



# Indian Society for Clinical Research

## 6th ANNUAL PHARMACOVIGILANCE SYMPOSIUM

*“Accelerating pharmacovigilance in India for comprehensive patient safety”*



Venue: IBIS,  
AEROCITY  
New Delhi

November 22, 2019

Timing: 8.30 am to 5.30 pm

ISCR Pharmacovigilance Council welcomes you to attend the 6th National Symposium on *‘Accelerating Pharmacovigilance in India for Comprehensive Patient Safety’* to be held on the 22 November 2019, Delhi, India.

The Symposium will provide different insights from key stakeholders such as Industry, HCPs, Pharmacists, Regulators and Academia on current Pharmacovigilance requirements, upcoming changes in regulations, Global Pharmacovigilance Practices, and opportunities and challenges in effective management of Pharmacovigilance operations in India. The agenda of this symposium is drafted by PV professionals from the pharma industry network and will have the top experts to discuss the current issues that matter most to all stakeholders involved in drug safety activities.

**The field of Pharmacovigilance is progressing rapidly and its evolution is making tremendous impacts in pharmaceuticals & patient’s health outcomes. This symposium focuses on the opportunities & challenges for Pharmacovigilance in achieving comprehensive patient safety in the current state of affairs. It will offer a platform to discuss valuable perspectives about drug safety from various stakeholders and understand recent developments in current PV regulatory framework in India.**

### Who Can Attend?

- ◆ Pharmacovigilance Professionals
- ◆ Students, Researchers & Faculty in Healthcare Domain
- ◆ Regulatory Professionals
- ◆ Pharmacovigilance Associations and Societies
- ◆ IT enabled Service Provider / CRO in Healthcare
- ◆ Third Party Pharma Manufacturers
- ◆ ADR Monitoring Centres (AMC)
- ◆ Pharmaceutical Industry
- ◆ Patient Advisory Groups
- ◆ Clinical Investigators & Health Care Professionals

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08.00 am - 09.00 am	Registration and Refreshments	
09.00 am - 09.30 am	<p>Welcome Address</p> <p>Chair’s Address</p> <p>President’s Address</p>	<p><b>Dr.Babita Kirodian</b> Org Committee, ISCR PV Symposium</p> <p><b>Dr.P.S.Karthik Babu</b> Chair, ISCR Pharmacovigilance Council</p> <p><b>Dr.Chirag Trivedi</b> President ISCR</p>
9.30 am to 9.45am	Inaugural Ceremony—Lighting the Lamp	<b>Mr. Somnath Basu, Mr. Srinivasan K.M , Dr.YK.Gupta, Dr.Bejon Mishra, Dr.Bikash Medhi ,Dr.Jai Prakash, Dr.Vivek Ahuja</b>
9.45 am - 10.25 am	Keynote & Chief Guest Address Pharmacovigilance in India	<b>Shri. Somnath Basu</b> - Assistant Drugs Controller (I), CDSCO
10:25 am - 11.05 am	Keynote address: Artificial Intelligence in Pharmacovigilance : Near yet far?	<b>Dr. Vivek Ahuja</b> - Vice President - Medical Affairs & GPV, Sun Pharmaceuticals Ltd.
11.05 am - 11.20 am	Tea break	
11.20 am - 11.40am	Safety Signal Identification and Validation	<b>Dr Pipasha Biswas</b> - Executive Director, Symogen Ltd, UK
11.40 am - 12.00 pm	Effective implementation of Risk Minimization measures in India	<b>Dr Sanjay Samantray</b> - Medical Safety Director & Clinical Development, Novartis
12.00 pm - 01.00 pm	Panel Discussion: Empowering Patients for Comprehensive Drug Safety	<p><b>Panellist:</b></p> <p><b>Dr. Bejon Misra</b> Founder Director, Patient Safety &amp; Access Initiative of India Foundation</p> <p><b>Prof. Dr. Y.K.Gupta</b>, President, AIIMS Bhopal</p> <p><b>Prof. Dr. Bikash Medhi</b> ,Professor Pharmacology PGIMER Chandigarh</p> <p><b>Dr. Jai Prakash</b> Head PvPI at IPC</p> <p><b>Dr.Chirag Trivedi</b> President ISCR</p> <p><b>Dr.Pipasha Biswas</b> Symogen Ltd, UK</p> <p><b>Dr. Vivek Ahuja</b> , Sun Pharmaceuticals</p> <p><b>Moderator: Dr. Vijay Venkatraman</b> Executive Council Member, ISCR</p>
01.00 pm - 02.00 pm	<b>LUNCH &amp; NETWORKING</b>	
02.00 pm - 02.20 pm	SAE Management Process in Clinical Trials	<b>Prof. Dr. Bikash Medhi</b> - Professor Pharmacology PGIMER Chandigarh , Member SAE review committee , NCC-PvPI Signal review panel

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02.20 pm - 02.40 pm	Safety Reporting with Medical Devices : Special Considerations	Dr. Sumati Randeo - Director QR Synergies
02.40 pm - 03.00 pm	Safety Management in Biosimilar Products	Dr. Nitu Sinha, Head - Biologics Pharmacovigilance, DRL
03.00 pm - 03.30 pm	TEA BREAK	
03.30 pm – 03.50 pm	Safety Reporting with Vaccines : Special considerations	Dr Deepak Polpakara Team Leader, AEFI Secretariat
03.50 pm - 04.10 pm	Evidence Based Medicine: Real World Evidence in India	Dr Arun Bhat Consultant - Clinical Research & Development
04.10 pm - 05.10 pm	Panel Discussion:  Pharmacovigilance requirements in New Drug & CT rules 2019	<b>Panellist:</b>  - Shri. Somnath Basu - Assistant Drugs Controller (I) CDSCO - Shri. Srinivasan K.M - Assistant Drugs Controller (I) CDSCO - Amita Bhawe -Regulatory Council ISCR - Dr.Jamal Baig Co-Chair ISCR PV Council - Dr.Shubhadeep Sinha, Head Global and Vice-President, Clinical Development and Medical Affairs, Hetero Drugs Ltd - Dr.Pooja Sharma Medanta hospital - Dr. Deepa Arora Founder- Director CLINEXEL Life Sciences Pvt Ltd  - Moderator: Dr. PS Karthik Babu Chair, ISCR PV Council
05.10 pm - 05.30 pm	Vote of Thanks	Dr. Jamal Baig Co-Chair, PV Council

**REGISTRATION DETAILS:**

**Delegate Fee:**

Academia – Student - Rs. 2500/- per person & Faculty - Rs. 3500/- per person

**ISCR Member :** Rs. 5500/-per person (For Individual & Corporate Members — AMOs)

**Non-Member :** Rs. 6000/-per person

**Online Registration (Mandatory):** <http://www.iscr.org/events-registration/>

**Group Registration:** 1 registration free on every 5 registrations from the same organization (6th registration will be free)

**Online Payment:** <http://www.iscr.org/payment-events-workshops/>

**Offline Payment:** Cheque /DD payable at Mumbai should be made in favour of “**Indian Society for Clinical Research**” & mailed to: ISCR Secretariat, C/o. Pfizer Centre, The Capital, 1802, 18th Floor, Plot No. C- 70, ‘G’ Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400 051

For any query please contact on email: [info@iscr.org](mailto:info@iscr.org) OR Call on +91-84548 27775