Members should know	Moderator: Dr. Sandhya Ravi • ***Dr. V G Somani-Joint Drugs Controller India, CDSCO*** • Dr. Roli Mathur, Scientist E, ICMR, Delhi • Dr. Denis Xavier, Professor and HOD, Pharmacology St Johns Research Institute • Dr. Usha Rani (NIMS), Professor & Head, Clinical Pharmacology and Therapeutics, NIMS • Dr. Surinder Kher: Head Research Triesta Sciences • Dr. Rajanna Sreedhara, (Nephrologist) & Member Independent Ethics Committee
3:45 pm to 4:00pm	Wrap-up and Key Takeaways from the Session	Dr. Denis Xavier
Fourth Session **CHALLENGES IN CONDUCTING ONCOLOGY STUDIES**		
4:00 pm to 4:20pm	Challenges of conducting Oncology Studies • Study Design and End Point Evaluation • Patient Recruitment • Patient Compliance & Retention • Study Conduct and Safety Reporting and Management • Role of Site Management Organizations	Dr. Surinder Kher Head Research Triesta Sciences

4:20pm to 5:10pm	**PANEL DISCUSSION** Practical Challenges with Oncology Clinical Trials and How to overcome them	Moderator Dr. Surinder Kher • Dr. Chetan Tamhankar, Head Clinical Development, Syngene International • Dr. Radhika Bobba, Regional Director PSI-CRO • Dr. Dhiraj Abhyankar, Director, Scientific Development Pharm-Olam • Dr. Ramesh Jagannathan Director and Head-Clinical Development, Global Clinical Management, Integrated Product Development Organization (IPDO) Dr. Reddy's Laboratories Ltd. • Dr. Sauren Das. Executive Director Excel Life Sciences Pvt. Ltd. NOIDA • Dr. AVS Suresh -Oncologist
5:10pm to 5:25 pm	Wrap-up and Key Takeaways from the Session	Dr. Dhiraj Abhyankar