INDIAN SOCIETY FOR CLINICAL RESEARCH

Organized by

South Chapter

ISCR AUTUMN CONFERENCE

on

"CLINICAL RESEARCH LANDSCAPE-POST 2020"

Day One Friday, 9 Oct 2020 (IST 2:00 to 6:00 PM)		***Day Two Saturday, 10 Oct 2020 (IST 4:00 to 8:00PM)***	
Track 1	***Clinical Trial Management***	***Track 3***	***Medical Writing, Pharmacovigilance & Real-World Evidence (RWE)***
Track 2	***Academia & Quality***	***Track 4***	***Data Management & Biostatistics***

Organizing Team

Dr. Gaurav Mathur (IQVIA)
Ms. Mala Srivastava (Nextvel)
Dr. Ramesh Jagannathan (ISCR-EC)
Mr. Rakesh Dadhania (Quinary)
Dr. Radhika Bobba (PSI-CRO)
Ms. Thanuja Naidu (Pharm-Olam)
Mr. Sachin Tonapi (Covance)
Ms. Swetha Khokale (Advarra)
Dr. Rajani Menon (Syneos Health)
Dr. Vijay Venkatraman (Oviya MedSafe)
Mr. Gaurab Chakraborty (Covance)
Dr. Poongothai (MDRF)
Ms. Anushila Vaishali (Eli Lilly)
Ms. Chandrika Arora (QMatra)
Ms. Lakshmi Achuta
Mr. Sanjay Kabra (Novotech)
Ms. Ami Shah (Speramed)
Mr. Abby Abraham (George Clinical)

Registration

Registration Fee: Rs 500/-

Students: Free

(Hurry Limited Seats!!!)

Sponsorship:

Rs 25,000/- per Sponsor

Track 1: Clinical Trial Management Track

Date October 9th, 2020, Friday

Time: 2:00 to 6:00 PM (IST)

	Time in IST	Topics	Speakers/Panel Members
DAY ONE TRACK 1	2:00 to 2:15PM	**Welcome and Introduction**	**Ms. Swetha Khokale** *(On behalf of ISCR South Chapter)* *Sr. Director – Business Operations Services* *Forte Research Systems, now part of Advarra.*
		Introduction to ISCR and South Chapter Activities	**Ms. Mala Srivastava** *Co-founder and Managing Partner* *Nextvel Consulting LLP*
	2:15 to 3:15 PM	**Vaccine Clinical Trials**	**Dr. Jerome Kim** *Director General* *International Institute of Vaccine* **Moderator: Dr. Radhika Bobba** *Regional Director, PSI CRO AG*
	3:15 to 3:20 PM	**Break**	
	3:20 to 4:00 PM	**Introducing the next talk and speaker**	**Mr. Sanjay Kabra** *Director, Global Services Center (India), Novotech*
		ISO 14155 (GCP for Medical Devices) Versus ICH GCP E6	**Mr. Sudhakar Mairpadi** *Head QA and Regulatory* *Philips India Limited*
		Conclusive Remarks on the talk and introducing the next speaker	**Mr. Sanjay Kabra** *Director, Global Services Center (India), Novotech*
	4:00 to 4:40 PM	**Leveraging Technology in the New Clinical Research Landscape**	**Mr. Jivan Achreja** *Chief Technology Officer, Advarra*
		Concluding the talk and announce the break	**Ms. Ami Shah** *Director and Co-founder* *SperaMed Consulting*
	4:40 to 4:45 PM	**Break**	
	4:45 to 5:45 PM	**Introducing Panel Discussion and Moderator**	**Ms. Ami Shah** *Director and Co-founder* *SperaMed Consulting*

		Panel Discussion **Stakeholder Perspectives: Clinical Trial Practices Rebooting -The Global Pandemic Impact** **(5 stakeholders to speak for 10 mins each (50 mins) followed by 10 mins of panel discussion and 10 mins of Q&A.**	**Moderator** **Mr. Abby Abraham** *Global Head, Data Sciences & Country Head- India, George Clinical* **Representing Ethics Committee:** **Dr. Ananya Chakraborty** *HOD, Pharmacology* *VIMS, Bangalore* **Representing Sponsor** **Mr. Sivakumar Vaidyanathan** *General Manager/ Therapeutic Area Lead Biocon Biologics* **Representing Site Principal Investigator** **Dr. Chirag Desai** *Chief Consultant & Program Director, Apollo Hospital, Ahmedabad.* **Representing** **Regulatory Affairs (Corporate)** **Ms. Smriti Bhat** *Manager Regulatory Affairs and Patient Safety* **Regulator (CDSCO):** *TBD*
	5:45 to 6:00PM	**Wrap-up and Vote of Thanks**	**Mr. Sanjay Kabra** *Director, Global Services Center (India), Novotech* **Ms. Swetha Khokale** *Sr. Director – Business Operations Services* *Forte Research Systems, now part of Advarra*

Track 2: Academia and Quality Assurance

Date October 9th, 2020, Friday

Time: 2:00 to 6:00 PM (IST)

DAY ONE TRACK 2	Time in IST	Topic	Speakers /Panel Members
	2:00 to 2:15PM	Inauguration Welcome About ISCR Introduction of Speaker	**Ms. Chandrika Arora** *Founder & CEO, Qmatra* **Mr. Rakesh Dadhania** *Executive Director Quinary Clinical Research*
	2:15 to 3:00 PM	Academic Topic: Challenges of Managing Multiple Stakeholders at Research Site in the Current Pandemic	**Ms. Priyadarshini Arambam** *General Manager, Academics & Research Department, Batra Hospital & Medical Research Centre, New Delhi*
		Wrap Up	**Mr. Rakesh Dadhania** *Executive Director Quinary Clinical Research*
	3:00 to 3:50 PM	Introducing the Speaker	**Ms. Lakshmi Achuta** *Strategic Advisor-Biotech, Pharmaceuticals & Medical Devices*
		Application of AI and Data Analytics in Clinical Quality	**Mr. Raghunandan Mishra** *Senior Product Manager, AI Innovation, Data Foundry*
		Wrap up	**Ms. Lakshmi Achuta** *Strategic Advisor-Biotech, Pharmaceuticals & Medical Devices*
	3:50 to 3:55PM	Break	
	3:55 to 4:40 PM	Introducing the speaker	**Ms. Chandrika Arora** *Founder & CEO, Qmatra*
		GDPR and its impact on the Conduct of Clinical Trials	**Ms. Susan Trainor** *CEO, Trainor & Partners*
		Wrap up and Introducing the next Speaker	**Ms. Chandrika Arora** *Founder & CEO, Qmatra*
	4:40 to 5:15 PM	Data Integrity in Clinical Trials	**Ms. Lakshmi Achuta** *Strategic Advisor-Biotech, Pharmaceuticals & Medical Devices*
		Wrap up	**Ms. Chandrika Arora** *Founder & CEO, Qmatra*
	5:15 to 5:20 PM	Break	
	5:20 to 6:00 PM	Introduction of Panelists /Moderator	**Ms Lakshmi Achuta**

			Strategic Advisor-Biotech, Pharmaceuticals & Medical Devices
		Panel Discussion **Stakeholders perspective: Remote Audits: Conduct and Management**	**Moderator Ms. Chandrika Arora,** *Founder & CEO, Qmatra* **Panellists:** **Mr. Ajit Simh** *President, Shiba Biotechnology Inc* **Ms. Susan Trainor** *CEO, Trainor & Partners* **Dr. Thuppil Venkatesh** *CEO & Director, Foundation for Quality India* **Dr. Moorthy** *Head, GCP QA, Syngene International Ltd* **Dr. Anvita Pandiya** *Site Quality Head, Hyderabad; Global head CQA DU Global Health, Novartis*
		Vote of Thanks	**Ms. Chandrika Arora** *Founder & CEO, Qmatra*

Track 3: Medical Writing and Pharmacovigilance & Real-World Evidence (RWE)

Date October 10th, 2020, Saturday

Time: 4:00 to 8:30 PM (IST)

MEDICAL WRITING 4:00 to 6:00 PM (IST)

DAY TWO TRACK 3	Time in IST	Topic	Speaker (s) / Panel members
	4:00 to 4:05 PM	**Introduction**	**Anushila Vaishali**
	4:05 to 4:45 PM	**Writing Clinical Trial Documents in The Post-Pandemic Time: Perspective from Protocol and Clinical Study Report (CSR)** • **What changed in protocol writing: impact, changes/updates, how to manage (15 min)** • **Managing a study report post pandemic: impact on trial, changes to the study**	**Protocol: Sunil Modali** *Clinical Development Medical Director, Novartis* **CSR: Teresa Armstrong** *Advisor-Submissions and Transparency, Global Scientific Communications (Eli Lilly, US)*

		report, how to handle the changes (15 min) • **Q&A (15 min)**	
	4:45 to 5:30 PM	**Writing a Vaccine Dossier: Especially in a Fast Track Mode** • **Planning for a vaccine dossier preparation** • **COVID19, its impact on vaccine trials and submission Q&A (10 min)**	**Albertina Fannelli** *Head, Scientific Communications, GSK, Italy* **Nivedita Sahoo** *Scientific Communications, GSK Vaccines, India*
	5:30 to 5:35 PM	**Break**	
	5:35 to 6:00 PM	**Panel discussion** **Medical Writers Embracing the Virtual Mode of Working: Managing the Changes While Maintaining Quality and Consistency in Documents**	**Chair: Dr. Rajesh Kher, Ms. Anushila Vaishali** **Panel: All the Speakers**
BREAK – 30 minutes			

PHARMACOVIGILANCE & REAL-WORLD EVIDENCE 6:30 to 8:30 PM (IST)

	Time in IST	Topic	Speaker (s) / Panel members
DAY TWO TRACK 3	**6:30 to 6:35 PM**	**Introduction and Context Setting**	**Dr. Ramesh Jagannathan** *VP, Medical Affairs, Bharat Serums and Vaccines Ltd., Navi Mumbai* **Dr. Vijay Venkataraman** *Managing Director & CEO, Oviya MedSafe*
	6:35 to 6:55 PM	**Role of Artificial Intelligence in improving efficiency of Life Cycle PV**	**Dr. Mahesh Kumar** *Senior Director & Client Partner – Strategic Accounts, Aris Global Darmstadt, Germany*

	6:55 to 7:35 PM	**Panel Discussion: Challenges in SAE Submissions in the Current Scenario**	**Moderator:** **Dr. P S Karthik Babu** *[Multi Country Safety Head (South Asia), Sanofi & Chair – ISCR PV Council]* **Panelists:** **Dr. Pingali Usharani** *(Ethics Committee) – Prof. & HOD, Clinical Pharmacology & Therapeutics, NIMS, Hyderabad* **Dr. Srikanth Krishnamurthy** *(Investigator) – Consultant Pulmonologist, Hindusthan Hospital, Coimbatore* **Dr. Jamal Baig** *(Industry) – Associate Director-Drug Safety, MSD & Co-Chair of ISCR PV Council*
	7:35 to 8:00 PM	**RWE: Key considerations for studies to generate data on safety and effectiveness of Medicinal products**	**Dr. Deepa Chodankar** *Sr. Medical Advisor Sanofi, Mumbai*
	8:00 to 8:30 PM	**Impact of RWE on Physician's choice of treatment options for optimal patients' outcomes: Focus on Safety and** **Quality of Life**	**Dr. L. Sreenivasa Murthy** *Senior Consultant Physician & Diabetologist* *Lifecare Hospital & Research Centre Bengaluru*

Track 4: Data Management & Biostatistics

Date October 10th, 2020, Saturday

Time: 4:00 to 8:00 PM (IST)

DAY TWO TRACK 4	Time in IST	Topics	Speaker (s) / Panel members
	4:00 to 4:45 PM	**How Is Artificial Intelligence and Machine Learning Changing the Data Management World?**	**Prasanna Rao** *Head, Artificial Intelligence and Data Science, Pfizer*
	4:45 to 5:30 PM	**Decentralized Clinical Trials in The Post COVID-19 World**	**Michelle Longmire** *Physician and CEO at Medable Inc, USA*
	5:30 to 6:15 PM	**Improving Prediction of Overall Survival Using Joint Modelling Approach**	**Arkendu Chatterjee** *Associate Director, Biostatistics, BMS, USA*
	6:15 to 7:00 PM	**Role of Public-Private partnerships in COVID Vaccine Development**	**Lehar Zaidi** *Associate Director, Biostatistics, IQVIA*
	7:00 to 8:00 PM	**A Check on the CDISC Interim User Guide on COVID-19**	**Sumeet Subhedar** *Principal Statistical Programmer*, *Covance*