



SAFETY360°: DIA Conference on Clinical & Post-Market Safety

Advancing Safety Science for Patient and Consumer Protection: An integrated lifecycle approach Clinical safety, Pharmacovigilance, Materiovigilance, and Cosmetovigilance.

June 11-12, 2026 | AIG Hospital Auditorium, Hyderabad, INDIA



The DIA SAFETY360° Conference on Clinical & Post-Market Safety 2026 brings together regulators, industry, and academia to advance an integrated approach to drug, device, and cosmetic safety – from clinical development to real-world use. The conference offers a neutral and comprehensive platform to examine healthcare product safety across the full lifecycle, addressing evolving expectations in clinical safety, pharmacovigilance, materiovigilance, and cosmetovigilance. Through expert-led discussions, the programme highlights advance in safety science, regulatory convergence, digital innovation, and real-world evidence to strengthen patient and consumer protection.

WHAT TO EXPECT

Learning Objectives

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

- Understand evolving regulatory expectations across clinical safety, pharmacovigilance, materiovigilance, and cosmetovigilance
- Apply a lifecycle-based approach to safety for drugs, medical devices, and cosmetics
- Leverage real-world evidence and digital tools to support safety decision-making
- Anticipate emerging trends in safety science to strengthen patient and consumer protection.

Featured Topics

- AI as a Regulated Enterprise Capability in Pharmacovigilance
- Lifecycle Safety Integration Across Product Categories
- Real-World Evidence for Proactive Benefit–Risk Management
- Inspection Readiness and PV Quality by Design
- Evolving Safety Paradigms for Complex and high-impact Therapies

Target Audiences (Who Should Attend)

This conference is designed for professionals involved in the development, regulation, and oversight of safety of healthcare products, including:

- Regulators and policy makers in drug, medical device, and cosmetic safety
- Clinical research, clinical safety, and pharmacovigilance professionals
- Materiovigilance and cosmetovigilance practitioners
- Regulatory affairs, quality, and compliance leaders
- Medical affairs, risk management, and safety scientists
- Data, digital, and real-world evidence professionals supporting safety functions
- Academia, researchers, and subject-matter experts in safety science

PROGRAM COMMITTEE



Vivek Ahuja, MD, MBA
Program Chair,
Executive Vice
President,
Pharmacovigilance
EVERSANA



**J Vijay
Venkatraman, MD,
MBA**
Program Co-Chair,
Managing Director
and CEO
Oviya Medsafe Pvt
Ltd



Kamal Shahani
Managing Director
Tenet Health Edutech
Pvt. Ltd. (Cliniminds,
CRQA, Thinki &
Mediminds)



Gurpreet Singh
Lifesciences & Pharma
Business Leader



Nitu Sinha
Vice President &
Global Head
Mankind Pharma Ltd



Kausik Maiti, MD
Executive Director,
Safety Medical
Sciences
Parexel International



Sumati Randeo
MD & Founder
QR Synergies



**Retesh Bhumbak,
MD**
World Wide Patient
Safety Site Head-
Hyderabad
Bristol Myers Squibb



**Sanjeev Sachdeva,
MCA**
Global Head - Advisory
and Business Process
Services, Life
Sciences
Tata Consultancy
Services



Avinash Kakade
Sr Vice President
Global Head of
Pharmacovigilance
Dr Reddy's Laboratories

AGENDA: Day 1, 11 June 2026; Thursday

8:00-8:45AM

Registration and Welcome Coffee

8:45- 9:00 AM

Opening Remarks- DIA

Dr Ashok Swain, General Manager, Executive Director, DIA India

9:00-9:30 AM

Keynote Address

Vivek Ahuja, MD, MBA, Program Chair, Executive Vice President, Pharmacovigilance, EVERSANA

9:30-9:45 AM

Opening Keynote Address: AI in Gastrosience enhancing Patient Safety

Dr G.V. Rao, Director, AIG Hospital, Gachibowli, Hyderabad

9:45-10:45AM

Session 1: REGULATORS INTERACTION

Session Chair(s): Kamal Shahani, Managing Director, Tenet Health Edutech Pvt. Ltd. (Cliniminds, CRQA, Thinki & Mediminds)

Session Overview: This session will explore evolving, 360-degree engagement between industry and regulators across the clinical and post-marketing safety continuum. Discussion will focus on proactive communication strategies, expectation setting for safety data, signal detection and management, benefit-risk assessment, and use of real-world evidence. Speakers will share recent experiences with regulatory queries, inspections, labeling negotiations, and risk-minimization commitments, highlighting best practices, common pitfalls, and opportunities to leverage digital tools and advanced analytics to enhance transparency, timeliness, and trust in safety decision-making.

Panel Discussion: Strengthening Pharmacovigilance in India: From Compliance to Public Health Impact

Moderator: Dr Vivek Ahuja, Executive Vice President, Pharmacovigilance
EVERSANA

1. **Dr Om Prakash Sadhwani**, former Maharashtra Drug Controller
2. **Shri Guguloth Ramdhan**, Joint Director & Licensing Authority (SLA), Drugs Control Administration (DCA), Government of Telangana, Hyderabad
3. **Dr. K. Narendran**, Deputy Drugs Controller (India), DDC(I), CDSCO, Zonal Office & Central Drugs Testing Laboratory (CDTL), Hyderabad

10:45-11:45AM

Tea/Coffee & Networking Activity (we have to design here the networking activities, so that it serves as an ice breaker)

11:45-1:10 PM

Session 2: AI IN PV

Session Chair(s): Sanjeev Sachdeva, Global Head - Advisory and Business Process Services, Life Sciences, Tata Consultancy Services

Session Overview: AI in Pharmacovigilance session provides drug safety professionals with a forward-looking perspective on how artificial intelligence is reshaping PV practices across the safety lifecycle. Moving beyond pilots and experimentation, the session focuses on what it takes to deploy AI with confidence, control, and measurable impact in regulated pharmacovigilance environments. The session opens with an expert perspective on the evolution of AI in PV, highlighting why the industry has reached a pivotal inflection point. This sets the stage for a high-impact panel discussion on agents with agency—AI systems that can reason, critique, and adapt across PV workflows. The discussion explores organizational readiness, regulatory expectations, validation, and the balance between system autonomy and human oversight. The session concludes with a real-world case study demonstrating how AI can be operationalised at scale in pharmacovigilance, translating strategic vision into production-ready deployment while maintaining quality, compliance, and auditability. Session delivers a cohesive narrative that blends strategic insight, regulatory realism, and operational depth—making this session essential for leaders and decision-makers shaping the future of pharmacovigilance, patient safety, and AI-enabled risk management at enterprise scale.

11:45-12:05 PM

S2.T1: Making Agentic AI in pharmacovigilance real and scalable

Narayanan R., Head of Product Strategy and Management, Tata Consultancy Services (TCS)

12:05-12:50 PM

S2.T2: Panel Discussion with Q&A: Agents with agency for Pharmacovigilance - Are we ready?

Moderator: Sanjeev Sachdeva, Global Head - Advisory and Business Process Services, Life Sciences, Tata Consultancy Services

Panelists:

1. **Dr Siva Kumar Buddha**, Medical Director Global Patient Safety, Amgen
2. **Dr Vasanth Gadipe**, Medical Director, BMS
3. **Dr Vivek Ahuja**, Executive Vice President, Pharmacovigilance, EVERSANA
4. **Mohan Kumar Adishesha**, VP, Business Consulting, Aris Global

12:50-1:10 PM

S2.T3: Operationalizing AI in Pharmacovigilance at Scale

Mohan Kumar Adishesha, VP, Business Consulting, Aris Global

1:10-2:10 PM

Lunch Break

2:10-3:35 PM

Session 3: MATEROVIGILANCE

Session Chair(s): Sumati Randeo, MD & Founder QR Synergies

Session Overview: DIA invites industry leaders to a focused session on strengthening medical device safety through regulatory alignment, robust vigilance practices, and collaborative action. This session will explore how evolving regulatory frameworks intersect with global standards and what that means for manufacturers, regulators, and healthcare providers. Attendees will examine practical approaches to turning adverse event data into effective risk mitigation, covering reporting pathways, root cause analysis, and corrective and preventive strategies that improve device performance and patient outcomes. A multi-stakeholder dialogue will highlight ways to elevate reporting culture and data quality, balance innovation with patient safety, and foster transparency and shared accountability across the ecosystem.

Participants will gain actionable insights for harmonizing compliance strategies, enhancing post-market surveillance, and implementing scalable vigilance processes that reduce risk and support product lifecycle management. This session is designed for senior executives, regulatory affairs and quality leaders, clinical safety professionals, and policy makers seeking high-value, practical guidance. Join peers, regulators, clinicians, and patient advocates to exchange best practices, identify collaboration opportunities, and leave with a clear roadmap to strengthen Materiovigilance Program, protecting patients while enabling responsible innovation.

2:10-2:30 PM	S3.T1: Global Medical Device Reporting and Materiovigilance Program in India: Building a Unified Safety Framework for Medical Devices Miang (Chanaporn) Tanakasemsub, Regional RA head, APJ Vision, Johnson & Johnson – Singapore
2:30-3:15 PM	S3.T2: Panel Discussion with Q&A: Collaborative Pathways for Materiovigilance: Bridging Regulators, Industry and Healthcare Providers Moderator: Sumati Randeo, MD & Founder QR Synergies Panelists: Speakers with the additional presence of 3. Dr. Shatrúnajay Shukla, Ph.D., M.S. (Pharm.), Scientific Officer, Materiovigilance Programme of India (MvPI)/Medical Device Division (MDD), Indian Pharmacopoeia Commission (IPC) 4. Prashanth Prabhakar - Associate Director Regulatory Affairs, India & ASEAN, Boston Scientific 5. Rajat Saxena, Lead Quality & Regulatory Affairs SEA & India SC, Cordis 6. Preety Sharma, Head- Regulatory Affairs, Edwards Lifesciences
3:15 - 3:35 PM	S3.T3: From Adverse Event Reporting to Risk Mitigation: Strengthening Medical Device Reporting / Materiovigilance Systems Dr Rama Sethuraman, Head of Quality and Regulatory Asia Pacific, Roche
3:35 - 4:05 PM	Tea/Coffee & Networking Break
4:05 - 5:35 PM	Session 4: QUALITY MANAGEMENT SYSTEMS Session Chair(s): Retesh Bhumbak, World Wide Patient Safety Site Head- Hyderabad Bristol Myers Squibb Session Co Chair: Kausik Maiti, Executive Director, Safety Medical Sciences Parexel International Session Overview: Quality Management Systems are no longer static compliance constructs in Pharmacovigilance; they are dynamic enablers of patient safety, organizational resilience, and regulatory confidence. This session sets the stage to reflect on how robust QMS frameworks support end-to-end safety operations—ensuring consistency, transparency, and continuous improvement in an increasingly complex environment. We will explore how quality thinking is embedded across processes, partnerships, and technologies, and how a strong quality culture helps organizations move from reactive issue management to proactive risk anticipation, ultimately strengthening trust in Pharmacovigilance outcomes.
4:05 - 4:25 PM	S4.T1: From Compliance to Intelligence - Reimagining QMS in PV Arunima Sen, Associate Vice President, Lead-Global Pharmacovigilance Operations, Product Safety and Risk Management, Viatris
4:25-5:15 PM	S4.T2: Panel Discussion with Q&A: CAPA That Sticks: Turning Findings into Preventive System Change Moderator: Retesh Bhumbak, World Wide Patient Safety Site Head- Hyderabad Bristol Myers Squibb Kausik Maiti, Executive Director, Safety Medical Sciences, Parexel International Panelists: 1. Joydeep Sengupta, General Manager and Global Head of Pharmacovigilance, Curateq Biologics 2. Anju Agarwal, Global Director -Patient Safety, ADVANZ PHARMA 3. Ankur Borkakoty, Head- Safety Case Processing, Novartis 4. Dr. Sailaja Sayana, Medical Safety Group Head, SANDOZ

5:15-5:35 PM

S4.T3: A PV QMS Turnaround Story: From Inspection-Readiness Assessment to Sustained Readiness

Kausik Maiti, Executive Director, Safety Medical Sciences, Parexel International

5:35-5:45PM

Day End / Wrap Up

AGENDA: Day 2, 12 June 2026; Friday

8:30-9:00 AM

Registration and Welcome Coffee

9:00-9:15 AM

Recap of Day 1 by Program Co Chair

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

9:15-9:30 AM

Keynote Address: Advancing Medical Device Safety through Materiovigilance: The Indian Experience

Dr. Shatrúnajay Shukla, Ph.D., M.S. (Pharm.), Scientific Officer, Materiovigilance Programme of India (MvPI)/Medical Device Division (MDD), Indian Pharmacopoeia Commission (IPC)

9:30-11:00 AM

Session 5: PV FOR BIOLOGICS/BIOSIMILARS

Session Chair(s): Dr Shubhadeep Sinha, Sr. Vice President & Medical Director, Hetero

Session Overview: PV for Biologics/Biosimilars session will highlight end-to-end (“360°”) safety management for biologics and biosimilars, focusing on proactive risk identification, real-world evidence integration, and continuous benefit–risk evaluation. This session will bring together perspectives from industry, regulators, and clinical experts and will equip attendees with actionable strategies to strengthen pharmacovigilance systems for biologics and biosimilars, ensuring patient safety, regulatory compliance, and sustained trust in these critical therapies. Participants will gain insights into how PV systems are evolving to address product variability, traceability challenges, and switching/interchangeability considerations, which are critical for these therapies.

9:30-9:50 AM

S5.T1 Patient Safety in Biologics’ Therapies

Dr Vamshi Krishna- MD, DM (Medical Oncology), Director and Head, Medical Oncology and Hematology, Institute of Oncology AIG Hospitals, Hyderabad

9:50-10:40 AM

S5.T2: Panel Discussion with Q&A: Collaborations from Regulators, MAH and Cross Functional Stockholders for PV for Biologics/Biosimilar

Moderator: Dr Shubhadeep Sinha, Sr. Vice President & Medical Director, Hetero

Panelists: Speakers with the additional presence of:

2. **Dr Bikash Medhi**, Head of Department, Pharmacology, PGIMER Chandigarh
3. **Debashish Dutta**, Vertical Head, Global Regulatory Affairs, Dr. Reddy's Laboratories Ltd., Biologics
4. **Dr Pranjal Bordoloi, MD**, Senior Vice President | Late Phase – Operations, Lambda Therapeutic Research Ltd.

10:40-11:00 AM

S5.T3: Lifecycle of Pharmacovigilance for Biologics Therapy: Study to Market

Nitu Sinha, Vice President & Global Head Mankind Pharma Ltd

11:00-11:30AM

Tea/Coffee & Networking Break

11:30-1:00PM

Session 6: Patient Safety Special Situations

Session Chair: Dr J Vijay Venkatraman, Managing Director & CEO, Oviya MedSafe Pvt Ltd

Session Overview: This session addresses patient safety scenarios that require heightened vigilance and tailored pharmacovigilance approaches in an increasingly complex regulatory and therapeutic environment. Discussions will focus on safety monitoring challenges associated with high-impact

therapies, evolving inspection expectations, and emerging technologies. The session will explore enhanced safety oversight for GLP-1 agonists, practical strategies for local-in-country regulatory compliance during inspections, and the potential role of advanced GenAI-enabled automation in strengthening pharmacovigilance processes, while maintaining regulatory control and human oversight. The session concludes with a forward-looking discussion on patient safety considerations for wearables across clinical trials and real-world use. This will include perspectives on data reliability, device performance, user adherence, and the unique challenges wearables introduce when digitally generated measures inform safety monitoring and decision-making. Together, these insights will help participants adapt pharmacovigilance systems and oversight practices to emerging wearable technologies within regulated environments.

11:30-11:50 AM

S6.T1: Patient Safety Considerations for Wearables Across Clinical Trials and Real-World Use

Akila Srinivasan, Director, Parexel

11:50-12:40 PM

S6.T2 Panel Discussion: Readiness for Local Affiliate PV Inspections in India and Emerging Markets

Panelists:

1. **Dr.S.Selvakumar**, Deputy General Manager, GBS GPV, Apotex
2. **Dr Kabil Kalathingal**, Global Head - Medical Assessment, Compliance and Digitalization, Dr. Reddy's Laboratories
3. **Vedraj Vellody**, Head of GVP Audit Practice - APAC, ADAMAS Consulting
4. **Dr Mohit Trivedi**, Country Safety Head India, Sanofi

12:40-1:00 PM

S6.T3: The critical importance of patient safety monitoring for GLP 1 Agonists

Dr. Maya Sharma, Sr Director, M&R, Novo Nordisk

1:00-2:00PM

Lunch Break

2:00-3:30PM

Session 7: FUTURE OF PV (People, Process, Technology and Partnerships)

Session Chair(s): Gurpreet Singh, Lifesciences & Pharma Business Leader

Session Overview: The future of pharmacovigilance (PV) is defined by a shift toward smarter, more proactive, and more connected drug-safety systems. By 2030, PV is expected to rely heavily on real-time data, AI-driven analytics, and closer engagement with patients and clinicians. Regulators anticipate major changes in how safety information is collected and used, including more efficient reporting of suspected adverse reactions and continuous monitoring of medicines' real-world performance.

2:00-2:20PM

S7.S1: The Next Frontier of Patient Safety - Harnessing Semantics, Graph RAG & Agentic AI for Intelligent Safety Insights

Prachet Mohanty, Associate Director, Research & Development BI&T (WWPS & GRS), BMS

2:20-3:10 PM

S7.T2: Panel Discussion with Q&A: Future of PV- The need for Patient Centric PV amidst evolving Regulations and Technology Transformations

Moderator: Gurpreet Singh, Lifesciences & Pharma Business Leader

Panelists:

1. **Dr J Vijay Venkatraman**, Managing Director & CEO, Oviya MedSafe Pvt Ltd
2. **Inder Sachdev** – Vice President, Syneos Health
3. **Prachi Arora** – Vice President and Head, Medical Safety APCER Life Sciences
4. **Rohini Pandey** – Director, Global PV Operations, , Abbott
5. **Anuja Jawale**, Associate Director, Area Safety Head, kenvue

3:10-3:30 PM

S7.T3: From Silos to Seamless: The Integrated Future of PV Process and Technology

Sanjeev Srivastava, Signal Management Lead, BioNTech SE

3:30-4:00 PM

Closing Remarks & Vote of Thanks

PAYMENT INFORMATION

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Vinita Shetty | Finance Manager

DIA (India) Pvt. Ltd.

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Andheri- Kurla Road, Andheri (East), Mumbai – 400059

Email: vinita.shetty@diaglobal.org Cell: +91 9769764645

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Category	Early Bird Rate (till 9 April 2026)	Advance Rate (10 April – 24 May 2026)	Standard Rate (from 25 May 2026)
Industry – Non-member	INR 12,000 +GST	INR 14,000 +GST	INR 16,000 +GST
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Dd Month 2026

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