



## South Asian Chapter of American College of Clinical Pharmacology

### 9<sup>th</sup> International Annual Conference on Clinical Pharmacology in Maternal and Child Care”

Organized in collaboration with

National Institute for Research in Reproductive Health, ICMR, Parel, Mumbai  
Maharashtra University of Health Sciences (MUHS)  
Department of Pharmacology & Clinical Pharmacology, Seth G S Medical  
College and KEM Hospital, Mumbai  
The Federation of Obstetric and Gynecological Societies of India (FOGSI) and  
Indian Academy of Pediatrics (IAP)

**on 28th – 30th April, 2016**

**Pre Conference Workshop Date : 28th April 2016**

**Regulatory Environment for conducting Clinical Research in India –  
Empowering Sites & Ethics Committees**

#### Conference Dates

**29th April 2016:** Clinical Pharmacology in Maternal Care

**30th April 2016:** Clinical Pharmacology in Child Care

**Venue: Nehru Centre, Dr Annie Besant Rd, Worli, Mumbai, MH 400018.**

## **9th Annual Conference Highlights:**

The Theme of 9th Annual Conference of SAC-ACCP is- Clinical Pharmacology in Maternal and Child Care. Needless to state, drug development for local-regional health needs is a very important topic for India and the South East Asia region. There are two parallel track pre-conference workshops – one in Epidemiology and the other in Regulatory changes that impact the Investigator, Ethics Committee and Patients taking into consideration needs of young researchers and the Industry. A conscious decision was taken by the organizing committee in this edition of the annual conference to concentrate on Clinical Pharmacology of both Women (PCOD, Contraceptives, Newer drugs) and Children (rare diseases, ethics, consent, drug development) from the perspective of Public health Importance in the South East Asia region. Every researcher would agree that ultimately, medical research must translate into improved treatments or treatment regimens for patients. The Organizing committee has been fortunate to have eminent faculty from Academia, Government and the Industry who have agreed to speak on their work in the chosen field and also provide information on how collaborations between different stakeholders are enabling development of better health care, improved quality of life, and enhanced treatment for patients. The faculty will enlighten the audience on how findings in the laboratory are getting translated into drug development and how it all goes into producing changes in clinical practice, from bench to bedside.

We have applied for MMC credit points for each day of the workshop and conference

**Preconference workshop on  
Regulatory Environment for conducting Clinical Research in India – Empowering Sites  
& Ethics Committees**

**Day 1: Thursday, 28<sup>th</sup> April 2016**

**Venue: Hall of Culture**

08.00 -09.00	Registration/Breakfast	
09.00 -09.15	Opening remarks Orientation to workshop	Dr Nilima Kshirsagar <u>Workshop Director:</u> Dr Sanish Davis
09.15-09.45	Changes in the scope, work and responsibilities of Ethics Committees, EC registration process	Dr Urmila Thatte
9.45-10.15	Changed Regulatory requirements for clinical trial process and documentation	Dr Suresh Menon
10.15-10.45	Impact of regulatory changes on vaccine studies	Dr Prasad Kulkarni
10.45-11.00	Tea	
11.00-11.30	Impact of amended regulations on Pharmacovigilance reporting	Dr Pooja Jadhav
11.30-12.00	Impact of amended regulations on Clinical Trial insurance indemnity, Penal provisions for investigators, compensation	Mr Kedar Suvarnapathki
12.00-13.00	Ethics Committee Inspection findings – lessons learnt over last 3 years of DCGI inspections : Exercises	Dr Shilpi Sinha
13.00-14.00	Lunch	
14.00-15.00	View from the workbench of EC members : calculating Compensation for Clinical Trial Injury :Exercises	Dr Renuka Munshi, Dr Yashashri Shetty and Dr Padmaja Marathe
15.00-15.30	Tea	
15.30-16.00	Role of Guidelines and regulations in Pediatric research – global perspective	Dr Varsha Bhatt-Mehta
16.00- 16.30	Impact of the amendments on Academic research with special reference to Pediatrics	Dr Sandeep Bavdekar
1630-17.00	Open House and participant feed back Concluding remarks	Dr Sanish Davis

**Main Conference**  
**Day 2: Friday, 29<sup>th</sup> April, 2016**  
**Venue: Hall of Culture**

<b>07.30-8.00</b>	<b>Registration and Breakfast</b>	
<b>08.00-9.00</b>	<b>Session 1: ORAL/POSTER PRESENTATIONS</b>	
	<b>Session 1a: Clinical-Oral</b> <b>Hall of Culture</b>	<b>Session 1b: Pre-Clinical-Oral</b> <b>Hall of Harmony</b>
	<b>POSTERS</b> <b>Session 1c: Clinical Poster Evaluation (CL/P)</b> <b>Session 1d: Pre-Clinical Poster Evaluation (PR/P)</b>	
<b>09.00-10.30</b>	<b>Session 2: REPRODUCTIVE YEARS : ISSUES AND CONTROVERSIES</b> <b>Chairpersons: Dr Kaizad Damania and Dr Marcus Hompesch</b>	
<b>09.05-09.25</b>	Drug- drug interactions with oral contraceptives	Dr. Rama Sivasubramanian
<b>09.25-9.45</b>	Programmes and Policies to improve Contraceptive acceptance in India	Dr Sikdar
<b>09.45-10.05</b>	Exploratory studies for leads from AYUSH systems for women's health	Dr. Rama Vaidya
<b>10.05-10.25</b>	PCOS management	Dr.Mohd Ashraf Ganie
<b>10.30- 11.00</b>	<b>Tea</b>	
<b>11.00-12.00</b>	<b>Session 3: INAUGURATION</b> <b>Felicitations: Lupin Ltd.;NIRRH Mumbai</b>	
<b>12.00-13.30</b>	<b>Session 4: Prof. Ranjit Roy Choudhary PANEL DISCUSSION-ETHICAL &amp; REGULATORY ISSUES CONCERNING RESEARCH &amp; DRUG DEVELOPMENT FOR WOMEN</b>  Moderators : Dr Nilima Kshirsagar and Dr Rishma Pai, Mumbai Panelists: Dr BipinPandit, Dr Madhuri Patel, Dr Bikash Medhi, Prof YK Gupta, Dr Malabika Roy, Dr R.S Sharma, Dr Robin Ferner, Dr Shravanti Bhowmik, Dr V.G Somani, Ms Dhvani Mehta	
<b>13.30 -14.30</b>	<b>Lunch</b>	

<b>14.30-16.00</b>	<b>Session 4: TRANSFORMING WOMEN'S HEALTH FROM RESEARCH TO PRACTICE</b> <b>Chairpersons: Dr Subir Kumar Maulik and Dr Sharad Gogate</b>	
<b>14.35-14.55</b>	An update on design of small molecules with FSH agonistic activity	Dr.Smita Mahale
<b>14.55-15.15</b>	New drugs in gynaecology	Dr.RishmaPai
<b>15.15-15.35</b>	Cardiovascular drugs for women	Dr.Ashim Ghatak
<b>15.35-15.55</b>	Endometriosis animal models	Dr Deepak Modi
<b>15.55-16.00</b>	<b>Q&amp;A</b>	
<b>16.00-16.30</b>	<b>Tea</b>	
<b>16.30-17.30</b>	<b>Session 5: CHALLENGES FOR WOMEN BEYOND 40 !!</b> <b>Chairpersons: Dr A.V.Umranikar and Dr Y.S. Nandanwar</b>	
<b>16.35-16.55</b>	Osteoporosis where we stand: status in India	Dr.Lalita Savardekar
<b>16.55-17.15</b>	Drugs for better bone health!!	Dr.Ritu Trivedi, Lucknow

**Day 3: Saturday, 30th April 2016**  
**Venue: Hall of Culture**

<b>7.30-8.00</b>	<b>Registration and Breakfast</b>	
<b>8.00-9.00</b>	<b>Session 6: ORAL/POSTER PRESENTATIONS</b>	
	<b>Session 8a:</b> Clinical-Oral <b>Hall of Culture</b>	<b>Session 8b:</b> Pre-Clinical-Oral <b>Hall of Harmony</b>
	<b>POSTERS EVALUATION</b> <b>Session 8c:</b> Clinical Poster Evaluation (CL/P) <b>Session 8d:</b> Pre-Clinical Poster Evaluation (PR/P)	
<b>9.00-10.30</b>	<b>Session 7 : UNMET CHALLENGES IN TREATING CHILDREN</b> <b>Chairpersons: Dr Mamta Manglani and Dr Mukesh Agrawal</b>	
<b>9.05-9.25</b>	“GRiP project. An European model of collaboration”	Dr. Carlo Giaquinto
<b>9.25-09.50</b>	Antibiotics: use & misuse	Dr.Pramod Jog
<b>09.50-10.10</b>	Alternative medicine in paediatrics: where are we?	Dr.Kuldeep Raj Kohli
<b>10.10-10.30</b>	Drugs for ADHD	Dr. Samir Dalwai
<b>10.30-10.40</b>	<b>Q &amp;A</b>	
<b>10.40-11.00</b>	<b>Tea</b>	
<b>11.00-12.30</b>	<b>Session 9: Prof U.K Sheth PANEL DISCUSSION- REGULATORY ISSUES IN DRUGS FOR CHILDREN</b> Moderators : Prof NilimaKshirsagar and DrSoumyaSwaminathan Panelists: DrPramod Jog, Dr Samir Dalwai, DrRoliMathur, DrChandrashekhar, Dr Bernd Meibohm, Prof YK Gupta, DrNusrat Khan, DrGangadharSunkara, Dr V.G. Somani, Dr Prasad Kulkarni, Dr Brian Tseng, Ms. Dhvani Mehta	
<b>12.30-13.30</b>	<b>Session 8: INAUGURATION</b> <b>Felicitation of Cyrus Poonawala, Serum Institute of India;</b> <b>&amp;</b> <b>Dr Soumya Swaminathan Secretary DHR Director General ICMR</b> <b>Key note address – Dr. SoumyaSwaminathan</b>	
<b>13.30-14.30</b>	<b>Lunch</b>	
<b>14.30-16.00</b>	<b>Session 10 :NEW DRUG DEVELOPMENT PROGRAMS FOR CHILDREN!</b> <b>Chairpersons: Dr Ruchi Nanavati and Dr. Khanindra Bhuyan</b>	
<b>14.35-14.55</b>	Ontogeny of Drug Metabolizing Enzymes and Transporters in Pediatric Drug Development and Pharmacotherapy	Dr. Bernd Meibohm
<b>14.55-15.20</b>	The Road to Ensuring Safe Use of Medications in Children: A US Perspective on Challenges and Lessons Learned	Dr.Dionna Green
<b>15.20 – 15.50</b>	Therapeutic foods	Dr. Dinesh Kumar

<b>15.50- 16.10</b>	Juvenile Diabetes Type 1: Are we progressing towards a cure? A review of current clinical development programs	Dr. Marcus Hompesch
<b>16.10-16.30</b>	Paediatric drug development	Dr.Brian Tseng
<b>16.30-16.40</b>	<b>Q &amp; A</b>	
<b>16.40-17.00</b>	<b>Session 11: DRUG DEVELOPMENT BEFORE AND AFTERMARKETING</b> <b>Chairpersons: Dr Milind Tullu and Dr Mamta Muranjan</b>	
<b>16.40-17.00</b>	Using Big Data to Improve Health Outcomes in the Pediatric Population	Dr.Deepa Ranka
<b>17.00-17.20</b>	Off Label use of drugs and FDCs regulatory and Clinical implications	Dr. Sandeep Bavdekar
<b>17.20-17.40</b>	Before and after marketing-a clinician's perspective on pediatric clinical trial challenges from a practical and regulatory standpoint.	Dr Varsha Bhatt-Mehta
<b>17.40-17.45</b>	<b>Q &amp; A</b>	
<b>17.45-18.15</b>	<b>Valedictory and Prize distribution (Oral &amp; Poster Presentations) function- Chief guest-Dr Mrudula Phadke</b>	