**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 *(Association for the Accreditation of Human Research Protection Programs, Inc.)*

***Day 1 (November 7, Friday)***

| **Prof. Rustom Choksi Auditorium (Hall A)** | | | |
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| **Time (mins)** | **Topic** | **Speaker** | **Chairperson/ Moderator** |
| 08.00 – 08.45 (45) | Registration | | |
| 08.45 – 09.00 (15) | Welcome | **Anil K D'Cruz,** *Director, Tata Memorial Hospital*; **Sudeep Gupta,** *Deputy director, ACTREC* | |
| | Overview of Scientific Program | **Siddhartha Laskar**, *Prof. of Radiation Oncology Member Secretary, TMH IEC* | |
| 09.00 – 09.25 (20+5) | **Talk 1**<br>Clinical Research: The Need & Challenges | **Anil K D'Cruz,** *Director, Tata Memorial Hospital*; **Sudeep Gupta,** *Deputy director, ACTREC* | **Tapan Saikia**, *IEC Chaiperson, TMH* |
| 09.25 – 09.50 (20+5) | **Talk 2**<br>Overview of Accreditation | **Elyse I. Summers**, *President & CEO, AAHRPP, US* | **Vinay Deshmane**, *IEC Co-Chair, TMH* |
| 09.50 – 10.40 (60) | **Panel Discussion 1**<br>Perspectives on Regulatory Issues in Clinical Research | **Vasantha Mutthuswamy** - *Senior Deputy Director General (retd.) ICMR;*<br>**CS Pramesh**, *Prof. of Thoracic Surgery, TMH*;<br>**A Visala**, *CDSCO*;<br>**Arun Bhatt**, *President Clininvent*;<br>**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 and Coffee - Networking Break** | | |
| 11.00 – 11.30 (30) | **Keynote 1**<br>The Helsinki Declaration: Its Evolution | **Jeffrey Wendel**, *President/CEO Chesapeake IRB, US* | |
| 11.30 – 11.55 (20+5) | **Talk 3**<br>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**<br>Evolution of Regulatory Guidelines & Implications on Ethical Research in India | **Urmila Thatte**, *Prof.& Head of Clinical Pharmacology, KEM Hospital Chairperson, TMH IEC* | |
| 12.20 – 13.00 (40) | **Panel Discussion 2**<br>Compensation for Research Related Injuries | **Vani Parmar**, *Prof. of Surgical Oncology, TMH;*<br>**A Visala**, *CDSCO*;<br>**Rachna Bhardwaj**, *Advocate*;<br>**Vikram Singh**, *National Insurance Company*;<br>**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**<br>Accreditation: The Only Way Ahead for Ethical & Efficient Clinical Research | **Ian Chen**, *National Taiwan University Hospital, Taiwan* | **Sudeep Gupta,** *Deputy director, ACTREC* |
| 14.30 – 14.55 (20+5) | **Talk 6**<br>Informed Consent Document: What is Ideal? | **Anil Sharma**, *CEO and Medical Director, IRB Company Inc. and Professor at UCLA, US* | |

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| 14.55 – 15.20 (20+5) | **Talk 7**<br>Protecting Vulnerable Population | **Nithya Gogtay**, *Asso. Prof. of Clinical Pharmacology, KEM Hospital* | |
| 15.20 – 15.55 (20+5) | **Talk 8**<br>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 and Coffee - Networking Break** | | |
| 16.15 – 16.40 (20+5) | **Talk 9**<br>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* | |
| 16.40 – 17.20 (40) | **Panel Discussion 3**<br>Managing Conflict of Interest In Clinical Trials | **Sudeep Gupta,** *Deputy director, ACTREC;*<br>**Nithya Gogtay**, *Asso. Prof.of Clinical Pharmacology, KEM Hospital;*<br>**Marjorie Speers,** *Ex CEO AAHRPP, Independent Consultant of HRPP, US;*<br>**Xiuqin Wang**, *Secretary & Permanent member IRB, The First Affiliated Hospital of Nanjing Medical University (Jiangsu Province Hospital), China***;**<br>**Ramanathan**, *Legal Adviser, TMH* | **Siddhartha Laskar**, *Prof. of Radiation Oncology Member Secretary, TMH IEC* |

## Dinner Symposium: "Preparing for Accreditation (AAHRPP)" (Discussion followed by dinner) Time: 19.00 – 21.00

***Day 2 (November 8, Saturday)***

| **Prof. Rustom Choksi Auditorium (Hall A)** | | | |
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| **Time (mins)** | **Topic** | **Speaker** | **Chairperson/ Moderator** |
| 08.00 – 09.00 (60) | Registration | | |
| 09.00 – 09.25 (20+5) | **Talk 10**<br>Ethical/ Regulatory Issues with Research involving Medical Devices | **Sanjay Mittal,** *Director- Clinical Cardiology and Research, Medanta* | |
| 09.25 – 09.50 (20+5) | **Talk 11**<br>Ethical/ Regulatory Issues with Bio-repositories | **Sangeeta Desai**, *Prof. & OIC Molecular Pathology Tata Memorial Hospital* | |
| 09.50 – 10.15 (20+5) | **Talk 12**<br>Central Independent IRB: Is It Viable?/ The Ethics Bill (ICMR) | **Roli Mathur**, *Scientist, ICMR* | |
| 10.15 – 10.45 (20) | **Talk 13**<br>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 and Coffee - Networking Break** | | |
| 11.00 – 11.30 (30) | **Keynote 2**<br>Research in India: Where do we stand | **Ranjit Roy Chaudhury**, *Prof. of Clinical Pharmacology Member Expert Committee* | |
| 11.30 – 11.55 (20+5) | **Talk 14**<br>Protecting Patients in Clinical trials: Regulators Perspective | **Sudhakar Bangera**, *Clinical Development Services Agency (CDSA) ** | |
| 11.55 – 12.20 (20+5) | **Talk 15**<br>IRB Review of Community Based Clinical Research | **Cristina Torres**, *FERCAP Adviser* | |
| 12.20 – 13.00 (40) | **Panel Discussion 4**<br>Investigational New Drug: Definitions & Interpretations | **Kumar Prabhash**, *Medical Oncologist, TMH;*<br>**Nandini Kumar,** *Deputy* | **Vikram Gota**, *Clinical Pharmacologist* |

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| | | *Director General of IMCR (Retd.);*<br>**A Visala**, *CDSCO*;<br>**Rachna Bharadwaj**, *Advocate;*<br>**Felix Gyi**, *Head Chesapeake IRB, U.S Secretary of Health and Human Services Human Research Protection Advisory Committee, Columbia, US* | *ACTREC* |
| 13.00 – 14.00 (60) | **Lunch** | | |
| 14.00 – 14.25 (20+5) | **Talk 16**<br>Clinical Research, Human Rights, & Medical Ethics: Striking the Right Balance | **Amar Jesani**, *Independent consultant & researcher in Bioethics* | |
| 14.25 – 14.50 (20+5) | **Talk 17**<br>Practical and Robust Evaluation Program of EC/IRB Members | **Felix Gyi**, *Head Chesapeake IRB, U.S Secretary of Health and Human Services Human Research Protection Advisory Committee, Columbia, US* | |
| 14.50 – 15.15 (20+5) | **Talk 18**<br>Handling Non-compliance & Unanticipated Problems | **Pratibha Pereira**, *HRPP consultant* | |
| 15.15 – 16.00 (10x4) | Selected Proffered Papers | | **George K**, *Assoc. Prof. & Asstt. Surgeon Member Secretary, TMC*;<br>**Prachi Patil**, *Assoc. Prof & Asstt. Physician Gastroenterology, TMH* |
| 16.00 – 16.15 (15) | **Tea and Coffee - Networking Break** | | |
| 16.15 – 17.15 (60) | Open Forum (Audience questions to experts from Academia/ Regulators/ Industry/ Patient Representative/ NGO) | **Anil K D'Cruz,** *Director, Tata Memorial Hospital*;<br>**Ranjit Roy Chaudhury**, *Prof. of Clinical Pharmacology, Member Expert Committee;*<br>**John Oidtman**, *Vice-President, Clinical Trial Support and Compliance, Pfizer* Inc. US;<br>**Urmila Thatte**, *Prof.& Head of Clinical Pharmacology, KEM Hospital Chairperson, TMH IEC* ;<br>**Harmala Gupta**, *President CanSupport;*<br>**Amir Khan**, *Actor & Social Activist** ;<br>**Elyse I. Summers**, *President & CEO AAHRPP, US* | **Sudeep Gupta,** *Deputy director, ACTREC* |
| 17.15 – 17.30 (15) | Valedictory Function & Closing Remarks | | |

* To Confirm