

Challenges in Clinical Research: The Global Landscape

Venue: Prof.Rustom Choksi Auditorium, Tata Memorial Centre, Mumbai

Date: 7 – 8th November 2014

Organisers: Tata Memorial Centre & AAHRPP

Day 1 (November 7, Friday)

Prof.RustomChoksi Auditorium			
Time (mins)	Topic	Speaker	Chairperson/ Moderator
08.00 – 08.45 (45)	Registration		
08.45 – 09.00 (15)	Welcome	RA Badwe , Director, Tata Memorial Centre	
	Overview of Scientific Program	S Laskar , Prof. of Radiation Oncology Member Secretary, TMH IEC-II	
09.00 – 09.25 (20+5)	Talk 1 Clinical Research: The Need & Challenges	RA Badwe , Director, Tata Memorial Centre	Rita Mulherkar , Chairperson IEC, ACTREC
09.25 – 09.50 (20+5)	Talk 2 Overview of Accreditation	Elyse I. Summers , President & CEO, AAHRPP, US	
09.50 – 10.40 (60)	Panel Discussion 1 Perspectives on Regulatory Issues in Clinical Research	Vasantha Mutthuswamy , Senior Deputy Director General (retd.) ICMR; CS Pramesh , Prof. of Thoracic Surgery, TMH; G N Singh , CDSCO; Arun Bhatt , President Clininvent; Yali Cong , Associate Professor, Department of Medical Ethics, Peking University Health Science Center, China	JV Divatia , Prof. & Head of Anesthesiology & Critical Care, TMH
10.40 – 11.00 (20)	Tea/Coffee- Networking Break		
11.00 – 11.30 (30)	Keynote 1 The Helsinki Declaration: Its Evolution	Jeffrey Wendel , President/CEO Chesapeake IRB, US	Tapan Saikia , Chair Person IEC, TMH
11.30 – 11.55 (20+5)	Talk 3 Capacity Building for Ethical Review & Conduct of Biomedical Research	Xiuqin Wang , Secretary & Permanent member IRB, The First Affiliated Hospital of Nanjing Medical University (Jiangsu Province Hospital), China	
11.55 – 12.20 (20+5)	Talk 4 Evolution of Regulatory Guidelines & Implications on Ethical Research in India	Urmila Thatte , Prof. & Head of Clinical Pharmacology, KEM Hospital; Chairperson, TMH IEC-II	
12.20 – 13.00 (40)	Panel Discussion 2 Compensation for Research Related Injuries	Vani Parmar , Prof. Of Surgical Oncology, Ethics Committee Member, TMH Regulator: TBC Viraj Suvarna , Medical Director, Boehringer Ingelheim; Rachna Bhardwaj , Advocate; Vikram Singh , National Insurance Company; Ian Chen , National Taiwan University Hospital, Taiwan	CS Pramesh , Prof. of Thoracic Surgery, TMH
13.00 – 14.00 (60)	Lunch		
14.00 – 14.30 (15x2)	Talk 5 Accreditation: The Only Way Ahead for Ethical & Efficient Clinical Research	Ian Chen , National Taiwan University Hospital, Taiwan	B B Singh , Ethics Committee Member ACTREC
14.30 – 14.55 (20+5)	Talk 6 Informed Consent Document: What is Ideal?	Anil Sharma , CEO and Medical Director, IRB Company Inc. and Professor at UCLA, US	

14.55 – 15.20 (20+5)	Talk 7 Protecting Vulnerable Population	Nithya Gogtay , Asso. Prof. of Clinical Pharmacology, KEM Hospital; Member, TMC IEC-I	B B Singh , Ethics Committee Member ACTREC
15.20 – 15.55 (20+5)	Talk 8 Human Research: Opportunities & Challenges for a Global Multinational	John Oidtman , Vice-President, Clinical Trial Support and Compliance, Pfizer Inc., US	
15.55 – 16.15 (20)	Tea/Coffee- Networking Break		
16.15 – 16.40 (20+5)	Talk 9 Preserving Research Integrity & Protecting Human Participants: The Need to Address Institutional and Individual Financial Conflict of Interest	Marjorie Speers , Ex CEO AAHRPP, Independent Consultant of HRPP, US	Urmila Thatte , Prof. & Head of Clinical Pharmacology, KEM Hospital Chairperson, TMH IEC;
16.40 – 17.20 (40)	Panel Discussion 3 Managing Conflict of Interest In Clinical Trials	Sudeep Gupta , Deputy director, ACTREC; Nithya Gogtay , Asso. Prof. of Clinical Pharmacology, KEM Hospital; Member, TMC IEC-I Marjorie Speers , Ex CEO AAHRPP, Independent Consultant of HRPP, US; Xiuqin Wang , Secretary & Permanent member IRB, The First Affiliated Hospital of Nanjing Medical University (Jiangsu Province Hospital), China; Rachna Bhardwaj , Advocate	Siddhartha Laskar , Prof. of Radiation Oncology Member Secretary, TMC-IEC-II

Dinner Symposium: “Preparing for Accreditation (AAHRPP)”**Time: 19.00 – 21.00****Day 2 (November 8, Saturday)**

Prof. Rustom Choksi Auditorium			
Time (mins)	Topic	Speaker	Chairperson/ Moderator
08.00 – 09.00 (60)	Registration		
09.00 – 09.25 (20+5)	Talk 10 Ethical/ Regulatory Issues with Research involving Medical Devices	Sanjay Mittal , Director- Clinical Cardiology and Research, Medanta	George K , Asst Prof Surgery & Member Secretary IEC, TMH
09.25 – 09.50 (20+5)	Talk 11 Ethical/ Regulatory Issues with Bio-repositories	Nandini Kumar , Deputy Director General of IMCR (Retd.)	
09.50 – 10.15 (20+5)	Talk 12 Biomedical & Health Research Regulations: The Road Ahead	Roli Mathur , Scientist, ICMR	
10.15 – 10.45 (20)	Talk 13 Comparative Effectiveness Research & Investigational New Drug Trials: Do we need different regulations?	Yali Cong , Associate Professor, Department of Medical Ethics, Peking University Health Science Center, Peking, China	
10.40 – 11.00 (20)	Tea/Coffee- Networking Break		
11.00 – 11.30 (30)	Keynote 2 Research in India: Where do we stand?	Vasantha Mutthuswamy , Senior Deputy Director General (retd.) ICMR	Priya Ranganathan , Assoc. Prof. Anaesthesiology & Ethics Committee Member, TMH/ N Gogtay

11.30 – 11.55 (20+5)	Talk 14 Protecting Patients in Clinical trials: Regulators Perspective	Sudhakar Bangera , <i>Clinical Development Services Agency (CDSA)</i>	
11.55 – 12.20 (20+5)	Talk 15 Improving IRB Review of Community Based Clinical Research	Cristina Torres , <i>FERCAP Adviser</i>	
12.20 – 13.00 (40)	Panel Discussion 4 Investigational New Drug: Definitions & Interpretations	IEC: K Prabhash , <i>Medical Oncologist, TMH;</i> Academia: B Sirohi; GN Singh , <i>DCGI;</i> Rachna Bharadwaj , <i>Advocate;</i>	Vikram Gota , <i>Asst. Prof, Clinical Pharmacology, ACTREC</i>
13.00 – 14.00 (60)	Lunch		
14.00 – 14.25 (20+5)	Talk 16 Clinical Research, Human Rights, & Medical Ethics: Striking the Right Balance	Amar Jesani , <i>Independent consultant & researcher in Bioethics</i>	Medha Joshi , <i>Head of Dept. Of Library Science</i>
14.25 – 14.50 (30)	Panel Discussion 5 Impact of Clinical Trial Regulation on Site Selection	Atul Chaudhary , <i>Clinical Operation Head, Novartis;</i> Manish Shah , <i>General Manager, Clinical Operations, Wockhardt;</i> Gayatri Jaiswal , <i>Sr. Clinical Project Leader, Sanofi;</i> Vikas Sharma , <i>Chief Medical Officer, India, Quintiles;</i> Jaideep Gogtay , <i>Head, Medical Services, Cipla</i>	Sadhna Joglekar , <i>Vice President, Medical & Clinical Research, GSK</i>
14.50 – 15.15 (20+5)	Talk 17 Handling Non-compliance & Unanticipated Problems	Pratibha Pereira , <i>HRPP consultant</i>	Ali Asgar Moyadi , <i>Asso. Prof. Neurosurgery & Member Secretary IEC, ACTREC</i>
15.15 – 16.00 (7x4)	Presentation by Accredited Institutes	Nagendra Swamy , <i>President & Chairman, Quality Council, Manipal Health Enterprises, Bangalore;</i> K L Bairy , <i>Director, Manipal Centre for Clinical Research, Manipal University;</i> Pathik Divate , <i>CEO, Jehangir Clinical Development Centre, Pune ;</i> Deepa Divekar , <i>Medical Director, Sahyadri Speciality Hospital, Pune;</i> Tata Memorial Hospital(TBC)	Elyse I. Summers , <i>CEO AAHRPP</i>
16.00 – 16.15 (15)	Tea/Coffee- Networking Break		
16.15 – 17.15 (60)	Open Forum (Audience questions to experts from Academia/Regulators/Industry/Patient Representative/NGO)	RA Badwe , <i>Director, TMC;</i> G N Singh , <i>CDSCO;</i> John Oidtman , <i>Vice-President, Clinical Trial Support and Compliance, Pfizer Inc. US;</i> Urmila Thatte , <i>Prof. & Head of Clinical Pharmacology, KEM Hospital Chairperson, TMH IEC;</i> Vandana Gupta , <i>V Care (NGO);</i> Elyse Summers , <i>President & CEO AAHRPP, US ;</i> Patient Rep: _____	Sudeep Gupta , <i>Deputy Director ACTREC</i>
17.15 – 17.30 (15)	Valedictory Function & Closing Remarks		