

DIA India

7th Pharmacovigilance Conference

Transforming Clinical Safety and Pharmacovigilance

5-6 April, 2019 | Courtyard by Marriott | Mumbai India

Today, innovations are revolutionizing the entire healthcare development and commercialization landscape and the need of the hour is, strategies that pave the way for a smarter and more patient centric tomorrow. With this background, DIA India is excited to bring you an insightful discussion on the latest innovations and the impact of real world evidence and digital transformation on drug safety, pharmacovigilance, risk management and post marketing surveillance.

At this event, DIA brings together key regulatory authorities, leading industry subject matter experts and thought leaders for collaborative discussions on driving innovation in drug safety and pharmacovigilance. With the support and enthusiasm of regulators and healthcare leadership across the country, we are excited to bring to you a forward looking program. Take a look at our key topics for the event and expected participation:

Program Highlights

- Innovations Driving Change In Pharmacovigilance And Risk Management
- Current Regulatory Trends In Pharmacovigilance: Understanding ICH E2B (R3), FAERS And Eudravigilance
- Impact Of Brexit On Pharmacovigilance And Drug Safety Guidelines
- Real World Evidence Studies To Assess Safety And Effectiveness Of Therapeutic Interventions
- Artificial Intelligence: Predictive Sciences For Pharmacovigilance
- Regulators, Industry And Academia Collaborating On Post-Marketing Surveillance

Who should attend

- Pharmacovigilance And Drug Safety
- Risk Management
- Pharmacovigilance Compliance
- Regulatory Affairs
- Medical Affairs
- Late Phase Professionals Conducting PMS, Observational And Non-Interventional Studies
- Real World Data And Real World Evidence
- Technology Professionals

PROGRAMME CHAIR



Moin Don
President and CEO
PVCON Consulting Pvt Ltd.

PROGRAM CO-CHAIR



Krishna Bahadursingh
Former Pharma Executive
Fellow of the Faculty of Pharmaceutical Medicine (UK)

PROGRAM COMMITTEE



Shirish Sherlekar
Global Head
Life Sciences
Practice & QA,
Tata Consultancy
Services



Chitra Lele
Chief Scientific
Officer,
Sciformix, A
Covance Company



**J Vijay
Venkatraman**
Managing Director
& CEO,
Oviya MedSafe Pvt
Ltd



Retesh Kumar
Global Safety
Practice Lead,
Cognizant
Technology
Solutions



Anju Agarwal
Head, Drug Safety,
Advanz Pharma



Avinash Kakade
Sr. Director &
Head of Global
Pharmacovigilance,
Cipla Ltd



Anand Harugeri
Director, Service
Operations, PV
Project Leadership
and Strategic
Solutions, Lifecycle
Safety, IQVIA



Aamir Shaikh
Founder
Assansa

KEYNOTE SPEAKER(S)



YK Gupta
Former Dean
AIIMS



Dhanajay Bakhle
Executive Vice President
Medical Research
Lupin Ltd

MEETING MANAGER

Pradeep Dass

Sr. Manager - Business Development & Event Operations
DIA (India) Private Limited
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DIA India Pvt. Ltd.

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DIA Global Center: Washington, DC, USA | Basel, Switzerland | Beijing/Shanghai, China | Horsham, PA, USA | Mumbai, India | Tokyo, Japan

AGENDA | DAY 1 | 5TH APRIL, 2019

8:00–9:00	Registration
9:00–9:30	Opening Ceremony
9:30–10:15	Key Note Presentation Indian Clinical Trial Safety Scenario Pre & Post Schedule Y Amendment
	Y. K. Gupta Former Dean AIIMS

10:15–11:00 Tea / Coffee Break

Session # 1 Regulatory Trends in Clinical Safety & Pharmacovigilance

Session Chair
J Vijay Venkatraman
Managing Director & CEO
Oviya Medsafe Pvt Ltd

11:00–11:30 **Current Regulatory Trends in Pharmacovigilance: Managing Challenges of Ever Evolving Eudravigilance**

Mangesh Kulkarni
Practice Lead, Medical Safety
Tata Consultancy Services

11:30–12:00 **Brexit and Its Pharmacovigilance After Effects**

Seema Jaitly
Managing Director
Essjay Solutions Limited, United Kingdom

12:00–12:30 **Resolving the R3 Tangle**

Punit Wason
Senior Manager
High Point Solutions - An IQVIA Company

12:30–14:00 Networking Lunch

Session # 2 – Digital Transformation and Impact of Artificial Intelligence

Session Chair
Anju Agarwal
Head - Pharmacovigilance
Advanz Pharma

14:00–14:30 **Reimagining end to end ICSR (Individual Case Safety Report) Case processing with Artificial Intelligence**

Sowmyanarayanan Srinivasan
Managing Director
Accenture Life Sciences

Sumanta Ghosh
Pharmacovigilance Practice Lead
Accenture Lifesciences

AGENDA | DAY 1 | 5TH APRIL, 2019

14:30-15:30	Impact of Artificial Intelligence and Predictive Sciences		
	Moderator Moin Don President & CEO PVCON Consulting Pvt Ltd	Co-Moderator Anju Agarwal Head - Pharmacovigilance Advanz Pharma	
	Panelists		
	Aparna Patkar Delivery Head Tata Consultancy Services	Saurabh Khurana Practice Leader Foresight - an IQVIA company	Saikat Biswas Global Head Medical Devices, Pharma & Services Wipro
	Retesh Kumar Global Safety Practice Lead Cognizant Technology Solutions	Krishna Asvalayan CEO & Director Ancla Corporation	
15:30-16:00	Tea / Coffee Break		
	Session # 3 – Emerging Pharmacovigilance Issues & Business Models in Safety		
	Session Chair Chitra Lele Chief Scientific Officer Sciformix - A Covance Company		
16:00-16:30	Role & Significance of DSP in Evaluating ICSRs & ARs		
	Avinash Kakade Sr. Director and Head - PV Cipla Ltd		
16:30-17:00	Managing a Global PV System with Multiple QPPVs & MAs		
	Ute Heffner EU QPPV Glenmark Arzneimittel GmbH		
17:00-17:30	Outsourcing Trends in Pharmacovigilance: Improving Quality and Operational Efficiency		
	Vijaykrishnan Ganesan Associate Director - Pharmacovigilance Safety Operations PAREXEL International		

Sponsorship and Exhibit Opportunities Open!

For further information, please reach out to: **Pradeep Dass**
+91 9160535566 | Pradeep.Dass@diaglobal.org

AGENDA | DAY 2 | 6TH APRIL, 2019

9:15-10:00 **Key Note Presentation | Striking the Right Balance Between Safety and Survival: The Curious Case of Cancer Immunotherapy**

Dhananjay Bakhle
Executive Vice President - Medical Research
Lupin Ltd

10:00-10:30 Tea / Coffee Break

Session # 4 – Medical Affairs 2020 And Beyond – Essential Evolution Or Radical Revolution?

Session Chair
Aamir Shaikh
Founder
Assansa

10:30-11:00 **Cultivating Core Medical Affairs Competencies and Mindset for Success**

Aamir Shaikh
Founder
Assansa

11:00-11:30 **Medical Affairs Functions's Role | Strengthening PV Systems at Affiliate and Global Level**

Vinod Mattoo
Medical Lead India
Amgen

11:30-12:00 **Risk Based Strategies for Safety Issues in Immuno-Oncology**

Krishna Bahadursingh
Former Pharma Executive and Fellow of the Faculty of Pharmaceutical Medicine (UK)

Session # 5 - Evolving Systems and Approaches to Effective Pharmacovigilance- Middle East and

Session Chair
Anand Harugeri
Director - Service Operations, PV Project Leadership and Strategic Solutions, Lifecycle Safety
IQVIA

12:30-13:00 **Emerging Pharmacovigilance Regulatory Scenario in Middle East**

Rawya Kredly
Head - Pharmacovigilance
Julphar Pharma, UAE

13:00-13:30 **Emerging Pharmacovigilance Regulations in Emerging Markets**

Manoj Swaminathan
Head - Global Pharmacovigilance and Medical Information
Piramal Enterprises Ltd.

13:00-14:00 Networking Lunch

AGENDA | DAY 2 | 6TH APRIL, 2019

Session # 6 - Pharmacovigilance Inspection Readiness

Session Chair

Shirish Sherlekar

Global Head Life Sciences Practice & QA
Tata Consultancy Services

14:00-15:00 **Panel Discussion | Designing, Developing and Managing a Quality System for PV- What will Digitization Change?**

Moderator

Krishna Bahadursingh

Former Pharma Executive and Fellow of the Faculty of
Pharmaceutical Medicine (UK)

Co-Moderator

Shirish Sherlekar

Global Life Sciences Practice & QA
Tata Consultancy Services

Panelists

Monica Bornani

Chief Manager - Quality Assurance
Piramal Healthcare

Prashant Joshi

Director-Domain & Process, Safety and Risk Management
Sciformix - A Covance Company

Anju Agarwal

Head - Pharmacovigilance
Advanz Pharma

Shubhadeep Sinha

Head Global and Vice-President
Clinical Development and Medical Affairs
Hetero Drugs

15:00-15:30 Tea/Coffee Break

Session # 7 – Enhancing Patient Safety Through Enhanced Vigilance Practices

Session Chair

Retesh Kumar

Global Safety Practice Lead
Cognizant Technology Solutions

15:30-16:00 **Planning, Execution and Monitoring of Effectiveness of Risk Minimization Activities- Real Life Experiences**

Dnyaneshwar Sanap

Associate Director - Risk Management
Boehringer Ingelheim, Germany

16:00-16:30 **Risk and Safety Issues of Biosimilars - the Reality**

Dhanaraj E

Global Pharmacovigilance Lead
Biocon Ltd.

16:30-17:00 **Process Reengineering to Enhance Quality & Productivity to Meet Client SIAs- A Service Provider's Perspective**

Kanchan Sakhare

Manager - Process Excellence Pharmacovigilance Lead
Cognizant Technology Solutions

17:00 **Conclusion and Wrap Up**

DIA India 7th Pharmacovigilance Conference: Transforming Clinical Safety and Pharmacovigilance
Event I.D. 19650 | 5-6 April, 2019 | Courtyard by Marriott I Mumbai India

VENUE:
COURTYARD BY MARRIOTT MUMBAI INTERNATIONAL AIRPORT
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CANCELLATION POLICY: ON OR BEFORE MARCH 18, 2019

- Cancellations must be in writing and received by March 18, 2019
- Registrants who do not cancel in writing by that date and do not attend the event will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.
- DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.
- UPON CANCELLATION, the administrative fee that will be withheld from refund amount is 25 % of the delegate fee

FULL MEETING CANCELLATION

- All refunds will be issued in the currency of the original payment

Online registrations: visit our website www.diaglobal.org

REGISTRATION FEES FOR TWO DAYS CONFERENCE (*Registration fee includes refreshment breaks and luncheons.*)

	Basic Rate (INR)	GST Tax 18 %(INR)	Total INR
Early Bird Fee on or before 11th March, 2019 (Subject to Payment Realization)			
INDUSTRY MEMBER	9000	1620	10620 <input type="checkbox"/>
INDUSTRY NON- MEMBER	11000	1980	12980 <input type="checkbox"/>
ACADEMIA / GOVERNMENT	8000	1440	9440 <input type="checkbox"/>
STUDENT	5000	900	5900 <input type="checkbox"/>
Standard			
INDUSTRY MEMBER	10000	1800	11800 <input type="checkbox"/>
INDUSTRY NON- MEMBER	12000	2160	14160 <input type="checkbox"/>
ACADEMIA / GOVERNMENT	8000	1440	9440 <input type="checkbox"/>
STUDENT	5000	900	5900 <input type="checkbox"/>

GROUP DISCOUNT : REGISTER 10 FROM YOUR COMPANY AND RECEIVE THE 11 FREE!

DIA MEMBERSHIP

Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diahomes.org and click on Membership for more details

PRIVACY POLICY

DIA respects the privacy of all of its members and customers. To view our policy click the link below
<https://www.diaglobal.org/en/about-us/privacy-policy>
You agree that your personal data will be transferred to DIA in the US.

STUDENT REGISTRATIONS

A student is an undergraduate/graduate who can document enrollment in a signature accredited, degree granting, academic program. Please send completed registration form, payment and copy of student identification.

CHEQUE / DRAFT

Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:

Bhavesh Vora

Senior Executive Accounts
Bhavesh.vora@diaglobal.org
DIA India Pvt. Ltd.

Office No. 250, Unit 1, Level 2, B Wing, Times Square, Andheri Kurla Road, Andheri East, Mumbai 400059
tel: +91 22.6608 9588 | cell: +91 98.2097.2630

PAYMENT DETAILS

Account Name: DIA (INDIA) PRIVATE LIMITED

Account No: 061010200024611

bank Name: AXIS BANK LIMITED

Branch Name: Dhiraj Baug, Near Hari Niwas Circle, LBS Marg, Thane (W) - 400602

IFSC Code: UTIB00000061

MICR Code: 400211013

Swift Code: AXISINBB061

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Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:

Bhavesh Vora

Senior Executive Accounts

bhavesh.vora@diaglobal.org | cell : +91 98 2097 2630

Please check the applicable category:

Industry Government Academia Student

PLEASE PRINT ALL INFORMATION CLEARLY

Last Name

First Name

M.I.

Please check one: Mr. Ms. Prof. Dr.

Job Position

Affiliation (Company)

Business Address

Home Address

Address (Please write your address in the format required for delivery to your country.)

City

Postal

Country/Region

Address

Telephone Number

Fax Number

Mobile Number (Required)

Email (Required for confirmation)

IF FAXING OR MAILING THIS FORM, PLEASE PROVIDE A COPY OF REGISTRANT'S BUSINESS CARD.