Global Pharmacovigilance and Risk Management Strategies Conference

Conference January 27-29

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Overview

Join us for DIA's *Global Pharmacovigilance and Risk Management Strategies Conference,* the premier event for advancing your expertise in pharmacovigilance and regulatory affairs. Developed in collaboration with regulators and industry experts, this neutral forum provides unparalleled insights into global regulatory harmonization, AI-driven signal detection, and advanced safety analysis tools. At this conference, you'll hear about updates, opportunities, and challenges shaping the future of drug safety and learn innovative problem-solving strategies that matter most to safety professionals.

Event Goals and Offerings

- Gain insights into key global pharmacovigilance and risk management updates from regulatory bodies in the US, Europe, UK, Asia, and other regions, all at one single location
- Stay informed on the latest regulatory guidances, including REMS, aRMMs, and benefit-risk assessment frameworks
- Engage with like-minded professionals through interactive sessions, featuring real-world case studies, regulatory updates, and pharmacovigilance success stories
- Network with solution providers to discover innovative tools and technologies that can enhance and streamline your pharmacovigilance operations, including AI applications and predictive technologies
- Explore high-end stores and decadent restaurants in the eclectic city of Baltimore!

Why You Can't Miss It

- Network with peers and industry leaders in pharmacovigilance and drug safety to discuss best practices and shared challenges amongst your organizations
- Participate in interactive sessions on pressing topics like risk management convergence, AI in pharmacovigilance, and hepatic drug safety considerations for complex cases
- Evaluate the application of different technologies, such as knowledge graphs, machine learning, and AI for signal detection and benefit-risk assessment
- Hear from global regulatory authorities on the latest pharmacovigilance guidances and harmonization efforts to ensure compliance and stay current in an evolving regulatory landscape

Who Should Attend

Professionals involved in:

- Benefit-risk Assessment and Communication
- Clinical Research
- Data Safety Monitoring and Analysis
- Drug Safety
- Health Outcomes
- Medical Affairs
- Medical Communications
- Medical Information
- Medical Writing
- Medical Product Safety Assessment
- Patient Engagement and Advocacy Groups
- Pharmacoepidemiology
- Pharmacovigilance
- Post-Market Studies
- Quality Assurance
- Quality Control
- Real-World Evidence Generation
- Regulatory Affairs
- Risk Management
- Safety Statistics

DAY ONE | MONDAY, JANUARY 27		ROOM
7:30AM-5:00PM	Conference Registration	Foyer
7:30-8:30AM	Networking Breakfast	Key Ballroom 1-6
8:30-8:45AM	Welcome and Opening Remarks	Key Ballroom 7-12
8:45-9:30AM	Session 1: Keynote Address	Key Ballroom 7-12
9:30-10:15AM	Networking Break in Exhibit Hall Sponsored by ArisGlobal	Key Ballroom 1-6
9:35-10:05AM	Hosted Session/Non-CE: **Case Study Spotlight hosted by RxLogix** How Does a Harmonized, Unified, and Integrated Platform Enhance Pharmacovigilance Processes, and What are the Key Benefits of Consolidating Multiple Systems into a Single Solution?	Foyer
10:15-11:30AM	Session 2: Regulatory Updates on Policies and New Guidances from Other Territories and International Harmonization	Key Ballroom 7-12
11:30-12:30PM	Networking Luncheon in the Exhibit Hall Sponsored by ArisGlobal	Key Ballroom 1-6
12:30-1:45PM	Session 3: Advancing PV: Industry Perspectives on FDA Updates, Risk Management, Data Standards, and Regulatory Alignment	Key Ballroom 7-12
1:50-3:05PM	Session 4: Europe and United Kingdom: Regulatory Updates on Policies and Guidances	Key Ballroom 7-12
3:05-3:45PM	Networking Break in the Exhibit Hall Sponsored by ArisGlobal	Key Ballroom 1-6
3:10-3:40PM	Hosted Session/Non-CE: **Case Study Spotlight hosted by APCER** Local Pharmacovigilance and Risk Management: An Important Puzzle to Solve for Global Compliance	Foyer
3:45-5:00PM	Session 5: Real-World Evidence in Action: Bridging Data for Regulatory Decisions and Drug Safety	Key Ballroom 7-12
5:00-6:00PM	Networking Reception	Key Ballroom 1-6
DAY TWO | TUESDAY, JANUARY 28		**ROOM**
7:30AM-5:00PM	Conference Registration	Foyer
7:30-8:00AM	Networking Breakfast	Key Ballroom 1-6
8:00-10:30AM	Session 6 and 7: Global Convergence in Risk Management Guidance Driving New Innovation Opportunities (Part I and Part II)	Key Ballroom 7-12
10:30-11:15AM	Networking Break in the Exhibit Hall Sponsored by ArisGlobal	Key Ballroom 1-6
10:35-11:05AM	Hosted Session/Non-CE: **Case Study Spotlight hosted by IQVIA** Optimizing Pharmacovigilance: Augmenting Human Expertise with Advanced AI/ML Technology	Foyer
11:15-12:30PM	Session 8: Harnessing AI in Pharmacovigilance: Insights, Applications, and Impact	Key Ballroom 7-12

12:30-1:30PM	Networking Luncheon and Roundtable Discussions in the Exhibit Hall Sponsored by ArisGlobal	Key Ballroom 1-6
1:30-3:00PM	Session 9: Advancing Hepatic Safety: Innovations in Predicting, Assessing, and Managing Drug-Induced Liver Toxicity	Key Ballroom 7-12
3:00-3:30PM	Networking Break in the Exhibit Hall Sponsored by ArisGlobal	Key Ballroom 1-6
3:30-5:00PM	Session 10: Enhancing Drug Development with Early Benefit-Risk Strategies and Decision-Driven Visualizations	Key Ballroom 7-12
DAY THREE | WEDNESDAY, JANUARY 29		**ROOM**
7:30AM-12:45PM	Conference Registration	Foyer
7:30-8:00AM	Networking Breakfast	Key Ballroom 1-6
8:00-9:15AM	Session 11: Navigating Pharmacovigilance in Small Pharma: Strategies for Building Sustainable Frameworks	Key Ballroom 7-12
9:20-10:35AM	Session 12: Mastering FDA's New Draft Guidance: Optimizing Data Monitoring Committees in Clinical Trials	Key Ballroom 7-12
10:35-11:15AM	Networking Break in the Exhibit Hall Sponsored by ArisGlobal	Key Ballroom 1-6
10:40-11:10AM	Hosted Session/Non-CE: Case Study Spotlight hosted by Truveta Transforming Post-Approval Research with Real-time EHR Data: Spotlight on Pregnancy Studies	Foyer
11:15-12:30PM	Session 13: Innovations in Safety Signal Detection and Causality Assessment: From Knowledge Graphs to Best Practices	Key Ballroom 7-12
12:30-12:45PM	Closing Remarks	Key Ballroom 7-12
12:45PM	Conference Adjourns	

Learning Objectives

- Analyze global regulatory changes and harmonization efforts across FDA, EMA, MHRA, and other authorities
- Examine AI tools to enhance signal detection, automate literature reviews, and improve safety data analysis within regulatory frameworks
- Recognize patient perspectives to improve decision-making and safety outcomes
- Identify advanced methodologies for RMPs and REMS to optimize patient safety and compliance
- Evaluate real-world evidence (RWE) from claims and electronic health records for regulatory submissions and safety monitoring
- Discuss advanced signal detection methods, such as knowledge graphs and FDA Medical Queries (FMQs), to evaluate safety signals effectively
- Interpret statistical data to assess safety profiles, prioritize risks, and communicate findings accurately
- Recognize how to address safety challenges in special populations, including pediatrics, geriatrics, and rare diseases, through targeted risk assessments
- Describe strategies for efficient pharmacovigilance operations in resource-constrained settings, including adverse event management and outsourcing

Continuing Education Credits

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education with Commendation. This program is designated for up to 15.5 contact hours or 1.55 continuing education units (CEU's). Type of Activity: Knowledge

ACPE Credit Requests MUST BE SUBMITTED by Wednesday, March 12, 2025

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ACPE CREDIT REQUESTS MUST BE SUBMITTED BY WEDNESDAY, MARCH 12, 2025.

Continuing Education Credit Allocation

January 27, 2025 - Global Pharmacovigilance and Risk Management Strategies Conference – Day 1: 5.75 contact hours or .575 CEUs, UAN: 0286-0000-25-005-L04-P Type of Activity: Knowledge
January 28, 2025 - Global Pharmacovigilance and Risk Management Strategies Conference – Day 2: 5.75 contact hours or .575 CEUs, UAN: 0286-0000-25-006-L04-P Type of Activity: Knowledge
January 29, 2025 - Global Pharmacovigilance and Risk Management Strategies Conference – Day 3: 4 contact hours or .4 CEUs, UAN: 0286-0000-25-007-L04-P Type of Activity: Knowledge

Continuing Legal Education

For attorneys who would like to receive continuing legal education credits for attending the 2025 *Global Pharmacovigilance and Risk Management Strategies Conference*, please complete your state's application for credit and submit accordingly. If you require additional information, please contact CE@DIAglobal.org.

Statement of Credit

If you would like to receive a statement of credit for the days you attend the conference, you must attend one, two, or all three days of the conference, (in their entirety), sign in at the DIA registration desk each day, upon arrival, and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, February 12.**

If you are claiming CE credit for the conference you must:

1. Attend one, two, or all three days of the conference, (in their entirety)
2. Sign in at the DIA registration desk each day, upon arrival
3. Access your DIA account and select My Transcript to claim your ACPE credit, available on **Wednesday, February 12, 2025**
4. ACPE credit must be submitted by **Wednesday, March 12, 2025**

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Disclosure statements are included with each speaker's biographical sketch.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

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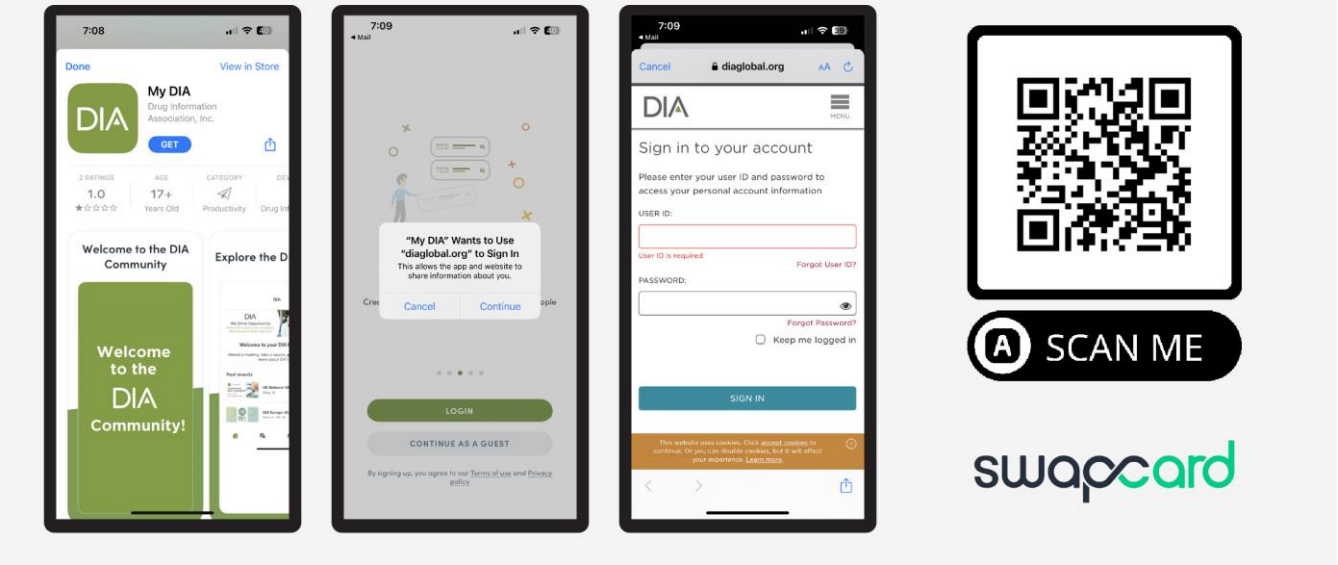

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DIA 2025 is the premier gathering for industry leaders, regulatory authorities, governmental representatives, academia, innovators, and patients. Set against the vibrant backdrop of Washington, DC, DIA 2025 will beckon stakeholders from around the world to converge, collaborate, and catalyze transformative change within the life sciences realm.

At DIA 2025, we will transcend boundaries, inviting diverse voices to the table to address both local and global challenges. From regulatory hurdles to technological innovations, from healthcare disparities to patient-centric solutions, our agenda is comprehensive and forward-thinking.