South Asian Chapter of
American College of Clinical Pharmacology

9th 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, Nasik
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

Details of registration and abstract on SAC-ACCP website

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 is a pre-conference workshop on 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 Pre conference workshop and each day of the conference

Preconference workshop-I

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

Day 1: Thursday, 28th April 2016
Venue: Hall of Culture

08.00 -09.00	**Registration/Breakfast**	
09.00 -09.15	Opening remarks Orientation to workshop	Dr Nilima Kshirsagar, ICMR, Mumbai India Workshop Director: Dr Sanish Davis, Covance India
09.15-09.45	Changes in the scope, work and responsibilities of Ethics Committees, EC registration process	Dr Urmila Thatte (TBC)
9.45-10.15	Changed Regulatory requirements for clinical trial process and documentation	Dr Suresh Menon, Novartis
10.15-10.45	Impact of regulatory changes on vaccine studies	Dr Prasad Kulkarni, Serum Institute of India
10.45-11.00	**Tea**	
11.00-11.30	Impact of amended regulations on Pharmacovigilance reporting	Dr Pooja Jadhav, SUN Pharmaceuticals
11.30-12.00	Impact of amended regulations on Clinical Trial insurance indemnity, Penal provisions for investigators, compensation	Mr Kedar Suvarnapathki, Boheringer Ingelheim
12.00-13.00	Ethics Committee Inspection findings – lessons learnt over last 3 years of DCGI inspections : Exercises	Dr Shilpi Sinha, Bristol Meyers Squibb, Mumbai
13.00-14.00	**Lunch**	
14.00-14.30	View from the workbench of EC members : calculating Compensation for Clinical Trial Injury :Exercises	Dr Renuka Munshi-Kulkarni Dr Yashashri Shetty and Dr Padmaja Marathe
14.30-15.00	Update on Guidelines for conducting Pediatric Research in India	Dr Reeta Rasaily, ICMR (TBC)
15.00-3.30	**Tea**	
15.30-16.00m	Role of Guidelines and regulations in Pediatric research – global perspective	Dr Varsha Bhatt-Mehta, University of Michigan,USA
16.00- 16.30	Impact of the amendments on Academic research with special reference to Pediatrics	Dr Sandeep Bavdekar, Mumbai
1630-17.00	Open House and participant feed back Concluding remarks	Dr Sanish Davis , Mumbai, India

Main Conference

Day 2: Friday,29th April, 2016

Venue: Hall of Culture

07.30-8.00	**Registration and Breakfast**	
08.00-9.00	**Session 1: ORAL/POSTER PRESENTATIONS**	
	Session 1a: Clinical-Oral **Hall of Culture**	**Session 1b:** Pre-Clinical-Oral **Hall of Harmony**
	POSTERS **Session 1c:** Clinical Poster Evaluation (CL/P) **Session 1d:** Pre-Clinical Poster Evaluation (PR/P)	
09.00-10.30	**Session 2: REPRODUCTIVE YEARS : ISSUES AND CONTROVERSIES**	
09.05-09.25	Drug- drug interactions with oral contraceptives	Dr. Rama Sivasubramanian, Novartis, Hyderabad
09.25-9.45	Male Contraceptives	TBC
09.45-10.05	Exploratory studies for leads from AYUSH systems for women's health	Dr. Rama Vaidya, Mumbai
10.05-10.25	PCOS management	Dr. Mohd Ashraf Ghani, Delhi
10.30- 11.00	**Tea**	
11.00-12.00	**Session 3: INAUGURATION** **Felicitations : Lupin;,NIRRH Mumbai**	
12.00-13.30	**Session 4: : Prof. Ranjit Roy Choudhary PANEL DISCUSSION-ETHICAL & REGULATORY ISSUES CONCERNING RESEARCH & DRUG DEVELOPMENT FOR WOMEN** **Moderators : Dr Nilima Kshirsagar and Dr Rishma Pai, Mumbai** **Panelists: Dr Bipin Pandit, Dr Madhuri Patel, Dr Bikas Medi, Prof YK Gupta, Dr Malabika Roy, Dr R.S Sharma, Dr Robin Ferner, DrShravanti Bhowmik, Dr V.G Somani**	
13.30 -14.30	**Lunch**	
14.30-16.00	**Session 4: TRANSFORMING WOMEN'S HEALTH FROM RESEARCH TO PRACTICE**	
14.35-14.55	An update on design of small molecules with FSH agonistic activity	Dr. Smita Mahale, Mumbai
14.55-15.15	New drugs in gynaecology	Dr. Rishma Pai, Mumbai
15.15-15.35	Cardiovascular drugs for women	Dr. Madhu Dixit, Lucknow
15.35-15.55	Endometriosis animal models	Deepak Modi, Mumbai
15.55-16.00	**Q&A**	
16.00-16.30	**Tea**	
16.30-17.30	**Session 5: CHALLENGES FOR WOMENBEYOND 40 !!**	
16.35-16.55	Juvenile Diabetes Type 1: Are we progressing towards a cure? A review of current clinical development programs	Dr. Marcus Hompesch,USA
16.55-17.15	Osteoporosis where we stand: status in India	Dr. Lalita Savardekar, Mumbai
17.15-17.35	Drugs for better bone health!!	Dr. Ritu Trivedi, Lucknow

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

7.30-8.00	**Registration and Breakfast**	
8.00-9.00	**Session 6: ORAL/POSTER PRESENTATIONS**	
	Session 8a: Clinical-Oral **Hall of Culture**	**Session 8b:** Pre-Clinical-Oral **Hall of Harmony**
	POSTERS EVALUATION **Session 8c:** Clinical Poster Evaluation (CL/P) **Session 8d:** Pre-Clinical Poster Evaluation (PR/P)	
9.00-10.30	**Session 7 : UNMET CHALLENGES IN TREATING CHILDREN**	
9.05-9.25	"GRiP project. An European model of collaboration"	Dr. Carlo Giaquinto,Italy
9.25-09.50	Controversies in drug treatment	Dr. Sunil Karande, Mumbai
09.50-10.10	Alternative medicine in paediatrics: where are we?	Dr. Kuldeep Raj Kohli, Mumbai
10.10-10.30	Drugs for ADHD	Dr. Samir Dalwai, Mumbai
10.30-10.40	**Q &A**	
10.40-11.00	**Tea**	
11.00-12.00	**Session 8: INAUGURATION** **Felicitation of Cyrus Poonawala, Serum Institute of India;** **&** **DrSoumya Swaminathan Secretary DHR Director General ICMR** **Key note address – Dr. Soumya Swaminathan**	
12.00-13.30	**Session 9: : Prof U.K Sheth PANEL DISCUSSION-REGULATORY ISSUES IN DRUGS FOR CHILDREN** **Moderators : Prof Nilima Kshirsagar and Dr Soumya Swaminathan** **Panelists: DrPramod Jog, Dr Samir Dalwai, Dr Roli Mathur, Dr Chandrashekhar, Dr. Bernd Meibohm Prof YK Gupta, Dr Nusrat Khan, DrGangadhar Sunkara, Dr V.G. Somani, Dr Prasad Kulkarni, Dr Tseng**	
13.30-14.30	**Lunch**	
14.30-16.00	**Session 10 :NEW DRUG DEVELOPMENT PROGRAMS FOR CHILDREN!**	
14.35-14.55	Ontogeny of Drug Metabolizing Enzymes and Transporters in Pediatric Drug Development and Pharmacotherapy	Dr. Bernd Meibohm,USA
14.55-15.20	Improving pediatric therapeutics through precision medicine	Dr. Dionna Green,USA
15.20 – 15.50	Therapeutic foods	Dr. Dinesh Kumar,Hyderabad

15.50- 16.10	Antibiotics: use & misuse Nutrition	Dr. Pramod Jog, Pune
16.10-16.30	Deciding the dose, in pediatric trials with the limited data.	Dr. Gangadhar Sunkara,USA
16.30-16.40	**Q & A**	
16.40-17.00	**Session 11: DRUG DEVELOPMENT BEFORE AND AFTERMARKETING**	
16.40-17.00	ChildrenUsing Big Data to Improve Health Outcomes in the Pediatric Population	Dr. Deepa Ranka,USA
17.00-17.20	Off Label use of drugs and FDCs regulatory and Clinical implications	Dr. Sandeep Bavdekar, Mumbai
17.20-17.40	Before and after marketing-a clinician's perspective on pediatric clinical trial challenges from a practical and regulatory standpoint.	Dr Varsha Bhatt,USA
17.40-17.45	**Q & A**	**-**
17.45-18.15	Dr. Mrudula Phadke Valedictory and Prize distribution (Oral & Poster Presentations) function	