

Redefining Pharmacovigilance Frontiers for Augmenting Healthcare

02nd &
03rd Dec
2021

08th Annual Pharmacovigilance Symposium

This symposium provides insights from Experienced Stakeholders such as industry, HCPs, Pharmacists, Regulators and academia on

- The current Pharmacovigilance Requirements
- Upcoming changes in the Regulations
- Global and Local Pharmacovigilance Practices, Opportunities, Challenges in effective management of Pharmacovigilance operations in India.

It is a Knowledge sharing opportunity where you can discuss about challenges, concerns or issues and find effective solutions, which will not only ensure Compliance to Regulations but also help us in implementing more efficient, and harmonized PV practices.

Members of the Organizing cum Scientific Committee



Dr. Babita Kirodian
Lead, ISCR PV organizing cum scientific committee,
Global Safety Manager, Amgen India



Dr. P.S. Karthik Babu
Senior Director, Global Pharmacovigilance, Sanofi



Dr. Jamal Anwar Baig
Chair ISCR PV council, MSCH Sanofi India.



Dr. J Vijay Venkatraman
EC member, ISCR Managing Director & CEO Oviya Medsafe



Nidhi Vaish Das
Manager Drug Safety Roche Products (India) Private Limited



Dr. Aniket Patil
Country Safety Lead, Pfizer India Drug Safety Unit



Dr. Chitra Bargaje
General Manager, Global Head, Drug Safety and Risk Management Lupin Limited



Indu Nambiar
Head-Local Pharmacovigilance/ LPVM Boehringer Ingelheim



Vijaykrishnan Ganesan
Director, Pharmacovigilance Safety Operations Parexel International



Dr. Arunima Sen
Director, Pharmacovigilance and Medical Writing MMS Holdings Inc

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Day 1: Thursday December 2nd 2021 Time: 1.30 p.m.– 6.00 p.m. (IST)

Time	Topic	Speaker
1.30 – 1.35	Welcome address	Dr. Babita Kirodian, Lead SOC, ISCR PV Council
1.35 – 1.45 pm	Chair's address	Dr. Jamal Baig, Chair ISCR PV Council, Country Lead- Global Safety (Pharmacovigilance), MSD
1.45 – 1.55 pm	ISCR President's address	Dr. Sanish Davis
1.55 – 2.40 pm	Key note address	Dr. Vivek Ahuja, Vice President, Medical Affairs & Global PV, Sun Pharmaceuticals limited
2.40 – 3.20 pm	Updates on Online CT SAE reporting	DCGI /CDSO Delegate (TBC) Dr. Ujjwala Naik, PV Taskforce-Lead Sugam Implementation, Johnson & Johnson
3.20 – 4.00 pm	TBC	Dr Gerald J Dal Pan Dr. Jamal Baig, Chair ISCR PV Council, Country Lead- Global Safety (Pharmacovigilance), MSD
4.00 – 4.15 pm		-----BREAK-----
4.15 – 5.00 pm	Panel discussion: Pharmacovigilance for augmenting healthcare in India.	Dr. Viraj Suvarna Dr. Subhrojyoti Bhowmick, Clinical Director, Academics, Quality and Research Peerless Hospital, Kolkata Dr. Kausik Maiti, Senior Medical Director, Parexel International Manoj Swaminathan, Founder Director, Vigisafe Moderator – Ms. Indu Nambiar, Head of Pharmacovigilance Boehringer Ingelheim India Pvt. Ltd.
5.00 -5.40 pm	Innovations in PV	Dr. Arunima Sen, Director, Pharmacovigilance and Medical Writing, MMS Holdings Inc.
5.40 – 6.00 pm	Wrap-up: Day 1	Dr. Jamal Baig, Chair ISCR PV Council

Day 2: Friday December 3rd 2021 Time: 1.30 p.m.– 6.00 p.m. (IST)

1.30–1.35 pm	Welcome address	Dr. Vijay Venkatraman CEO, Oviya Medsafe & EC Member ISCR
1.35 – 2.15 pm	Key note address	Claudia Lehman Head of PV Operations, Boehringer Ingelheim International, GmbH
2.15 – 2.45 pm	Safety Outsourcing- Journey from Vendor Management to Partnership	Akila Kanishk, Associate Director, Parexel Global Safety Services Project Leadership
2.45 – 3.25 pm	EU CT regulations – Impact on PV	Dr. Jose Ortiz, PVpharm CEO, EU QPPV, EudraVigilance EVWeb-XEVMPD Trainer, Pharmacovigilance Consultant, LCPPV Services Spain, GVP Audit
3.25 – 3.40pm		-----BREAK-----
3.40 – 4.20pm	Accelerating Vaccine Safety Surveillance in the Post COVID Era	Mr. Samir Desai, President & Head BU Biologics at Cadila Healthcare Limited (Zydus Cadila)
4.20-5.00pm	Protection of personal data and proprietary info in PV	TBC
5.00- 5.45pm	Panel Discussion PV Audits and Inspections- Is Remote the Way forward.	Vijaykrishnan Ganeshan, Director Pharmacovigilance Safety Operations, Parexel International Sangeeta Myles, Director Auditor Quality Assurance Compliance Pfizer. Dr. Kirti Chavan, Abbott India PV Durga Mane, Associate Director, Delivery Excellence at Cognizant Technology Solutions Moderator – Dr. Chitra Bargaje General Manager, Global Head, Drug Safety and Risk Management Lupin Limited
5.45 – 6.00 pm	Closing Remarks/ Vote of thanks	Dr. Aniket Patil, SOC, ISCR PV Council

*All registered participants will receive a "Certificate of Participation" from ISCR

Online Registration: https://www.iscr.org/Upcoming_Events.aspx

Online Payment: Once you will complete the registration, you will receive payment details along with the confirmation email on your registered email id.

Offline Payment: Cheque/DD payable at Mumbai should be made in favor of "Indian Society for Clinical Research" & mailed to us at ISCR Secretariat, c/o Pfizer Limited, The Capital 1802, 18th Floor, Plot No. C-70, 'G' Block, Bandra Kurla Complex, Bandra (E), Mumbai – 400051

REGISTRATION DETAILS:

Registration fees by 20th Nov 2021 - Students, 250,
ISCR Members 800/-, Non-Member - 1000/-

Registration fees post 20th Nov - Students 400/-
ISCR Members - 1000/- Non-Member - 1200/-
Group registration: One free on 5 registrations

Indian Society for Clinical Research

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