

**International Clinical Trial Day Celebration by Regulatory Council & North Chapter At FDA Bhawan on 21-May-2019**

For the fifth consecutive year, ISCR's Regulatory Council celebrated this day by holding an event at FDA Bhawan bringing together different stakeholders involved in clinical research. This year, the event was jointly organized by Regulatory Council in collaboration with North Chapter.

Theme for this year was "[New Regulations to further strengthen clinical research in India](#)".

A holistic view on the new regulation was provided by the various stakeholders who participated in this even, namely

- CDSCO representatives - Dr. V. G. Somani (JDC), Dr Bangarurajan (JDC), A. K. Pradhan (DDC), Dr Naresh Sharma (DDC) other CDSCO officials
- Ethics Committee representative - Dr Pooja Sharma, Obs & Gynae, Member of Medanta EC
- Investigator representative - Dr Amit Bhargava, Oncologist
- Academics - Dr Y. K. Gupta,
- SEC - Dr. Sameer Baxi, Pediatric Oncologists, AIIMS and Onco SEC member
- Patient representatives
- BA/ BE studies- Dr Kiran Marthak
- Sponsor and CRO representatives - ISCR members

In absence of DCGI, Dr Eswara Reddy, who was overseas, the event was chaired by Ms Rita Teotia, Chairperson FSSAI (Food Safety Standards Authority of India). She highlighted the need to define regulatory processes for conducting clinical trials on nutraceuticals which are regulated under the Food regulation.

***FSSAI Chairperson, Ms Rita Teotia welcoming all participants***



Dr Chirag Trivedi, ISCR President thanked CDSCO for consistently providing an opportunity to ISCR to conduct this event at FDA Bhawan. He gave a brief introduction of mission of ISCR, short and long term strategic priorities and intent of conducting ICTD event.

The two patient representatives who were suffering from different types of cancer narrated their experience with clinical research and highlighted the benefits of participating in clinical trials. They also expressed the need for bringing in more innovative medicine to treat life threatening diseases for patient benefit.

#### *Patient sharing clinical trial experience*



#### *Felicitation of patient : Ambassadors of clinical research*



Dr Suneela Thatte, ISCR Executive Council member gave a short presentation on clinical research updates on International front. She briefly described newer aspects such as eCRF, adaptive monitoring etc.

The highlight of the evening was the panel discussion which followed.

Panel discussion involved representatives from CDSCO (Dr Somani, A. K. Pradhan), Industry (Anirban Roy Chowdhury), Ethics Committee (Dr Pooja Sharma), Investigator (Dr Amit Bhargava), Academics (Dr Y K Gupta), SEC member (Dr Sameer Baxi), Dr Kiran Marthak (BA/BE studies) and moderator (Dr Suresh Menon, ISCR executive council member). Theme of the panel discussion was "Impact of the revised Drug & Cosmetic Act/Rules to various clinical research stakeholders in India"

Important aspects discussed in panel discussion included :

- Overall feedback of the new CT Drug Rules from all stakeholders : Most of the feedback was positive and overall the new rules sent a good message to the global community to conduct more clinical research in India.
- Some major challenges faced by each stakeholder
- Few critical/grey areas that have still not been addressed in the new rules despite the FAQs which have been released.



*An engaging Panel discussion*

It has always been ISCR's intent to ensure maximum participation by CDSCO officials in such events, and considering highly positive response in 2017 and 2018, this year too, a short quiz was conducted for all participants from CDSCO. The quiz had multiple choice questions related to clinical trial regulation, to make the event more interactive and enjoyable. CDSCO officials - Technical Officers, Drug Inspectors and Asstt Drugs Controllers participated in the quiz. Winners were announced at the end of the event and awards were distributed by various panelists.

*Congratulations to the Quiz Award winner*



Overall we had a good discussion and an insightful event. We are thankful to the CDSCO team, led by DCGI, Dr Eswara Reddy for their wholehearted participation and Dr Naresh Sharma, CDSCO, for his support in the organization of a memorable International Clinical Trials Day.

*The team who made the event a great success*



*We all stand together for the success of clinical research*



**We couldn't have done it  
without YOU!**

**CDSCO officials  
Patients  
Panelists  
Presenters  
Volunteers**



**ISCR Team:**

- **Regulatory Council and North Chapter**

Yasmin Shenoy, Amita Bhave, Sneha Gupta, Lipi Chakkhaiyar, Gaurav Mathur, Shehnaz Vakharia, Rahul Chauhan, Dr Sanjay Maroo, Arun Mishra, Parveen Jain, Sandeep Verma, Manali Agrawal, Rahul Goswami, Samir Sangitrao, Sandhya K.

- **ISCR EC members**

Dr Suresh Menon, Dr Chirag Trivedi, Dr Arun Bhatt, Dr Y K Gupta, Dr Anirban Roy Chowdhury, Dr Suneela Thatte

- **ISCR Secretariat**

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