India Annual Meeting 2025

Innovation Through Integration:
Shaping the Future of Patient-Centric Healthcare

19-20 September 2025
The Grande, **NESCO**, Goregaon (East)
Mumbai, India

The **DIA India Annual Meeting** is a premier platform that brings together diverse stakeholders from the life sciences, pharmaceutical, and healthcare industries. The conference serves as a hub for innovation, collaboration, and knowledge sharing, addressing key challenges and opportunities across the drug development spectrum. With a focus on advancing healthcare solutions, the meeting fosters discussions that drive impactful outcomes for patients, industry professionals, and regulators alike.

This year's meeting will feature multiple tracks, covering critical areas such as Pharmacovigilance, Clinical Trial Innovation, Regulatory Science, Medical Affairs, Data Science, RWE, and Artificial Intelligence. Each track offers a unique opportunity to explore emerging trends, cutting-edge technologies, and best practices shaping the future of life sciences. Attendees will engage with thought leaders, exchange ideas, and collaborate on solutions to address the evolving needs of the global healthcare ecosystem.

Proposed Tracks:

1. Pharmacovigilance (PV)
2. Clinical Trial Innovation (CT)
3. Medical Affairs (MA)
4. Regulatory Science (RS)
5. Data Science (DS)

WHAT TO EXPECT

Learning Objectives

The DIA India Annual Meeting 2025 aims to foster innovation, collaboration, and knowledge exchange across the life sciences and healthcare sectors. The conference seeks to address critical challenges in drug development, clinical trials, regulatory landscape, and patient safety while showcasing advancements in technology, data science, and medical affairs.

By bringing together industry leaders, regulators, academicians, and healthcare professionals, the event strives to create actionable insights, promote cross-functional collaboration, and drive impactful outcomes that benefit patients and the global healthcare ecosystem.

Target Audiences (Who Should Attend)

Life science professionals involved in all stages of drug development, from innovation and discovery to post-market applications:

- **Pharma, Biotech, and Medical Device Professionals**: Leaders in R&D, Clinical Research, Regulatory Affairs, and Drug Safety
- **Regulatory Authorities**: Officials from CDSCO, FDA, and other global agencies
- **Academia and Research**: Academicians, researchers, and clinical trial experts
- **Service Providers**: CROs, technology, and IT solution providers
- **Students & Young Professionals**: Aspiring individual in life science, pharmacy & healthcare
- **Policy Makers and Industry Associations**: Representatives from IPA, IDMA, and public health advocacy groups

PROGRAM COMMITTEE

Prof. Moin Don
Program Committee Chair
Founder & CEO, PVCON Consulting, ISoP South Asia Chapter Lead

Dr Chitra Lele
Managing Director, Life Sciences Consulting, NTT DATA

Dr Sanish Davis
R&D Director, Johnson & Johnson Innovative Medicine

Dr Manjusha Rajarshi
Founder, Regulus Health Care

Fahd Khan
Business Development Head, Emmes

Dr Sonica S Batra
Associate Vice President, Indegene

Dr Gaurav Mathur
Senior Director, Regulatory Affairs, Parexel

Dr Qayum Mukaddam
Director-Business Strategy, CLINICA Research Solutions LLP

Dr Viraj Suvarna
Medical Head, A&R

Suraj Ravindran
Senior Director, GSK

KEY SPEAKERS

Dr Angela Caro-Rojas
President- ISoP, (International Society of Pharmacovigilance)

Mr Gregory Smith,
FDA Country Director-India, US FDA

Dr Sadhna Joglekar
Senior Vice President and Head, Global Drug Development, Novartis

Dr Vineet Kacker
Managing Director & Global Technical Head, APCER Life Sciences

Dr Jaideep Gogtay
Chief Medical Officer, CIPLA.

Dr Ashwini Mathur
Executive Director, Onesto Consulting

Dr Krishna Bahadursing
Co-Founder, Liorta Innovations Pvt. Ltd

Rajeev Sibal
President India Business, Lupin

Dr Mahesh Iyer, Head Global Biometrics and Data Sciences, Bristol Myers Squibb

José Alberto Ayala Ortiz, Founder and CEO, PVpharm, QPPV

Dr Swashraya Shah Medical Director, BSV Ltd.

Dr Artem Andrianov CEO & Co founder, RBQM solutions in Clinical Trials

Abhinav Manda Director, PSS Practice and Solutions, Fortrea

Dr Padma V. Devarajan Advisor Vision & Strategy and Chair Professor, SIES School of Pharmaceutical Sciences, Mumbai

Dr Phillip P. Nguyen, Regulator and Policy Advisor U.S. FDA Office, U.S. Embassy New Delhi

Dr Baseer Ahmed, Executive Director PV Operations, Ionis Pharmaceuticals

Dr Dhananjay Bakhle CEO, MedRenova Pvt Ltd

Dr Nithya Gogtay Professor & Head, Dept. of Clinical Pharmacology, SGS Medical College & KEM Hospital

Gurpreet Singh, Vice President, Managing Director - Integrated Safety, IQVIA. UK

Dr Shalini Menon Medical Director, GSK

Suneela Thatte Head R&D India, Merck KGaA

Dr Ritu Jaswal Vice President Pharmacovigilance Operations, Parexel

Dr Subrat Ray, Regional Director Medical Affairs WH (APJ & EEMEA), Organon

Anirban Roy Chowdhury, Associate Vice President & Head- Development Center of Excellence Specialty Medicine, SUN Pharma

Dr Vijay Venkatraman Managing Director & CEO, Oviya MedSafe

Dr Anitha Kumari Head of Clinical Data Management Sanofi

Amita Bhave Director, Regularly Affairs, AstraZeneca

Prashant Joshi General Manager & Global Head Account Delivery, MDPS, Wipro Ltd. And Wipro Life Science (WLS)

Dr Mrutyunjay Suar

CEO, KIIT-TBI, Director General Industry-Institute-Innovation-Interface

Kedar Suvarnapathaki, Director - Regulatory Affairs, Southeast Asia & India, Johnson & Johnson

Dr Ashish Indani General Manager – Clinical and Medical Affairs, Advance MedTech Solutions (AMS), Mumbai / Vadodara

Viswanadh Kuppa

Vice president, Parexel Biotech

Dr Arati Borkar

Director, Quality Assurance & Training at DiagnoSearch Life Sciences Pvt. Ltd.

PROGRAM AGENDA

Day 1 Agenda: 19 September 2025, Friday

Day 2 Agenda: 20 September 2025, Saturday

*[**Note:** Each session is 90 minutes long (09:30–11:00 / 11:30–13:00 / 14:00–15:30 / 16:00–17:30). The timings listed in the left panel correspond to **Track 1 (PV)** and are only indicative of the timing of individual presentations and panel discussions under other tracks (2-CT, 3-MA, 4-RS, 5-DS). For clarity, please refer to the overall session timings and individual topics duration under each session.]*

AGENDA: Day 1, 19 September 2025; Friday			
8:00-8:45AM	**Registration and Welcome Coffee**		
8:45-9:00AM	**Welcome Remarks from DIA:** [5 min] **Meeting Opening Remarks by Program Chair:** [10 min]		
9:00-11:00AM	**Day 1 Opening Plenary Session:** Session Chair: **Prof. Moin Don,** CEO & Founder, PVCON		
9:00-9:30AM	**P1.T1. Keynote Address: Navigating Tomorrow: Brief Updates and Perspectives from the U.S. FDA** **Mr Gregory Smith,** FDA Country Director- India, US FDA		
9:30-10:00AM	**P1.T2. Keynote Address: Strategic Role of Medical Affairs 2030 and Beyond – Bridging Patient-Centricity with Business Value** **Dr Jaideep Gogtay,** Chief Medical Officer, CIPLA		
10:00-10:20AM	**P1.T3. Keynote Address: Emerging Therapies, Evolving Regulations: Navigating Safety and Risk in a Complex Landscape** **Dr Vineet Kacker,** Managing Director & Global Technical Head, APCER Life Sciences		
10:20-10:40 AM	**P1.T4. Keynote Address: Steering the Future: Insights from the Regulator - DSCO** **CDSCO** *(invited)*		
10:40 – 10:55AM	**P1.T5: Keynote Address: Democratizing "Living Drugs" – New Frontiers in Medicine: What Does It Take to Reach Millions of Patients?** C. Palani Palaniappan, Ph.D, CEO - Aridica Corporation, USA, **DIA Global Board of Directors**		
10:55-11:00AM	**Closing, Next Steps & Action Points – by Session Chairs** [5 min]		
11:00-11:30AM	**Tea/Coffee & Networking Break**		
	Track 1 – Pharmacovigilance (PV)	**Track 2 – Clinical Trial Innovation (CT)**	**Track 3 – Medical Affairs (MA)**
11:30-1:00PM	**PV.S1: PV Global Regulatory Intelligence Updates** Session Chair:	**CT.S1: Innovative Strategies for Successful Clinical Trial Conduct** Session Chair:	**MA.S1: Real World Evidence (RWE) – Are (R) WE Ready?** Session Chair: **Dr Viraj Suvarna**, *Medical Head, A&R*

	Dr Vijay Venkatraman, *CEO, Oviya MedSafe* Session Overview: *This session will provide a comprehensive update on the latest global regulatory developments in pharmacovigilance (PV), highlighting key changes, emerging trends, and regional variations that impact drug safety operations. Experts will discuss recent guidance from major health authorities such as the FDA, EMA, MHRA, PMDA, and CDSCO, as well as evolving expectations in regions like APAC, LATAM, and MENA. Attendees will gain actionable insights into how to align their PV systems with current regulations, navigate compliance challenges, and adopt a proactive approach to regulatory intelligence for risk mitigation and strategic planning.*	**Dr Sonica S Batra**, *Associate Vice President, Enterprise Medical, Global Head - Regulatory Affairs, Indegene* Session Overview: *This session explores innovative strategies driving successful clinical trials in today's era of complex clinical designs, and the need for faster access to safe and effective therapies. While there are challenges, there are unique opportunities too, including the transformative role that automation and AI are playing in this entire clinical development space.* *A thought-provoking panel discussion will further discuss the current context, and what the future holds, providing insights into optimizing clinical trials in an increasingly digital and collaborative ecosystem.*	Session Overview: *The session will provide an insightful exploration of the growing importance of Real-World Evidence (RWE) in Medical Affairs. Experts will clarify the distinction between real world data and RWE, discuss challenges and practical solutions for RWE generation, and highlight evolving regulatory perspectives in India, as compared to that in USA & EU. A spotlight on RHYTHM, a landmark RWE study, will offer a real-world example of robust evidence generation. The session will conclude with a dynamic panel featuring key stakeholders, including industry and regulatory voices. Attendees can expect rich insights, practical guidance, and ample opportunities for dialogue through audience questions and expert interaction*
11:30-12:00PM	**PV.S1.T1. EMA strategies and future plans: PRAC contribution, master data management plan and EU Network data strategy including Signal Management** **José Alberto Ayala Ortiz,** Founder and CEO, PVpharm, QPPV	**CT.S1.T1. Introduction by SC: Setting the Stage for Success: Effective, Efficient and Inclusive Clinical Trials** [10 min] **Dr Sonica Batra,** Indegene **CT.S1.T2. Evolving Scenario in Clinical Trials- Challenges and Opportunities** [20 min] **Dr Charu Gautam;** Senior Director- Medical Science and Strategy, IQVIA	**MA.S1.T1. RWE: What, Why, How, Why – Setting the context** [5 min] **Dr Viraj Suvarna** **MA.S1.T2. Real World Data vs Real World Evidence – How one can generate RWE of a higher quality standard** [15 min] **Dr Shalini Menon**, Medical Director, GSK
12:00-12:30PM	**PV.S1.T2. The Immunogenicity Paradox: Harmonizing Pharmacovigilance Strategies Across Originator Biologics, Biosimilars, and Next-Generation Bispecific Antibodies** **Dr Krishna Bahadursingh**, Co-Founder, Liorta Innovations Pvt. Ltd	**CT.S1.T3. Smarter, Inclusive Trials: Uniting Teams and AI to Break Enrolment Barriers while being highly patient centric** [20 min] **Dr Sundaresh Nanjundappa,** Independent Consultant	**MA.S1.T3. Regulatory and medical affairs challenges in conducting RWE generation studies** [15 min] **Dr Viraj Suvarna** **MA.S1.T4. The RHYTHM study** [15 min] **Dr Swashraya Shah,** Medical Director, BSV
12:30-1:00PM	**PV.S1.T3. Keeping track of worldwide PV regulatory intelligence and CAPA trending** **Dr Prasad Deshmukh**, PV Head, Cipla	**CT.S1.T4. Panel Discussion: Innovative and effective clinical trials- where are we, and what next?** [40 min] Moderator: **Dr Sonica Batra,** Indegene Panellists: Speakers with the additional presence of: 3. **Dr. Nithya Gogtay,** Professor and Head, Department of Clinical	**MA.S1.T5. Panel Discussion with Q&A: RWE – Are (R) WE Ready?** [40 min] Moderator: **Dr Viraj Suvarna** Panellists: Speakers with the additional presence of: **4. Ram Prasanna**, Sr. Director HEOR & RWE, EVERSANA

		Pharmacology, SGS Medical College & KEM Hospital, Mumbai 4. **Deepti Goel,** Executive Director, Harrison's Tech Consultants	
1:00-2:00PM		**Lunch Break**	
2:00-3:30PM	**PV.S2: Harnessing AI and Real-World Data in PV and how Regulators view automation and AI** Session Chair: **Fahd Khan**, Business Development Head, Emmes Session Overview: *As pharmacovigilance (PV) functions evolve to manage increasing data volumes and complexity, AI and Real-World Data (RWD) are becoming essential tools in the day-to-day operations of safety teams. This session is designed for PV professionals who are directly engaged in case processing, signal management, compliance, and safety analytics—and are navigating the challenges of integrating advanced technologies into routine workflows.* *The discussion will focus on measurable efficiencies, implementation considerations, and lessons learned from real-world deployments.* *In parallel, the session will delve into how global regulatory bodies view the use of AI and automation in PV. Attendees will gain clarity on current expectations for validation, audit readiness, and algorithm transparency, as well as updates from recent guidance issued by EMA, FDA, and other health authorities.*	**CT.S2: Quality Management in Clinical Trials – Embedding ICHE6(R3) Principles** Session Chair: **Dr Sanish Davis,** R&D Director, GCO India, Johnson & Johnson Innovative Medicine Session Overview: *This session delves into the evolving landscape of quality management in clinical trials, anchored in the principles of ICH E6(R3). Speakers will discuss the shift from compliance-driven approaches to a culture of proactive quality, emphasizing Quality by Design, Risk-Based Quality Management, and the role of AI. The panel will explore how to strategically embed quality across trial planning and execution—balancing innovation, regulatory oversight, and patient trust to elevate outcomes in today's complex research environment.*	**MA.S2: Measuring the Value of Medical Affairs to the Business** Session Chair: **Dr Qayum Mukaddam,** Director-Business Strategy, CLINICA Research Solutions LLP Session Overview: *This session delves into how the value of Medical Affairs can be measured, the expectations from business leaders, and the inherent challenges in quantifying strategic and scientific impact. Presentations and a panel discussion will explore frameworks, leadership perspectives, and real-world barriers to demonstrating tangible business value.*
2:00-2:20PM	**PV.S2.T1. Real World Data as a Catalyst for Early Safety Signal Detection in Pharmacovigilance** **Dr Siva Kumar Buddha**, Director Global Safety Sciences, Amgen	**CT.S2.T1. Introduction by SC: Embedding Quality by Design-A Mindset Shift for Modern Clinical Trials** [10 min] **Dr Arati Borkar.** Director, Quality Assurance & Training at DiagnoSearch Life Sciences Pvt. Ltd **CT.S2.T2. From Compliance to Culture – Reimagining Quality as a Strategic Driver in Clinical Trials** [20 min] **Dr Shehnaz Vakharia,** Vice President, ADAMAS Clinical Quality Consulting Pvt. Ltd	**MA.S2.T1. Expectations of a CEO from Medical Affairs** [20 min] **Rajeev Sibal,** President India Business, Lupin

2:20-2:40PM	**PV.S2.T2. The Future of Safety Operations: Preparing the Workforce for AI-Augmented Decision-Making** **John Praveen**, Associate Vice President - PV & MW Portfolio, Accenture	**CT.S2.T3. Embracing ICH E6 (R3) principles, harnessing Risk-Based Quality Management (RBQM) and AI for Proactive Decision-Making** [20 min] **Dr Artem Andrianov,** CEO & Founder, Cyntegrity Germany GmbH	**MA.S2.T2. How can one measure the Value of Medical Affairs to the Business?** [20 min] **Dr Srirupa Das,** Healthcare Industry Leader
2:40-3:30PM	**PV.S2.T3. Panel Discussion: Unlocking the Potential of AI in Pharmacovigilance: From Automation to Augmentation** Moderators: **Fahd Khan** and **Dr Siva Kumar Buddha** Panellists: 1. **Dr Krishna Bahadursingh**, Co-Founder, Liorta 2. **Syed Firasatullah**, Principal Solutions Consultant, Oracle Life Sciences 3. **Vivek Kalagara**, Founder & CEO, Datafoundry 4. **Dr Aniket Patil,** Senior Manager, Country Safety Lead - Pfizer India Drug Safety Unit	**CT.S2.T4. Panel Discussion: Redefining Quality in Clinical Trials: Balancing Innovation, Oversight, and Patient Trust** [40 min] Moderator: **Dr Sanish Davis** Panellists: Speakers with the additional presence of 4. **Dr Nithya Gogtay,** Professor and Head, Department of Clinical Pharmacology, SGS Medical College & KEM Hospital, Mumbai 5. **Divakar Kolli**, Director-Development Quality Assurance, Cipla Ltd	**MA.S2.T3. Panel Discussion: Measuring the Value of Medical Affairs to the Business** [50 min] Moderator: **Dr Qayum Mukaddan** Panellists: Speakers with the additional presence of 3. **Dr Pankaj Gupta**, Sr Medical Director, Pfizer India 4. Annaswamy Vaidheesh, Healthcare Leader
3:30-4:00PM	**Tea/Coffee & Networking Break**		
4:00-4:30PM	**PV.S2a.T4: The End of AI Theater: Real-World AI for Real-World Safety** **Antara Gaur,** Vice President - Client Growth and Account Management – Europe. Global Customer Excellence	**CT.S3: The Evolving Clinical Trial Ecosystem in India** Session Chair: **Anirban Roy Chowdhury,** Associate Vice President & Head-Development Center of Excellence Specialty Medicine, SUN Pharma Session Overview: *India's clinical research ecosystem has undergone a remarkable transformation in the last three decades—from a rescue destination for global studies to an innovation-driven hub driving the global drug development through the capability centers of various pharma companies and CROs.* *In this session we will discuss opportunities for India to build a resilient future-ready global clinical trial ecosystem, while positioning itself as a strategic hub shaping the future of global drug development through the GCCs.*	**MA.S3: Evolution of Medical Affairs: *Kal, Aaj aur Kal* (Past, Present, Future)** Session Chair: **Dr Subrat Ray**, Regional Director Medical Affairs WH (APJ & EEMEA), Organon Session Overview: *This session explores the evolution of Medical Affairs from a support function to a strategic partner in driving market success. It covers the expanding scope of Medical Affairs, focusing on compliance with UCPMP guidance, and to a more integrated position informed by strong medical evidence, regulatory strategy, risk mitigation plan, innovation, and digital transformation. Real-world examples will showcase how emerging technologies like AI/ML are enhancing efficiency and impact. A distinguished panel of industry and regulatory experts will discuss current challenges, digital opportunities, and future directions. Attendees will gain actionable insights through expert dialogue and interactive Q&A in this rapidly evolving healthcare landscape*
4:30-5:30PM	**PV.S3: PV Outsourcing Strategies and Dynamics** Session Chair: **Dr Ritu Jaswal**, *Vice President PV Operations, Parexel* Session Overview: *As pharmacovigilance (PV) requirements grow in complexity and volume, outsourcing has become a strategic lever for biopharmaceutical companies seeking scalability, cost-efficiency, and global compliance. This session explores the evolving landscape of PV outsourcing, including key drivers, partnership models (full-service, FSP, hybrid), and vendor selection criteria. Industry leaders will share best practices for successful collaboration, managing oversight and quality, and leveraging technology and automation in outsourced PV*		

	operations. The discussion will also cover emerging outsourcing trends across regions, including the rise of nearshore and offshore delivery models, and the role of regulatory expectations in shaping outsourcing decisions		
		CT.S3.T1. Introduction by SC: India's Clinical Research Landscape: A Cycle of Growth, Crisis, and Comeback [10 min] **Anirban Roy Chowdhury,** Sun Pharma	**MA.S3.T1. Charting the Course: A legacy of the Past, Leadership for Today** [15 min] **Dr Dhananjay Bakhle**, CEO, MedRenova Pvt Ltd
		CT.S3.T2. Navigating global landscape: Multinational clinical trials – Challenges and Opportunities [20 min] **Partha Chatterjee,** Head, Clinical Trials, CDM & BSP, Syngene	**MA.S3.T2. Medical Affairs – Custodian of Healthcare Compliance?** [15 min] **Dr Rahul Rathod**, Director Medical Affairs, AbbVie
4:30-5:00PM	**PV.S3.T1. India's Role in the Evolving Global Safety Ecosystem: From Cost Centre to Innovation Hub** **Dr Baseer Ahmed,** Executive Director PV Operations, Ionis Pharmaceuticals	**CT.S3.T3. GCCs in India: How leading Pharma companies are harnessing India's Strategic Talent Potential for advancing Global Clinical Research** [20 Min] **Suneela Thatte,** Head R&D India, Merck KGaA	**MA.S3.T3. Can Medical Affairs innovate for the future in the digital era?** [15 min] **Dr Kamlesh Patel,** Head - Medical, Clinical, Regulatory & Health Tech, Lupin India
5:00-5:30PM	**PV.S3.T2 – Complexities of Business Partner agreements and fulfilling authorities' expectations around them** **Dr Chitra Bargaje,** Head PV QA, Lupin	**CT.S3.T4. Panel Discussion: India's Clinical Research Landscape: How Do We Build a resilient future-ready global clinical trial ecosystem in India, while positioning itself as a strategic hub shaping the future of global drug development Opportunities** [40 mins] Moderator: **Anirban Roy Chowdhury** Panelists: Speakers with additional presence of **3. Dr Phillip P. Nguyen,** MD Regulator and Policy Advisor U.S. FDA Office, U.S. Embassy New Delhi	**MA.S3.T4. Panel Discussion: The Future of Medical Affairs – Navigating Challenges and Embracing Opportunities** [45 mins] Moderator: **Dr Subrat Ray** Panellists:Speakers with the additional presence of
5:30-5:45PM		**Day 1 Ends: Wrap Up**	

AGENDA: Day 2, 20 September 2025; Saturday			
8:45-9:00AM	**Welcome by DIA to Day 2:** [5 min] **Day 2 Opening Remarks by Program Co-Chair & Introduce the Session Chair:** [10 min]		
9:00-11:00AM	**Day 2 Plenary Session** Session Chair: **Dr Chitra Lele**, Managing Director, Life Sciences Consulting, NTT DATA		
9:05-9:30AM	**P2.T1. Keynote Address: Pharma and Life Science GCCs in India – Catalysts for Global Innovation and Contributing to Unmet Therapies** **Dr Sadhna Joglekar,** Senior Vice President and Head, Global Drug Development, Novartis		
9:30-10:00AM	**P2.T2. Keynote Address: Role of Data Science, AI, and ML in Pharmaceutical Healthcare** **Dr Mahesh Iyer**, Head Global Biometrics and Data Sciences, Bristol Myers Squibb		
10:00-10:20AM	**P2.T3. Keynote Address: Medication Errors & Patients Centric Approaches – New Emerging Paradigms in Drug Safety** **Dr Angela Caro-Rojas**, President- International Society of Pharmacovigilance (ISoP)		
10:20-10:40AM	**P2.T4. Keynote Address: Navigating the Evolving Medical Device Landscape – Regulatory Innovations, Clinical Trial Methodologies, and Emerging Technologies** **Dr Ashish Indani**, General Manager & Head – Clinical and Medical Affairs, Advanced MedTech Solution		
10:40-11:00AM	**P2.T5. Keynote Address: Talent for Next-Gen Trials- Building India's Clinical Research Workforce of the Future** **Viswanadh Kuppa,** Vice president, Parexel Biotech		
11:00-11:30AM	**Tea/Coffee & Networking Break**		
	Track 1 – Pharmacovigilance (PV)	**Track 4 – Regulatory Science (RS)**	**Track 5 – Data Science (DS)**
11:30-1:00PM	**PV.S4: Pharmacovigilance New Horizons** Session Chair: **Dr Krishna Bahadursingh**, Co-Founder, Liorta Innovations Pvt. Ltd Session Overview: *As the scope of PV expands beyond traditional pharmaceuticals, this session explores emerging frontiers reshaping the safety landscape. Experts will discuss the growing importance of pharmacovigilance for OTC products and nutraceuticals, examining regulatory expectations, risk profiles, and how safety strategies differ from prescription medicines. The session will also delve into innovations in signal detection and management, highlighting the integration of advanced analytics and automation to improve proactivity*	**RS.S1: India Regulatory Affairs: Advancing Compliance and Innovation** Session Chair: **Dr Manjusha Rajarshi,** Regulus Health Care; Roots-Simplified Research & Consulting LLP Session Overview: *This session will explore the evolving regulatory landscape in India, focusing on how policy developments, digital transformation, and regulatory reforms are shaping the future of pharmaceutical and biopharmaceutical oversight. Special focus is on regulatory challenges for start-up innovations and new academia-industry partnerships. With an emphasis on enhancing compliance standards while fostering innovation, it will highlight recent initiatives by Indian regulatory bodies, and other key stakeholders. Topics will include*	**DS.S1: Responsible Innovation: Governance, Transparency and Future of AI** Session Chair: **Dr Anitha Kumari,** Head of Clinical Data Management, Sanofi Session Overview: *This session will examine the evolving regulatory landscape and how pharmaceutical companies are adopting AI responsibly. A keynote presentation will set the stage, followed by a panel discussion addressing key issues: balancing innovation with GxP compliance, ensuring data privacy and transparency, AI governance in wearables, and the rise of DCTs and smart platforms. Experts will share insights into building trustworthy, compliant, and patient-centric AI systems. The session aims to provide practical perspectives on navigating the fine line between innovation and*

	and precision. Finally, attendees will gain insights into the increasing role of social media monitoring and local literature surveillance in identifying safety signals, along with the operational and compliance challenges these unconventional sources present. This session aims to equip PV professionals with the foresight and tools needed to navigate the evolving safety paradigm	*efforts to streamline clinical trial approvals, digitize regulatory submissions, and align with international standards. Through expert insights and real-world case studies, the discussion will delve into the practical aspects of maintaining regulatory compliance in a fast-evolving environment, while also encouraging scientific progress and patient access to new therapies. This session is essential for members of innovative start-ups, regulatory professionals, policy makers, and industry leaders navigating the dynamic Indian regulatory ecosystem in healthcare and pharmaceutical world.*	*responsibility in a rapidly advancing digital health ecosystem.*
11:30-12:00AM	**PV.S4.T1 Having a Re-Look at Vaccine Safety & its Epidemiological Impact** **Raghavendra Pai**, Takeda Singapore	**RS.S1.T1. Academia-Industry Collaboration – Regulatory Challenges** [15 min] **Dr Mrutyunjay Suar**, CEO, KIIT-TBI, Director General Industry-Institute-Innovation-Interface, KIIT UNIVERSITY. Chairman of Bhubaneswar City Knowledge Innovation Cluster (An initiative of the Office of PSA to GoI) **RS.S1.T2. Readiness towards GxP Compliance & Inspections – Data Governance & Data Integrity** [15 min] **Dr Anupama Ramkumar**, Principal Consultant and CEO, Arkus Research Pvt Ltd	**DS.S1.T1. Evolution of Regulatory Landscape and Adoption by Pharma companies** [30 min] **Dr Ashwini Mathur**, Executive Director, Onesto Consulting, Dublin
12:00-12:30PM	**PV.S4.T2. Innovation & Signal Management Perspective** **Dr. Pranav Sikka,** Global Head Safety Detection and MQM, Novartis	**RS.S1.T3. Quality Compliance & GMP challenges: Ensuring consistency in India Pharmaceutical Manufacturing** [15 min] **Lakshmi Achuta,** Strategic Advisor AshrinBio	**DS.S1.T2. Panel Discussion with Q&A** [60 mins] Moderator: **Dr Anitha Kumari,** Sanofi Panellists: Speakers with the additional presence of: 2. **Kishore Kumar**, Co-Founder and Chief Data Scientist, ConsilX Digital. 3. **Ram Mudaliar,** Global Head Oncology Clinical Data Management, AstraZeneca.
12:30-1:00PM	**PV.S4.T3. Growing importance of social media monitoring and its challenges in PV and Local Literature Surveillance** **Abdul Rahim,** Founder & Director, ALWIS	**RS.S1.T4. Panel Discussion: Regulatory Strategies for Indian Pharma to compete in Global Markets** [45 mins] Moderator: **Dr Manjusha Rajarshi** Panellists: Speakers with the additional presence of: 4. **Dr. Padma V. Devarajan**, Advisor Vision & Strategy and Chair Professor, SIES School of Pharmaceutical Sciences, Ex-Dean Research & Innovation, Institute of Chemical Technology 5. **Dr Kunal Khanna**, Founder and CEO, EffecMed Pvt. Ltd	
1:00-2:00PM	**Lunch Break**		

2:00-3:30PM	**PV.S5: New Trends in Enhancing PV Operational Outcomes** Session Chair: **Abhinav Manda,** Director, PSS Practice and Solutions, Fortrea Session Overview: *This session highlights strategic operational innovations that are transforming pharmacovigilance delivery models across the globe. Discussions will center around the formation of Global Capability Centers (GCCs) and regional affiliate clusters—an emerging approach to streamline PV operations, enhance compliance, and drive efficiency in managing regional safety obligations. The session will also critically examine India's growing role as a pharmacovigilance hub, exploring whether its expanding talent pool represents a strategic advantage or a potential operational bottleneck. Attendees will gain insights into how organizations can optimize global PV delivery through smarter resource deployment, regional collaboration, and organizational design.*	**RS.S2: Global Regulatory Affairs – Achieving Synergy in International Drug Approvals** Session Chair: **Dr Gaurav Mathur,** Senior Director, Regulatory Affairs, Parexel Session Overview: *This session will focus on the challenges and opportunities associated with securing regulatory approvals across multiple international markets. As pharmaceutical companies pursue global drug development and seek synchronized launches, the need for regulatory alignment and collaboration has become more critical than ever. The session will explore current global initiatives such as ICH guidelines, WHO prequalification, and regional harmonization strategies like ASEAN, EU-MDR, etc. It will also examine the practical implementation of reliance models, joint reviews, and mutual recognition agreements. Featuring insights from global regulatory experts and industry veterans, the session aims to uncover actionable strategies that reduce redundancy, enhance efficiency, and ultimately accelerate patient access to innovative therapies across borders.*	**DS.S2: Data Science Enabling Real-Time Decision Making (reducing time from molecule to medicine)** Session Chair: **Dr Chitra Lele,** Managing Director, Life Sciences Consulting, NTT Data Session Overview: *This session highlights how data science is accelerating drug development and reducing time to market through real-time decision-making. Discussions will cover the application of AI/ML in patient identification and recruitment, the use of continuous monitoring for early detection of protocol deviations and safety signals, and the integration of real-world data with innovative study designs to streamline development—underscoring the power of data-driven insights to enhance clinical development efficiency and deliver better outcomes for patients.*
2:00-2:30PM	**PV.S5.T1. Formation of GCCs (Global Capability Centers/ Affiliate Clusters within a region to collectively manage regional PV obligations** **Dr Rashmi Hegde,** Global Pharma Consultant- Medical, PV & Clinical Studies	**RS.S2.T1. Navigating through the changes and unpredictability of the evolving global regulatory landscape** [30 mins] **Dr Samuel Solomon**, Vice President Regulatory Affairs, Intas Pharmaceuticals.	**DS.S2.T1. Data-driven approach to patient identification and recruitment** [30 min] **Shreenath Sreenivas**, Director, Drug Development Business Insights & Technology India, Bristol Myers Squib
2:30-3:00PM	**PV.S5.T2. India's PV Talent Maturity: Boon or Bottleneck?** **Gurpreet Singh,** Vice President, Managing Director - Integrated Safety, IQVIA. UK	**RS.S2.T2. Post-approval Change Management: Global Variations & Strategic Approaches** [30 mins] **Yogananth Rajendran**, VP Regulatory Affairs, Kashiv BioSciences	**DS.S2.T2. Continuous Monitoring for Early Detection of Protocol Violations, AE Patterns, and Safety Risks** [30 min] **Bijal Trivedi,** Project Manager, TCS
3:00-3:30PM	**PV.S5.T3. Role of PV KPI & Inspection Metrics towards PV Excellence** **Rajendra Kumar Kasi**, Head Global PV, Glenmark Pharma	**RS.S2.T3. Evolving global clinical development and regulatory landscape for Biosimilar approvals – time for India to Act.** [30 mins] **Dr Gursharan Singh,** General Manager- Global Clinical Development & Medical Affairs and Portfolio Strategy, Biocon Biologics	**DS.S2.T3. Innovative study designs and use of real-world data to expedite development timelines** [30 min] **Dr Angshuman Sarkar**, Senior Director Head Statistics, India, GSK
3:30-4:00PM		**Tea/Coffee & Networking Break**	

4:00-5:30PM	**PV.S6: Increasing Regulators' Expectations & Challenges to MAHs** Session Chair: **Prof. Moin Don,** Founder, PVCON Session Overview:	**RS.S3: Regulatory Sciences: Innovation, Technology and Future Readiness** Session Chair: **Amita Bhave,** Director, Regularly Affairs, AstraZeneca Session Overview: *This session will examine how cutting-edge scientific innovation and digital technology are reshaping the regulatory sciences landscape. With the rise of complex biologics, advanced therapy medicinal products (ATMPs), and AI-driven platforms, regulatory authorities and industry stakeholders must adapt to evolving paradigms of drug development and evaluation. The discussion will explore advanced regulatory tools and methodologies, such as model-informed drug development (MIDD), real-world evidence (RWE), digital biomarkers, and machine learning applications in regulatory review. In addition, the session will address the importance of regulatory agility, workforce upskilling, and cross-sector collaboration in preparing for the future. By fostering a shared vision between regulators, scientists, and innovators, the session aims to advance regulatory systems that are not only robust and science-driven, but also responsive to emerging global health needs.*	**DS.S3: Redefining Data Management in Healthcare** Session Chair: **Suraj Ravindran,** Senior Director, Head of Global CDM Service Delivery, GSK Session Overview: *This session explores the transformation of data management in healthcare through intelligent automation and AI. A case study-driven presentation will illustrate scalable automation across clinical trial and real-world data workflows. The panel will delve into advanced applications—reducing SDV burden via ML-driven risk assessment, smart query generation, coding, CRF reconciliation, and annotation of diverse data types. It will also examine the evolving standards for regulatory-grade real-world data, highlighting frameworks like FDA's QCARD in oncology.*
4:00-4:30PM	**PV.S6.T1. Pragmatic Approaches towards RMP Management & Challenges in aRMMs implementation** [30 min] **Dr Anju Agarwal,** Global PV Head, Advance Pharma	**RS.S3.T1. Global Regulatory Harmonization for Gene Therapy Products** [20 min] **Swapna Gundala,** Manager Regulatory Affairs, Parexel International	**DS.S3.T1. Scaling intelligent automation across data management functions – case studies in clinical trials and real-world studies** [30 min] **Allwyn Dsouza**, Director- Clinical AI & Analytics Solutions, Saama
4:30-5:30PM	**PV.S6.T2. Panel Discussion: Harmonization of Global PV Regulations – Need, Impact and Challenges** [60 min] Moderator: **Prof. Moin Don** Panellists: Speakers with the additional presence of: 2. **Avisek Dutta**, Deputy General Manager**,** Cognizant 3. **Dr Nitu Sinha**, Vice President & Global Head-Mankind Pharma Ltd. 4. **Joydeep Sengupta**, Global Pharmacovigilance - Site Head, SUN Pharma 5. **Prashant Joshi,** General Manager & Global Head Account Delivery, MDPS, Wipro Ltd. And Wipro Life Science (WLS)	**RS.S3.T2. Use of AI in Drug Development and Regulatory Affairs** [20 min] **Kedar Suvarnapathaki**, Director - Regulatory Affairs, Southeast Asia & India, Johnson & Johnson **RS.S3.T3. Panel Discussion and Q&A: Regulatory Pathways for innovative medicinal products such as CAR-T, Radio ligands, Cell and gene therapy** [50 min] Moderator: **Amita Bhave** Panellists: Speakers with the additional presence of 3. **Dr Rishi Jain**, Medical Director, Novartis 4. **Dr Dipankar Das,** Director Biologics, US Pharmacopeia	**DS.S3.T2. Panel Discussion with Q&A** [60 min] Moderator: **Suraj Ravindran** Panellists: Speakers with the additional presence of: 2. **Arnab Sengupta,** VP CDM and Centralized Data Review, Novo Nordisk 3. **Sujit Nair,** Senior Director Strategic Operations, IQVIA
5:30-5:45PM		**Closing Remarks & Vote of Thanks**	

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For **India Annual Meeting 2025**: Register online

For group registrations, please contact the meeting manager (below table).

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Vinita Shetty | Finance Manager
DIA (India) Pvt. Ltd.
Cowork30, Office #201, ACME Plaza-2, Chakala
Andheri- Kurla Road, Andheri (East), Mumbai – 400059

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Category	Early Bird Rate (Up to 20 July)	Advance Rate (21 Jul – 04 Aug)	Standard Rate (from 5th August)
Industry – Member	INR 7,650 +GST	INR 10,200 +GST	INR 11,000 +GST
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Dd Month 2025

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