# Global Pharmacovigilance and Risk Management Strategies Conference

VIRTUAL
Short Courses: Sunday, January 25
Conference: January 26-28

## PROGRAM CHAIR

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## PROGRAM ADVISORS

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**Barbara Hendrickson, DrMed, MD**
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## 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.

*We Would Like to Thank Our Exclusive Media Partner!*

RIC REMS Industry Consortium
*Innovating Patient Safety. Mitigating Risk.*

## 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

## 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

## Schedule At-A-Glance (All times listed are Eastern Time)

| IN-PERSON SHORT COURSE \| SUNDAY, JANUARY 25 | | VIRTUAL |
|---|---|---|
| 8:30AM-12:00PM | Short Course: Introduction to Benefit–Risk Management: Building Strong Assessments for Smarter Decisions<br>**This Short Course requires an additional registration fee. You do not need to be registered for the conference to attend** | |
| 1:00-4:30PM | Short Course: Translating Global Risk Management Guidance Into Innovation and Patient Safety<br>**This Short Course requires an additional registration fee. You do not need to be registered for the conference to attend** | |
| **DAY ONE \| MONDAY, JANUARY 26** | | **VIRTUAL** |
| 9:30-10:00AM | Hosted Session/Non-CE: Case Study hosted by APCER Life Sciences: From Acquisition Support to Strategic Partnership: A Case Study of Global Pharmacovigilance and Risk Management System Setup | |
| 10:15-11:30AM | Welcome and Session 2: Navigating FDA, EMA, and MHRA Regulatory Policy Shifts Updates to Stay Ahead of Compliance | |
| 11:30AM-12:30PM | Meal Break – Visit the Virtual Exhibits! | |
| 12:30-1:45PM | Session 3: Adapting Risk Minimization Strategies Across the Product Lifecycle | |
| 1:50-2:20PM | Hosted Session/Non-CE: Case Study hosted by ArisGlobal: Signal Management Reimagined: Harnessing Data Science for Smarter Risk Management | |
| 2:30-3:45PM | Session 4: Turning Guidance into Action -- Practical Pathways for Effective Risk Management | |
| 3:50-5:05PM | Session 5: Fit-for-Purpose Pharmacovigilance: Real-World Best Practices and Strategic PV Planning for Small and Emerging Companies | |
| **DAY TWO \| TUESDAY, JANUARY 27** | | **VIRTUAL** |
| 7:55-8:25AM | Hosted Session/Non-CE: Case Study hosted by COD Research USA Inc: Decode the Risk Management for Combination Products: The Operational Challenges and Actionable Safety Strategies | |
| 8:30-9:45AM | Session 6: Let's Go Global: Regional Regulatory Updates from Africa and the Middle East | |
| 9:50-10:20AM | Hosted Session/Non-CE: Case Study hosted by SeltaSquare: Reimagining Pharmacovigilance: Human-AI Interactive Intelligence | |
| 10:30-11:45AM | Session 7: Driving Understanding of Human Risk Through Nonclinical Studies in Early Clinical Trials | |
| 11:45AM-1:00PM | Meal Break – Visit the Virtual Exhibits! | |
| 1:00-2:15PM | Session 8: What's New in Advancing Signal Detection? Smarter Tools for Safety Evaluation | |
| 2:20-2:50PM | Hosted Session/Non-CE: Case Study hosted by RxLogix Corporation: One System, One Truth: Transforming Safety Surveillance Through End-to-End Integration | |
| 3:00-4:15PM | Session 9: Harnessing AI and Emerging Tech to Transform Pharmacovigilance | |

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|---|---|
| 4:15-4:45PM | Hosted Session/Non-CE: Case Study hosted by Veeva Systems: Connecting Data to Simplify and Accelerate Signal and Risk Management |
| **DAY THREE \| WEDNESDAY, JANUARY 28** | **VIRTUAL** |
| 8:00-8:45AM |  Session 1: Fireside Chat with **Dr. Robert Califf**: Shaping the Future of Post-Market Safety, Global Harmonization, and More |
| 8:45-10:00AM | Session 10: DIAmond Session: The Safety Pulse: Executive Insights from Global Chief Safety Officers on Maintaining Best-in-Class PV Organizations |
| 10:00-10:30AM | Break – Visit the Virtual Exhibits! |
| 10:30-11:30AM | Session 11: Even Big Data Can Feel Small: Addressing Safety Evidence Challenges with Practical RWE Solutions |
| 11:30AM-12:45PM | Session 12: Hot Topics in PV -- Timely Insights Shaping the Future of Safety and Closing Remarks |
| 12:45PM | Conference Adjourns |

## 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

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. **All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity.** If ACPE credit is not requested by Friday, March 13, 2026, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit www.cpemonitor.net.

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.

## Statement of Credit

This should read: If you would like to receive a statement of credit for the days you attend the short course(s) and/or 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, 2026.**

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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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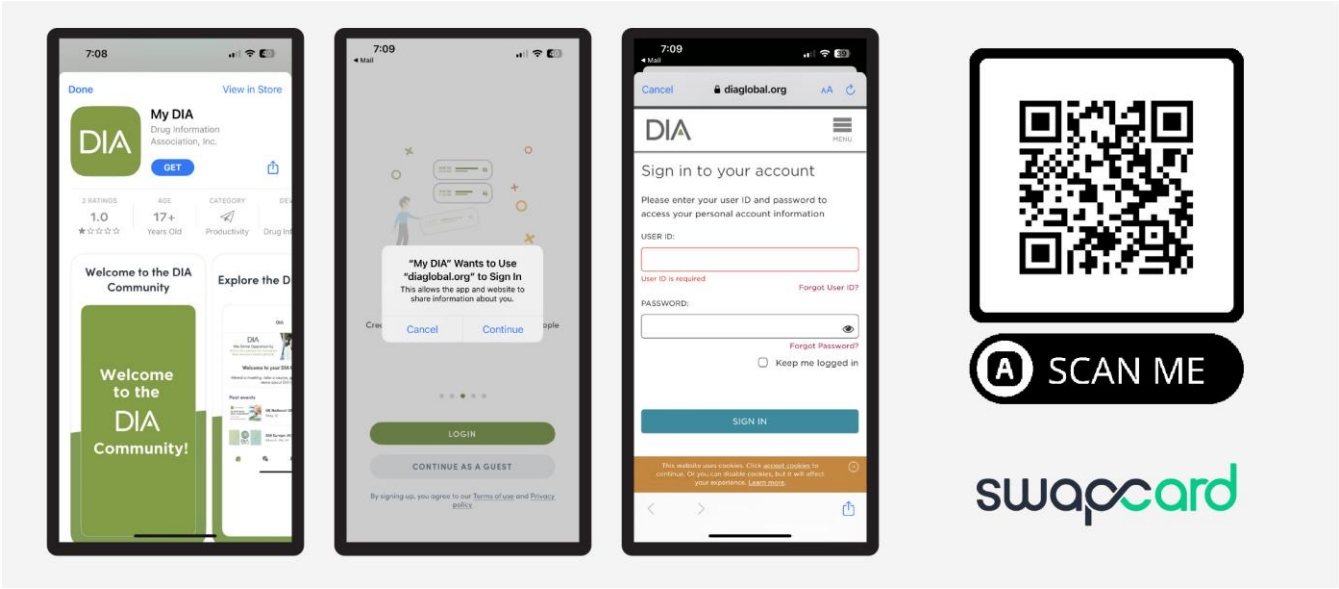


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Follow the instructions on screen, or please see the registration desk/contact NAEvents@DIAglobal.org if you need additional assistance.


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.