



# Global Pharmacovigilance and Risk Management Strategies Conference

North Bethesda, MD  
Short Courses: Sunday, January 25  
Conference: January 26-28

## PROGRAM CHAIR

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Pharmacovigilance  
Compliance  
Amneal Pharmaceuticals

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Practice  
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OSE, CDER  
FDA

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Risk Evaluation, Safety  
and Surveillance  
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### **James Buchanan, PharmD**

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Clinical Associate, Pediatric Infectious Diseases  
University of Chicago

## Overview

Join us for DIA's *Global Pharmacovigilance and Risk Management Strategies Conference*, the leading forum for advancing drug safety and regulatory expertise. Developed with regulators and industry leaders, this event offers insights on global harmonization, AI-driven signal detection, benefit-risk assessment, and real-world evidence for safety monitoring. Learn best practices for optimizing RMPs and REMS, integrating patient perspectives, and managing compliance in resource-constrained settings. Connect with experts, regulators, and patient advocates to explore innovative solutions and stay ahead in pharmacovigilance and risk management.

## Event Goals and Offerings

- Provide actionable insights on evolving pharmacovigilance and risk management strategies across global regulatory landscapes
- Highlight real-world applications of advanced technologies such as AI, ML, and real-world data in safety and signal management
- Facilitate regulatory-to-industry dialogue on risk communication, safety assessments, and benefit-risk evaluations
- Equip attendees with the tools to navigate the latest REMS and aRMM guidance and implementation frameworks, including CIOMS XII and the FDA REMS Logic Model

## Why You Can't Miss It

- Network with global pharmacovigilance leaders across regulatory agencies, large pharma, small biotech, and public health foundations
- Hear directly from FDA, EMA, MHRA, and other global regulators about the latest policies, guidance, and structural shifts in safety and surveillance
- Engage in case-based discussions around REMS, signal detection, predictive technologies, and the application of real-world evidence in safety monitoring
- Participate in interactive short courses on risk management convergence and benefit-risk planning aligned with CIOMS XII
- Explore global and regional regulatory updates in Asia, Africa, Europe, and the Middle East in a dedicated session

## 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



IN-PERSON SHORT COURSE   SUNDAY, JANUARY 25		ROOM
8:30AM-12:00PM	Short Course: Introduction to Benefit-Risk Management: Building Strong Assessments for Smarter Decisions <i>*This Short Course requires an additional registration fee. You do not need to be registered for the conference to attend*</i>	Brookside AB (Lower Level)
1:00-4:30PM	Short Course: Translating Global Risk Management Guidance Into Innovation and Patient Safety <i>*This Short Course requires an additional registration fee. You do not need to be registered for the conference to attend*</i>	Brookside AB (Lower Level)
DAY ONE   MONDAY, JANUARY 26		ROOM
7:30AM-5:00PM	Conference Registration	Grand Ballroom Foyer (Upper Level)
7:30-8:30AM	Networking Breakfast	Grand Ballroom A-D
8:30-8:45AM	Welcome and Opening Remarks	Grand Ballroom E-H
8:45-9:30AM	Session 1: Fireside Chat with Dr. Robert Califf: Shaping the Future of Post-Market Safety, Global Harmonization, and More	Grand Ballroom E-H
9:30-10:15AM	Networking Break	Grand Ballroom A-D
9:40-10:10AM	Hosted Session/Non-CE: Case Study Spotlight hosted by	Brookside AB (Lower Level)
10:15-11:30AM	Session 2: Navigating FDA & MHRA Regulatory Policy Shifts Updates to Stay Ahead of Compliance	Grand Ballroom E-H
11:30AM-12:30PM	Networking Luncheon	Grand Ballroom A-D
12:30-1:45PM	Session 3: Adapting Risk Minimization Strategies Across the Product Lifecycle	Grand Ballroom E-H
1:45-2:30PM	Networking Break	Grand Ballroom A-D
1:50-2:20PM	Hosted Session/Non-CE: Case Study Spotlight hosted by	Brookside AB (Lower Level)
2:30-3:45PM	Session 4: Turning Guidance into Action -- Practical Pathways for Effective Risk Management	Grand Ballroom E-H
3:50-5:05PM	Session 5: Fit-for-Purpose Pharmacovigilance: Real-World Best Practices and Strategic PV Planning for Small and Emerging Companies	Grand Ballroom E-H
5:05-6:05PM	Networking Reception	Grand Ballroom A-D
DAY TWO   TUESDAY, JANUARY 27		ROOM
7:45AM-4:15PM	Conference Registration	Grand Ballroom Foyer (Upper Level)
7:45-8:30AM	Networking Breakfast	Grand Ballroom A-D
7:55-8:25AM	Hosted Session/Non-CE: Case Study Spotlight hosted by	Brookside AB (Lower Level)

8:30-9:45AM	<b>Session 6:</b> Let's Go Global: Regional Regulatory Updates from Africa and the Middle East	Grand Ballroom E-H
9:45-10:30AM	<b>Networking Break</b>	Grand Ballroom A-D
9:50-10:20AM	<b>Hosted Session/Non-CE:</b> Case Study Spotlight hosted by	Brookside AB ( <i>Lower Level</i> )
10:30-11:45AM	<b>Session 7:</b> Driving Understanding of Human Risk Through Nonclinical Studies in Early Clinical Trials	Grand Ballroom E-H
11:45AM-1:00PM	<b>Networking Luncheon and Roundtable Discussions</b>	Grand Ballroom A-D
1:00-2:15PM	<b>Session 8:</b> What's New in Advancing Signal Detection? Smarter Tools for Safety Evaluation	Grand Ballroom E-H
2:15-3:00PM	<b>Networking Break</b>	Grand Ballroom A-D
2:20-2:50PM	<b>Hosted Session/Non-CE:</b> Case Study Spotlight hosted by	Brookside AB ( <i>Lower Level</i> )
3:00-4:15PM	<b>Session 9:</b> Harnessing AI and Emerging Tech to Transform Pharmacovigilance	Grand Ballroom E-H
<b>DAY THREE   WEDNESDAY, JANUARY 28</b>		<b>ROOM</b>
8:00AM-12:35PM	<b>Conference Registration</b>	Grand Ballroom Foyer ( <i>Upper Level</i> )
8:00-8:30AM	<b>Networking Breakfast</b>	Grand Ballroom A-D
8:30-9:45AM	<b>Session 10:</b> DIAMond Session: The Safety Pulse: Executive Insights from Global Chief Safety Officers on Maintaining Best-in-Class PV Organizations	Grand Ballroom E-H
9:45-10:20AM	<b>Networking Break</b>	Grand Ballroom A-D
9:50-10:20AM	<b>Hosted Session/Non-CE:</b> Case Study Spotlight hosted by	Brookside AB ( <i>Lower Level</i> )
10:20-11:20AM	<b>Session 11:</b> Even Big Data Can Feel Small: Addressing Safety Evidence Challenges with Practical RWE Solutions	Grand Ballroom E-H
11:25AM-12:25PM	<b>Session 12:</b> Hot Topics in PV -- Timely Insights Shaping the Future of Safety	Grand Ballroom E-H
12:25-12:35PM	<b>Closing Remarks</b>	Grand Ballroom E-H
12:35PM	<b>Conference Adjourns</b>	

## Learning Objectives

- Integrate real-world data and evidence into safety evaluations and regulatory decisions
- Assess the use of AI, ML, and digital tools for signal detection and safety monitoring
- Identify effective methods for communicating safety information and benefit-risk outcomes
- Explain how nonclinical data and NAMs inform early risk assessment
- Discuss strategies for addressing safety challenges in special populations and small organizations
- Summarize key global regulatory and policy updates in pharmacovigilance and risk management
- Apply structured approaches to REMS, aRMMs, and benefit-risk frameworks

## 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 21 contact hours or 2.1 continuing education units (CEU's)

### **ACPE Credit Requests MUST BE SUBMITTED by Friday, March 13, 2026**

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**ACPE CREDIT REQUESTS MUST BE SUBMITTED BY Friday, March 13, 2026.**

## Continuing Education Credit Allocation

**January 25, 2026 – Short Course: Introduction to Benefit-Risk Management: Building Strong Assessments for Smarter Decisions:**

ACPE: 3.25 contact hours or .325 CEUs, Type of Activity: Application, 0286-0000-26-003-L04-P

**January 25, 2026 – Short Course: Translating Global Risk Management Guidance Into Innovation and Patient Safety:** ACPE: 3.25

contact hours or .325 CEUs, Type of Activity: Application, 0286-0000-26-004-L04-P

**January 26, 2026 – Global Pharmacovigilance and Risk Management Strategies Conference – Day 1:** ACPE: 6 contact hours or .6 CEUs,

Type of Activity: Knowledge, 0286-0000-26-005-L04-P

**January 27, 2026 – Global Pharmacovigilance and Risk Management Strategies Conference – Day 2:** ACPE: 5 contact hours or .5 CEUs,

Type of Activity: Knowledge, 0286-0000-26-006-L04-P

**January 28, 2026 – Global Pharmacovigilance and Risk Management Strategies Conference – Day 3:** ACPE: 3.5 contact hours or .35

CEUs, Type of Activity: Knowledge, 0286-0000-26-007-L04-P

## Continuing Legal Education

For attorneys who would like to receive continuing legal education credits for attending the 2026 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](mailto: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 11**.

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

1. Attend the short course(s) 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 11, 2026**
4. ACPE credit must be submitted by **Friday, March 13, 2026**

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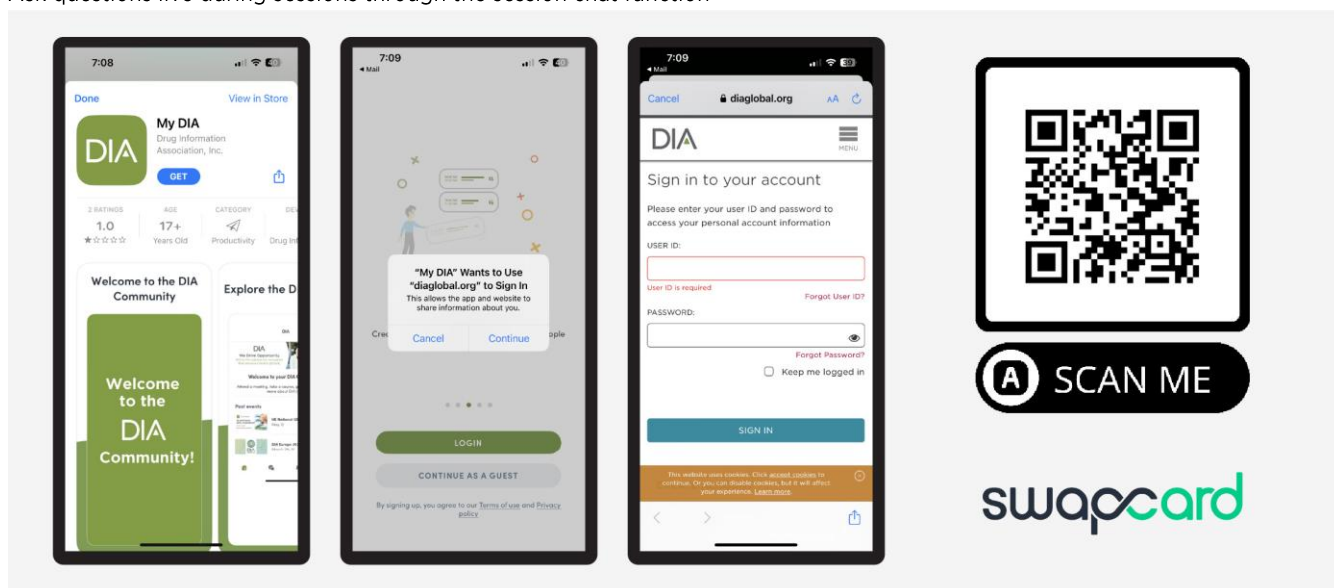
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JUNE 14-18

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DIA 2026 is the premier gathering for industry leaders, regulatory authorities, governmental representatives, academia, innovators, and patients. Set against the vibrant backdrop of Philadelphia, PA, DIA 2026 will beckon stakeholders from around the world to converge, collaborate, and catalyze transformative change within the life sciences realm.

At DIA 2026, 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.