13th Annual Conference
Beyond New Regulations- Increasing Participation and Enhancing Patient Safety
January 24-25, 2020, Mumbai

Pre-Conference Workshop – Real World Evidence in Healthcare
23-Jan-2020

Speakers Profile
Mr. Mahendra Kumar Rai
Head, Real World Insights Solution, IQVIA South Asia

- Mahendra leads the Real World Insights vertical for IQVIA for South Asia and has experience in Health Economics and Real World Evidence Analytics
- Mahendra has around 14 years of experience in outcomes research, health economics, real world insights (observational & clinical research) spanning across the healthcare spectrum covering pharmaceuticals, medical devices, diagnostics and OTC categories
- Mahendra has worked with leading Healthcare Consulting Agencies, handling a range of categories and has worked on a range of Outcomes Research requirements across different aspects of Business and Marketing
- His area of expertise is Outcomes research, Health economics, Real world Insights & Observational research
- Publications in peer-reviewed international journals
- M. Pharm from University of Delhi
- Health Technology Assessment (Certificate Course) – University of Sheffield, UK
- Statistics in Medicine (Certificate Course), Stanford University, US
- Writing in Sciences (Certificate Course), Stanford University, US
Ms. Amita Bhave
Head, Regulatory Affairs
Novartis India

• Amita Bhave, is Head of Regulatory Affairs, Global Drug Development India and is working with Novartis for more than 10 years. She had earlier handled added responsibility as Head Regulatory Affairs Business Operations Excellence of Novartis Hyderabad office serving AMAC/LACan countries.

• Amita has overall 20+ years’ experience in Indian Pharma industry in past companies such as Solavy Pharmaceuticals, Bristol Myers Squibb in multiple domains of Medical support, Clinical Operations, Regulatory Affairs.

• Amita has a huge experience of handling New drug applications, Import registrations, clinical trial applications and is instrumental in designing robust regulatory strategy for Novartis pipeline products.

• Amita is well connected in Indian pharma industry and Indian regulators’ office. She is an active member of Associations like OPPI in Medical- regulatory committee and is co-chair of ISCR regulatory council. She is also on editorial board of peer reviewed journal named Perspectives in Clinical Research (PICR) and has various publications in well reputed journals. Amita has been guest invitee as speaker/panelists in Industry forums.

• Amita has been honorary faculty at NMIMS University, Mumbai. She delivers guest lectures on Regulatory Affairs subject for curriculum of Executive MBA in Pharma Management.
Manju Sengar [MD (Medicine), DM (Medical Oncology)] is Professor, Adult hematolymphoid disease management group, Medical Oncology at the Tata Memorial Hospital, Mumbai. Dr Sengar completed her training in Medical Oncology from All India Institute of Medical Sciences, New Delhi. She has done her post graduate diploma in clinical trials from London School of hygiene and tropical medicine (external programme). She is an ACORD alumnus. She is a recipient of American Society of Hematology visitor training program fellowship at Duke University, Durham. Her main areas of clinical research are non Hodgkin lymphomas in HIV/AIDS and adult acute lymphoblastic leukemia. She is the principal investigator for several investigator-initiated studies. She is the core group member of National Cancer Grid.
Dr. Kavitha Rajasekar is a Senior Scientist at Department of Health Research, Ministry of Health and Family Welfare, Government of India.

She holds a MSc, MPhil, PhD in Biochemistry and Molecular Biology from the University of Madras, India. Kavitha has to her credit diploma courses in Health Technology Assessment from University of Sheffield. She has almost 21 years of experience in teaching, research and administrative positions.

Dr. Kavitha is Coordinating the Health Technology Assessment in India under Department of Health Research, India.

She has also been a part of the team that has drafted the Surrogacy Regulation Bill 2017 under the Ministry of Health and Family Welfare.

Dr. Kavitha is a part of many Technical Committees. She is also coordinating the National Costing Study for Health care services in India.
Dr. Arun Bhatt
Consultant,
Clinical Research & Drug Development

- Dr Bhatt has extensive experience of over three decades in the Indian pharmaceutical industry in clinical research, drug development, and regulatory affairs. He has managed clinical development of novel molecular entities in diverse therapeutic areas in all clinical development phases.

- Dr Bhatt has worked as a consultant in pharmaceutical medicine and clinical pharmacology. His past positions held include President, Clininvent Research Private Limited – a CRO, CEO of CMI (India) Private Limited and Medical Director of Novartis India Limited.

- Dr Bhatt has been active in industry associations and was earlier the President of Indian Society for Clinical Research (ISCR). He is Editor-in-Chief of Perspectives in Clinical Research – the journal of ISCR.

- In 2009, the Institute of Clinical Research UK nominated Dr Bhatt for the Honorary Fellowship of Institute of Clinical Research.

- Dr Bhatt is the recipient of Drug Information Association Outstanding Service award 2012 for his immense contributions in his field of specialization.

- Dr Bhatt was awarded ISCR Special Award 2017 for Notable Contribution to Clinical Research Fraternity in India.

- Dr Bhatt delivered the prestigious Prof U K Sheth Oration in 2013.

- Dr Bhatt is a qualified assessor for NABH Accreditation for Clinical Trials – sites, investigators and Ethics Committees.

- Dr Bhatt has more than 150 publications in national and international journals. He runs a regular monthly column on “Good Clinical Practice – Question Answers” and has published a book “Clinical Trials and “Good Clinical Practice in India – Questions and Answers”.
Madhur Garg is Director, Real World Evidence and Market Access at Covance.

Madhur has worked across global and regional roles in the pharmaceutical industry. He is a market access and pricing strategist with health economics and outcomes research background. His career has spanned across Europe and Asia working for various life science companies (including J&J, Lundbeck & LEO Pharma). He possesses experience with all major payers and health technology assessment (HTA) bodies across Europe, North America, Middle East and Asia Pacific.

Madhur holds a Master’s in Medical Sciences (specialization in global health, health economics) from Karolinska Institutet, Stockholm and Master’s in Health Administration from Tata Institute of Social Sciences, Mumbai.

He serves as a board of studies member at Manipal University and is an adjunct faculty for health economics. He is a speaker/ faculty for HEOR, MA & RWE at various forums and peer reviewer for journals.

He continues to be an active learner esp. in data analytics/ HEOR/ RWE and completed an executive course in advanced Big Data Analytics from IIM- Ahmedabad in 2019.
Prof. Manjunath
Advanced Centre for Treatment, Research and Education in Cancer, Tata Memorial Hospital

• Dr. Manjunath **MD,DM**, is Assistant Professor at Dept. of Clinical Pharmacology, ACTREC, Tata Memorial Hospital,

• He is a Clinical Pharmacologist working as Scientific Officer E in Tata Memorial Centre, Mumbai.

• Dr. Manjunath completed Super-specialization in Clinical Pharmacology from Nizams Institute of Medical Sciences, Hyderabad.

• He is currently involved in the Pharma sponsored early phase clinical trials, bioequivalence trials. Investigator initiated research areas include Quality of Life studies in cancer patients, dose optimization of anti-cancer drugs, drug re-purposing studies, rational prescription of drugs in ICU.

• Dr. manjunath is actively involved in the quality management of the department for achieving NABL accreditation.
Denny John works as Evidence Synthesis Specialist, Campbell South Asia, New Delhi. His research interests lie in the field of evidence synthesis, health technology assessment, health economics and health financing. He has deep interest in building capacity of researchers, practitioners and policy makers on the conduct and use of evidence, and has conducted workshops in Ghana, India, Nepal, and Scotland. He is Advisory Member, Disability Coordinating Group, Campbell Collaboration; and Co-Chair, Early Career Network, Health Technology Assessment International (HTAi). He is also on international working groups related to nutrition economics, public health HTA, and public and patient engagement in HTA in LMICs. He is an Associate Editor with Cost Effectiveness and Resource Allocation, International Journal of Technology Assessment in Health Care (IJTAHC), and BMC Public Health journals. He is attached as Adjunct Scientist with National Institute of Medical Statistics (NIMS), Indian Council of Medical Research (ICMR), New Delhi.
Dr. Vinay Rajan
Regional Clinical Leader of Indian Subcontinent region in the Corporate Clinical Affairs division of Medtronic.

Dr. Vinay Rajan is a Regional Clinical Leader of Indian Subcontinent region in the Corporate Clinical Affairs division of Medtronic.

In this role Vinay is responsible for clinical and economic outcome evidence generation and dissemination in partnership with leading academic Institutes and Physicians to support evidence-based medicine and improve patient access to lifesaving Medical device therapies.

Since joining Medtronic in 2009, Vinay has been leading Medical Device Research & Development and Clinical projects on various disease conditions. With more than 15 years’ experience in Medical device R&D Vinay has published more than 30 articles and abstracts and 6 issued patents. Vinay has his Master of Science Degree in Laser Physics from Pondicherry Central University, India; Ph.D in Biophysical Engineering from University of Twente, the Netherlands and Post-doctoral fellowship from Erasmus Medical Center, the Netherlands.