

# Innovations in Pharmacovigilance – the era of e-PV

Meeting ID 16650

May 13-14, 2016 | Holiday Inn, Mumbai

## PROGRAM CHAIR



**Moin Don**  
CEO and President  
PVCON

## PROGRAM VICE CHAIR



**Vivek Ahuja**  
VP Global  
Pharmacovigilance  
ArisGlobal

## KEYNOTE SPEAKER



**Stewart Geary**  
Chief Medical Officer,  
Vice President and General  
Manager, Eisai



**David Balderson**  
Global Vice President Safety  
Operations, Sciformix

## ADVISORY COMMITTEE

**Arun Bhatt**  
Consultant – Clinical Research & Development

**Chitra Lele**  
Chief Scientific Officer  
Sciformix

**Himanshu Verma**  
Head Life Sciences  
Cognizant

**Shravanti Bhowmik**  
Associate VP, Clinical Research,  
Sun Pharma

**Sibin Kurian**  
Head, DS&E, Hyderabad  
Clinical Scientific Director – Established  
Medicines  
Drug Safety & Epidemiology  
Novartis Pharmaceuticals Private Limited

## PROGRAM COMMITTEE

**Anish Desai**  
Medical Director – Medical Devices  
Johnson & Johnson

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

**Jamal Anwar Baig**  
Country Head- Pharmacovigilance  
Merck Sharp & Dohme

**Mangesh Kulkarni**  
Head Safety Operations (Pharmacovigilance),  
Global Drug Safety & Epidemiology  
Novartis

**Manoj Swaminathan**  
Lead - Pharmacovigilance & Medical Information  
Brill Pharma

**Milind Sardesai**  
GM – Medical Safety Services  
Cognizant

**Retesh Kumar**  
Senior Business Consultant and  
Engagement Lead  
TCS

The discipline of pharmacovigilance has undergone immense transformation throughout the world, in the last decade than ever before. With more regulatory actions being pronounced and with many countries enacting pharmacovigilance legislations, it is being increasingly recognized that patient safety is a concern for not only the regulators but other stakeholders too. Application and adoption of appropriate technology coupled with the exponential growth in the science of pharmacovigilance is revolutionizing patient safety in real time. Developing innovative workflows and deployment of relevant automation in carrying out pharmacovigilance activities indicates that the era of Electronic Pharmacovigilance has already arrived and is here to stay. Today, India holds a unique position in the pharmacovigilance space as the most preferred destination for global pharmaceutical companies to outsource their drug safety activities. In parallel, India is also firming up the country's regulatory system to ensure utmost safety in clinical trials as well as in the post-marketing stages, which is a significant step into a promising future.

This conference aspires to bring together thought leaders representing many of the stakeholders of pharmacovigilance to deliberate the current best practices, debate on the available technology tools for data mining, elucidate on novel initiatives to augment handling of drug safety data and many other niche topics, with the focus being on pharmacovigilance and related professionals in India. The two-day conference will ensure enough opportunity to interact with speakers and colleagues from the entire spectrum of the pharmacovigilance domain in India."

## Program Highlights

- Post Marketing Safety Studies in era of e PV
- Clinical Trial Safety – The Indian Scenario
- Increasing trends of e-Submission by Regulators
- Innovative Models in Pharmacovigilance Operations
- Mining Drug Safety Insights from Social Media
- Cutting Edge Technologies to Handle Safety Data
- Global Perspectives of Benefit-Risk Assessment
- Signals Detected from Indian Drug Safety Data
- Pharmacovigilance of Vaccines, Biologics & Medical Devices

## Learning Objectives

At the end of this conference, the participants should be able to:

- Comprehend multiple facets of global drug safety concepts along with insights on Indian pharmacovigilance
- Understand how new technologies can help in improving adverse event reporting and processing of safety data
- Discuss the advancements in pharmacovigilance in the European Union and how it influences the global drug safety
- Brainstorm on special interests like pharmacovigilance of vaccines, biologics, medical devices & alternative medicines



**DIA India Pvt. Ltd.**

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# AGENDA

## DAY 1 | Friday, 13th May

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8:30–9:30 **REGISTRATION**

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9:30–9:45 **OPENING CEREMONY**

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9:45–10:30 **KEYNOTE PRESENTATION**

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*“The role of Post Marketing Safety Studies in Pharmacovigilance in the era of ePV”*

**Stewart Geary**

Chief Medical Officer, Vice President and General Manager  
Eisai

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10:30 – 11:00 **Tea / Coffee Break**

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11:00 – 12:30 **Session 1: e-PV**

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Session Chair

**Stewart Geary**

Chief Medical Officer, Vice President and General Manager  
Eisai

Speakers

*“From Paper to E Submissions – New Emerging Regulatory Requirements”*

**Dr Seema Jaitly**

Managing Director, Essjay Solutions Ltd

*E Signaling – Technology to aid Signal detection*

**Sameer Thapar**

Global PV Operations & Quality Assurance, Oracle

*Understanding: Eudravigilance & XEVMPD*

**Jose Alberto Ayala Ortiz**

CEO, Pharmacovigilance consultant, PVpharm

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12:30 – 13:30 **Lunch**

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13:30 – 15:00 **SESSION 2: Regulatory**

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Session Chair

**Y K Gupta**

Head, Dept. Of Pharmacology, AIIMS

Panel Discussion | 13:30 – 14:30

*Drug Related Injuries during Clinical Trials & Compensation Enigma?*

Moderator

**Moin Don**

CEO & President, PVCON

Panelists

**Suneela Thatte**

Vice President Global Operations, Quintiles

**Renuka Munshi**

Associate Professor & Head, Dept. Of Pharmacology,  
T N Medical College & BYL Nair Hospital

**Swapnali Raut**

Director Compliance & Oversight, Pfizer

**Y K Gupta**

Head, Dept. Of Pharmacology, AIIMS

Speaker

*PVPI Recommendation & Regulatory Actions*

**V Kalaiselvan**

Principal Scientific Officer, Indian Pharmacopoeia Commission  
Ministry of Health and Family Welfare, Govt of India

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15:00 – 15:30 **Tea / Coffee Break**

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15:30 – 17:30 **SESSION 3: PV Sciences**

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Session Chair

**Sibin Kurian**

Head, DS & E, Clinical Scientific Director  
Novartis Pharmaceuticals Pvt. Ltd.

Speakers

*New PBRER Challenges Evaluation of Benefit V/S. Risk*

**Sibin Kurian**

Head, DS & E, Clinical Scientific Director  
Novartis Pharmaceuticals Pvt. Ltd.

*Medical Device Vigilance*

**Christine G Lim**

Head, Regional Medical Safety (APAC, EMEA and LATAM)  
Medical Devices, J&J

Panel Discussion | 16:30 – 17:30

*Medical Evaluation of Aggregate Reports & RMP's*

Moderator

**Milind Sardesai**

GM- Medical Safety Services, Cognizant

Panelists

**Ambili Bhaskaran**

Team Manager Medical Safety, Cognizant

**Pooja Jadhav**

Drug Safety Physician, Sun Pharma

**Sanyogita Rane**

Sr. Lead Safety Physician, Sciformix

**Gunjan Shah**

Delivery Manager, Sciformix

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17:30

**END OF FIRST DAY**

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# AGENDA

## DAY 2 | Saturday, 14th May

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### 9:30 – 10:00 KEYNOTE PRESENTATION

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#### *Social Media the New Challenge in PV*

David Balderson

Global Vice President Safety Operations, Sciformix

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### 10:00 – 10:30 Tea / Coffee Break

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### 10:30 – 12:30 Session 4: PV Tools

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#### Session Chair

Rajesh Jain

Director Operations, Cognizant

#### Speakers

#### *A SWOT Analysis of Hosted Pharmacovigilance Systems*

Jayathirtha Gopalakrishna

Principal Sales Consultant, Oracle Inc

#### *Global Literature Search Tools, & Challenges Facing Pharma Companies*

Sameer Thapar

Global PV Operations & Quality Assurance, Oracle

#### *Risk Based Validation*

Balaji Shantharam & Padmanabhan G M

Compliance Lead, ArisGlobal

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### 12:30 – 14:00 Session 5: Emerging PV Areas

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#### Session Chair

Shravanti Bhowmik

Associate Vice President, Clinical Research, Sun Pharma

#### Speakers

#### *Vaccine Vigilance*

Sanjay T Gandhi

Vice President Public Health, GSK

#### *Pharmaco Environmentology – Aligning PhV with Environment*

Syed Ziaur Rahman

Associate Prof. - Dept. of Clinical Pharmacology

Aligarh Muslim University

#### *Safety Reporting using Mobile Applications*

Sachin Kuchya

Associate Professor in Pharmacology, NSCB Medical College

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### 14:00 – 14:45 Lunch

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### 14:45 – 16:30 SESSION 6: PV Miscellanea

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#### Session Chair

Dr. Jamal Baig

Country Head Pharmacovigilance, Merck Sharp & Dohme

#### Panel Discussion | 14:45 – 15:30

#### *Destination India - PV outsourcing*

#### Moderator

Dr J Vijay Venkatraman

Managing Director & CEO, Oviya Medsafe Pvt. Ltd.

#### Panelists

Rajesh Jain

Director Operations, Cognizant

Shefali Gupta

Head of Strategic Initiatives , LS - BPS TCS

Sumanta Ghosh

VP Operations, PV Capability Lead, Accenture

Vineet Shastri

Sr. Director & Head, Life Style Medical Services, Global Delivery Network, Quintiles

#### Speakers

#### *Talent Acquisition, Training, & Attrition Challenges*

Manish Paralikar

Process Excellence Lead - Life Sciences BPS, Cognizant

#### *An Insight into REMS as Risk Management Tool for FDA*

Sanjeev Miglani

Head PV, US Operations, APCER Life Sciences

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### 16:30 – 17:00 Conference Wrap Up

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### 17:00 Tea / Coffee

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Innovations in Pharmacovigilance – the era of e-PV  
Event I.D. 16650 | May 13-14, 2016 | Holiday Inn Mumbai, India

**VENUE: Holiday Inn Mumbai International Airport**

Sakinaka Junction, Andheri Kurla Road,  
Andheri East, Mumbai - 400072.  
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**CONTACT**

Nandita Sarmah, Reservations, Holiday Inn Mumbai International  
Airport. | +91-9004617703 | email:nandita.sarmah@himia.in  
Please mention booking for DIA conference to avail of discounted  
room rate. Valid upto : 6th May 2016

**MEETING MANAGER**

Manoj TRIVEDI, Senior Manager, Business Development  
DIA (India) Private Limited  
cell: +91 98.1977.7493 | Manoj.Trivedi@diaindia.org

**CANCELLATION POLICY: ON OR BEFORE MAY 1, 2016**

- Cancellations must be in writing and received by MAY 1, 2016. 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

For more details, please visit [www.DIAglobal.org](http://www.DIAglobal.org)

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

**Early Bird on or before 15<sup>th</sup> April 2016**

	BASIC RATE (INR)	SERVICE TAX 14.5 %(INR)	TOTAL INR
INDUSTRY MEMBER	8000	1160	9160 <input type="checkbox"/>
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ACADEMIA / GOVERNMENT	8000	1160	9160 <input type="checkbox"/>
STUDENT	5000	725	5725 <input type="checkbox"/>

**After 15<sup>th</sup> April 2016**

	BASIC RATE (INR)	SERVICE TAX 14.5 %(INR)	TOTAL INR
INDUSTRY MEMBER	9000	1305	10305 <input type="checkbox"/>
INDUSTRY NON- MEMBER	11000	1595	12595 <input type="checkbox"/>
ACADEMIA / GOVERNMENT	8000	1160	9160 <input type="checkbox"/>
STUDENT	5000	725	5725 <input type="checkbox"/>

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**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.

**DRUG INFORMATION ASSOCIATION**

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**PAYMENT DETAILS**

Account Name: DIA (INDIA) PRIVATE LIMITED  
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**PAYMENT INFORMATION**

Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:  
Bhavesh Vora  
Senior Executive Accounts  
[Bhavesh.Vora@diaindia.org](mailto:Bhavesh.Vora@diaindia.org) | cell : +9198.20972630

**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.



# Application and Contract form for Support Opportunity and Tabletop display

# DIA

Innovations in Pharmacovigilance – the era of e-PV

May 13-14, 2016 | Holiday Inn, Mumbai

Meeting ID 16650

## Company Contact Information

Exhibiting Company Name *(for signage and directory listing)*

Contact Name  
*(all correspondence will be sent to the contact information provided below)*

Address Line 1

Address Line 2

City, State, Postal Code, Country

Telephone Number

Fax Number

Email Address *(required for confirmation)*

## Exhibit Space Rates and Information

**Tabletop: INR 75000+Service Tax**

Each tabletop includes one and one (1) exhibit personnel registration. Any staff required above those allotted per tabletop must register as a full attendee incurring full registration fees.

Services/Products to be exhibited:

## Cancellation Policy

Cancellations requests MUST be in writing and may be emailed to [manoj.trivedi@diaglobal.org](mailto:manoj.trivedi@diaglobal.org).

Cancellation fees are non-transferable.  
Cancellation/Downsizing fees will be withheld as follows:  
Notifications received on or before **May 10,2016 = 50% FEE**  
Notifications received after **May 10,2016 = NO REFUND**

## Meeting Manager

Manoj Trivedi | Senior Manager Business Development  
Phone: +91.22.67653226 Cell:9819777493,  
Email: [manoj.trivedi@diaglobal.org](mailto:manoj.trivedi@diaglobal.org)  
[www.diaglobal.org](http://www.diaglobal.org)

## Billing Information

Check here if billing address is the same as the contact's address

Billing Company Name *(for invoice)*

Contact Name

Address Line 1

Address Line 2

City, State, Postal Code, Country

Email Address *(where invoice should be sent)*

## Payment Options and Information

Payment may be made only by demand draft/cheque. Please note that exhibiting companies with an outstanding balance will be prohibited from moving in at The Holiday Inn Mumbai.

**Demand Draft/Cheque**

Should be made payable to **DIA (India) Private Limited** and sent to

DIA (India) Pvt. Ltd.  
Office No. 250, Unit 1, Level 2, B Wing, Times Square,  
Andheri-Kurla Road, Marol  
Andheri (East), Mumbai 400 059, India

## Contract Signature

The undersigned hereby authorizes DIA to reserve exhibit space in The Holiday Inn Mumbai for use by the above company or organization during the Innovations in Pharmacovigilance - the era of e-PV meeting. DIA reserves the right in its sole and absolute discretion to reject any application that in its judgment does not enhance the purpose of the Innovations in Pharmacovigilance - the era of e-PV meeting and its associated Exposition or is in direct competition with DIA. This contract shall be deemed accepted by DIA when received, together with the required payment. However, no contract shall be deemed accepted if the contracting exhibitor has outstanding financial obligations to DIA, of which DIA is aware, for booth space, advertising, or any service(s) provided by DIA.

After signing the agreement DIA should receive the payment within 15 days

Authorized signature

Date

**DIA (India) Private Limited**  
Andheri-Kurla Road, Marol  
Andheri (East)  
Mumbai 400 059  
India

Completed form should be emailed to [manoj.trivedi@diaglobal.org](mailto:manoj.trivedi@diaglobal.org)