A network for Heads of Safety of Indian Life Science companies & multi-nationals with a presence in the Indian market

pvindia

What topics will the pvindia Forum cover?

Continue the PV excellence journey – current and future

- Global and domestic regulatory update
- PV today – moving towards operational excellence
- PV Vision 2025 – Continue the visioning journey

What our members say

"The event was simply excellent and we could learn a lot and gain insight on the subject from other companies. We certainly look forward to attending the next pvindia forum"

- Chief Manager - Head of Global PV, Top 10 Pharma Company

"*The forum meetings and the gathering of peers is always a fantastic opportunity to network and gain insight, excellent leadership through the sessions - thank you*"

- Global Head of Pharmacovigilance, Top 10 Global Pharma Company

"*Our experience with Navitas Networks confirms the membership provides a unique opportunity to uncover strategic and operational insights, which we then apply across our Global PV business, it is highly valuable in shaping our future PV direction*"

- Head of PV operations - Top 5 Global Pharma Company

Following the successful launch of pvindia in 2016, with participation from: Ajantha, Akums, Alkem, Allergan, Amgen, Bayer, Bliss GVS, Boehringer Ingelheim, Inventia, Cipla, Colgate Palmolive, Concordia, Ferring, Glenmark, GSK, Hetero Drugs, IPCA, J B Chemicals, J&J, Macleods, Mankind, Marksans, Merck and Co, Merck Group, Mylan, NATCO, Novartis, Novo Nordisk, Piramal, Reliance, Roche, Sanofi, Torrent, and Unichem. We are delighted to be hosting our seventh event.

pvindia leverages the approach, format, and experience gained from successfully running pvnetworks over the past 15 years in Europe and the USA. This is a unique opportunity to be part of the industry leading global network for Pharmacovigilance professionals.

Whilst we believe that drug safety can be a source of competitive advantage, we see a greater mutual benefit in sharing experience and common challenges. Through our pharmacovigilance networks; pvnet, pvconnect, pvtech, and pvindia, our vision is to shape the future of pharmacovigilance by providing PV leaders with an environment to meet and discuss alternative solutions with other industry thought leaders and enable ongoing improvements.

What is pvindia?

Launched in March, 2016 **pvindia** provides a neutral platform for pharmacovigilance leaders facing similar challenges to network, debate, compare performance, and share ideas on how to tackle the latest hot issues.

For information on our upcoming forums and events, please visit **www.navitaslifesciences.com/nets**

Who should participate in the pvindia forum?

- Global or Regional Heads of Safety/Pharmacovigilance
- PV Senior leadership teams at Life Science companies with Pharma, Consumer, Generics, or Mixed Portfolios, responsible for deploying the PV Strategy and System within their organisation

Why come to the pvindia meeting?

- Be part of the only global PV network
- Over 50 global member companies
- Hear the very latest Global Regulatory and industry insights with representation from Health Authorities
- Compare your PV performance with Industry-wide benchmark data
- Unique networking opportunities with Global PV peers
- Hear case studies from Global Industry Leaders
- Discuss and develop strategies and best practices with Indian PV leaders
- Explore and debate how the Indian PV Region brings value to the Global PV system
- 300+ global industry professionals participate in our meetings each year

Who to contact

For further information or to register your interest in participating, please contact a member of our networks team at: pvindia@navitaslifesciences.com

A summary of the key topics discussed at **pvindia** to date

October 2018 - themes	• Latest regulatory challenges – tackling GDPR • Technology for automation in PV space • PSMF – compliance to Automation • SDEA – blue print for success	**Speakers from: Cipla, Glenmark, Oracle, Piramal, and Roche**
March 7th 2018 - Themes	**The PV change journey - continued** • Reflections on PvGI implementation • E2B (R3) expectation vs. reality • Managing PV change and growth	**Speakers from: Concordia, J&J, and PvPI**
March 16th 2017 - themes	**The latest PV Regulatory context** • Crunch time for EudraVigilance: latest framework/timelines • Experience sharing of cross country regulations • Deep dive and industry discussion on PvGI guidelines	**Speakers from: PvPI**
October 25th 2016 – themes	**PV 360 - regulations, process, technology** • Global regulatory update - crunch time for Eudravigilance • Current tech landscape, future outlook and the possibilities for automation • Getting clarity on PvGI and the impact on the PV system globally and locally	**Speakers from: PvPI** **Case studies: Glenmark Macleods**

Key "take outs" from previous pvindia meetings

GDPR Compliance, Technology for Automation, PSMF & SDEA (October 2018)

Observations	Challenges	Opportunities
• PV changes is moving from incremental to transformational • Patient centric PV is a good concept but it is futuristic	• Compliance issues in managing Safety Data Exchange Agreements • Preparation & maintenance of PSMFs • Continued lack of clarity of domestic PV Regulations	• Leveraging PV Automation technologies (RPA and AI) to improves process efficiency • IDMP readiness from PV point-of-view • Automation of PSMF and SDEA

Technology upgrade, clarity of PvPi Regulations, PV automation (March 2018)

Observations	Challenges	Opportunities
• Technology upgrade (Argus 8.x, E2B R3, vendor readiness) • GDPR and Brexit will be near term key priorities • Deeper understanding of PvGI guidelines around areas such as Periodic Reporting, RMP, and Labeling	• Lack of automation solutions to handle increase of MLM/L2A case volumes • Lack of clarity in India Regulatory Authorities' role: PvPi, CDSCO, and DCGI • Managing PV change during M&A - people, process, and technology	• PV ecosystem is set to transform or evolve over the next 3 years - need to be ready • PvPi inspections are now expected. Preparation is important • More streamlined ways of handling signal detection and risk management

Update and discussion on PvGI (Mar 2017)

Observations	Challenges	Opportunities
• Ongoing dialogue between pvindia and PvPI since October 2016 • Positive sentiment about the spirit of the new regulations • Aspiration to add global value and enhance patient safety	• Complexity in the detail of the PvGI that requires further dialogue and agreement • Implementation timeline not yet clear • Interface and influence between global and local needed for implementation • New skills, processes and technology may be needed	• Required resource qualifications • Data needed for AE reporting purposes • Alignment with global reporting timelines • Requirements for having an RMP

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