DIA

# Global Pharmacovigilance and Risk Management Strategies Conference

Short Course January 24, Virtual | Short Course February 27, Virtual
Short Course February 4, In-Person | Conference February 5-7

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## Overview

DIA's Global Pharmacovigilance and Risk Management Strategies Conference is a neutral event developed by regulators and industry experts discussing the updates, opportunities, and challenges alongside fresh problem-solving strategies that matter most to safety professionals.

## Event Goals and Offerings

- Gain intelligence on key global safety and pharmacovigilance regulatory updates at one single location
- Stay informed on the most up-to-date information on the latest regulations, industry trends, and emerging best practices
- Interact with like-minded professionals and hear success stories to motivate and inspire you to excel in your field
- Network with solution providers to meet the needs of your organization and explore innovative solutions that can streamline your work
- Explore high-end stores and decadent restaurants in the eclectic city of Baltimore!

## Why You Can't Miss It

- Network with like-minded professionals focused on safety and pharmacovigilance to discuss best practices and lessons learned
- Participate in interactive sessions with speakers and other attendees discussing safety considerations for special populations
- Evaluate the application of technology, visualization tools, machine learning, and artificial intelligence to advance safety practices
- Gain insights from global regulatory speakers to stay current with the latest safety and pharmacovigilance updates

## Who Should Attend

Professionals involved in:

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

## VIRTUAL SHORT COURSE | WEDNESDAY, JANUARY 24 AND TUESDAY FEBRUARY 27

| | | |
|---|---|---|
| **10:00AM-2:00PM** | **Short Course: Introduction to Statistics in Pharmacovigilance** | |
| **10:00AM-2:00PM** | **Short Course: Good Pharmacovigilance Practices (GVP) Operations Development – From Clinical Trial to Post Marketing** | |

## IN-PERSON SHORT COURSE | SUNDAY, FEBRUARY 4

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|---|---|---|
| **9:00AM-4:00PM** | **Short Course: Aggregate Safety Assessment Planning (ASAP) Process** | **Laurel AB** |

## DAY ONE | MONDAY, FEBRUARY 5

| | | |
|---|---|---|
| **7:00AM-5:35PM** | **Conference Registration** | **Ballroom Foyer** |
| **7:30-8:30 AM** | **Networking Breakfast in the Exhibit Hall** | **Ballroom VI - X** |
| **8:30-8:40AM** | **Welcome and Opening Remarks** | **Ballroom I-V** |
| **8:40-9:25AM** | **Session 1:** Keynote:<br>  <br>Personalized Medicine and the Pharmaceutical Industry<br>by **Michael Ybarra, MD Chief Medical Officer, PhRMA** | **Ballroom I-V** |
| **9:25-10:10AM** | **Networking Break in the Exhibit Hall** | **Ballroom VI-X** |
| **9:35-10:05AM** | **SPONSORED SESSION: Case Study Spotlight hosted by PharSafer®**<br>Empowering Transformation: Tackling Concerns in Implementing Automated Safety Solutions<br>*Please note that this is an exhibitor sponsored event and is not eligible for CE credit.* | **Dover A-C** |
| **10:10-11:25AM** | **Session 2:** Updates on Policies, Guidances, and Regulations – North America | **Ballroom I-V** |
| **11:25AM-12:25PM** | **Networking Luncheon in the Exhibit Hall** | **Ballroom VI-X** |
| **11:40AM-12:25PM** | **Roundtable Discussions** | **Ballroom VI-X** |
| **12:25-1:40PM** | **Session 3:** Updates on Policies, Guidances, and Regulations – Europe | **Ballroom I-V** |
| **1:40-2:25PM** | **Networking Break in the Exhibit Hall** | **Ballroom VI-X** |
| **2:25-3:40PM** | **Session 4:** Updates on Policies, Guidances and Regulations – Asia | **Ballroom I-V** |
| **3:45-5:00PM** | **Session 5:** Safety Management Considerations for Advanced Therapeutics | **Ballroom I-V** |
| **5:00-6:00PM** | **Networking Reception in the Exhibit Hall** | **Ballroom VI-X** |

## DAY TWO | TUESDAY, FEBRUARY 6

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|---|---|---|
| **7:00AM-4:35PM** | **Conference Registration** | **Ballroom Foyer** |
| **7:00-8:00AM** | **Networking Breakfast in the Exhibit Hall** | **Ballroom VI-X** |
| **8:00-9:15AM** | **Session 6:** Application and Use of Machine Learning, Artificial Intelligence, Automation, and Technology in Pharmacovigilance | **Ballroom I-V** |
| **9:15-10:00AM** | **Networking Break in the Exhibit Hall** | **Ballroom VI-X** |
| **9:25-9:55AM** | **SPONSORED SESSION: Case Study Spotlight hosted by Caidya** Challenge and Opportunities with Safety Management and Reporting in Multinational Studies<br>*Please note that this is a sponsored event and is not eligible for CE credit.* | **Dover A-C** |
| **10:00AM-11:15AM** | **Session 7:** Insights on Benefit-Risk Assessment | **Ballroom I-V** |
| **11:20-12:35PM** | **Session 8:** Risk Management, Past, Present and Future? | **Ballroom I-V** |
| **12:35-1:35PM** | **Networking Luncheon in the Exhibit Hall** | **Ballroom VI-X** |
| **12:45-1:30PM** | **Sponsored Roundtable Discussions**<br>**Roundtable 1 Hosted by PPD, part of Thermo Fisher Scientific**<br>**Roundtable 2 Hosted by Digital Science & Research Solutions Inc**<br>**Roundtable 3 Hosted by Ultragenic Research and Technologies LLC** | **Ballroom VI-X** |
| **1:35-2:50PM** | **Session 9:** Use of Real-World Data and Real-World Evidence in Safety | **Ballroom I-V** |
| **2:50-3:20PM** | **Networking Break in the Exhibit Hall** | **Ballroom VI-X** |
| **3:20-4:35PM** | **Session 10:** Insights into the Collection of Safety Data in Pregnancy | **Ballroom I-V** |
| **4:35-7:00PM** | **Global Annual Meeting Kick-off Session and Reception sponsored by IQVIA** | |

## DAY THREE | WEDNESDAY, FEBRUARY 7

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|---|---|---|
| **7:00AM-12:00PM** | **Conference Registration** | **Ballroom Foyer** |
| **7:30-8:30AM** | **Networking Breakfast in the Exhibit Hall** | **Ballroom VI-X** |
| **8:30-9:45AM** | **Session 11:** Signal Detection and Evaluation | **Ballroom I-V** |
| **9:45-10:05AM** | **Networking Break in the Exhibit Hall** | **Ballroom VI-X** |
| **10:05-11:20AM** | **Session 12:** Implementation of Safety Surveillance Plans Roundtables | **Ballroom I-V** |
| **11:20–11:40AM** | **Networking Break in the Exhibit Hall** | **Ballroom VI-X** |
| **11:40AM-12:55PM** | **Session 13:** The World is Changing, How do We Adapt? | **Ballroom I-V** |
| **12:55-1:00PM** | **Closing Remarks** | **Ballroom I-V** |

## Learning Objectives

At the conclusion of this conference, participants should be able to:

- Describe the new internationally harmonized guidance on a selective approach to safety data collection in specific late-stage pre-approval or post-approval clinical trials
- Discuss safety regulatory updates in the U.S, U.K, Europe, Japan, and China.
- Recognize MHRA's progress on updating clinical trial regulations in the UK and its impact on pharmacovigilance activities.
- Define FDA draft guidance on the Benefit-Risk Assessment for New Drug and Biological Products for Industry
- Identify new signal detection tools and reinforce the FMQ method and analysis
- Evaluate how regulatory differences impact global risk management organizations and design/implementation of risk minimization materials
- Describe challenges to establishing global approaches to risk minimization and identify risk analysis approaches to developing risk minimization materials
- Analyze recent advances in the use of AI/ML with respect to safety surveillance
- Identify the latest strategies for managing literature requirements at local and global level
- Examine various ways RWE/RWD are utilized in regulatory interactions during clinical development and its role in the evaluation of safety signals arising from clinical trial data
- Recognize MHRA's progress on updating clinical trial regulations in the UK and its impact on pharmacovigilance activities:
- Evaluate how regulatory differences impact global risk management organizations and design/implementation of risk minimization materials:
- Describe the new internationally harmonized guidance on a selective approach to safety data collection in specific late-stage pre-approval or post-approval clinical trials

## Continuing Education Credits

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 29.75 contact hours or 2.975 continuing education units (CEU's). Type of Activity: Knowledge

**ACPE CREDIT REQUESTS MUST BE SUBMITTED BY WEDNESDAY, MARCH 20, 2024.**

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 **Wednesday, March 20, 2024**, 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

- **January 24, 2024** - Short Course #1 Introduction to Statistics in Pharmacovigilance -Virtual: 3.75 contact hours or .375 CEUs Type of Activity: Knowledge, 0286-0000-24-001-L04-P; .4 IACET CEUs; CME - 3.75 *AMA PRA Category 1 Credit(s)™*
- **February 27, 2024** - Short Course #2 Good Pharmacovigilance Practices (GVP) Operations Development – From Clinical Trial to Post Marketing – Virtual: 3.75 contact hours or .375 CEUs Type of Activity: Knowledge, 0286-0000-24-003-L04-P; .4 IACET CEUs; CME – 3.75 *AMA PRA Category 1 Credit(s)™*
- **February 4, 2024** - Short Course #3 Aggregate Safety Assessment Planning (ASAP) Process – In Person: 6.5 contact hours or .65 CEUs Type of Activity: Knowledge, 0286-0000-24-002-L04-P; CME – 6.5 *AMA PRA Category 1 Credit(s)™*
- **February 5, 2024 –** Global Pharmacovigilance and Risk Management Strategies Conference – Day 1: 5.75 contact hours or .575 CEUs Type of Activity: Knowledge, 0286-0000-24-004-L04-P; CME - 4.5 *AMA PRA Category 1 Credit(s)™*
- **February 6, 2024** - Global Pharmacovigilance and Risk Management Strategies Conference – Day 2: 6.25 contact hours or .625 CEUs Type of Activity: Knowledge, 0286-0000-24-005-L04-P; CME - 6.25 *AMA PRA Category 1 Credit(s)™*
- **February 7, 2024** - Global Pharmacovigilance and Risk Management Strategies Conference – Day 3: 3.75 contact hours or .375 CEUs Type of Activity: Knowledge, 0286-0000-24-006-L04-P; CME - 3.75 *AMA PRA Category 1 Credit(s)™*

## Joint Accreditation Statement

In support of improving patient care, this activity has been planned and implemented by Partners for Advancing Clinical Education (PACE) and Drug Information Association. PACE is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

## Physician Continuing Education

PACE designates this live activity for a maximum of 28.5 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Drug Information Association (DIA) is accredited by the International Accreditors for Continuing Education and Training (IACET) and offers IACET CEUs for its learning events that comply with the ANSI/IACET Continuing Education and Training Standard. IACET is recognized internationally as a standard development organization and accrediting body that promotes quality of continuing education and training.

As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to .8* CEUs for this program.

Participants must attend the entire virtual short course to be able to receive an IACET statement of credit. No partial credit will be awarded.

***IACET CEUs are only available for the virtual Short Course.**

As an Accredited Provider by the Accreditation Council for Pharmacy Education (ACPE) the American Nurses Credentialing Center (ANCC) recognizes ACPE Credit(s)™ issued by DIA as acceptable toward license Nurses Credentialing Center (ANCC) recognizes ACPE Credit(s)™ issued by DIA as acceptable toward license CE requirements for nursing. Please refer to page five in the requirements for additional information.

https://www.diaglobal.org/Tools/Content.aspx?type=eopdf&file=%2fproductfiles%2f7955382%2frenewal-requirements%2Epdf

## Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the conference, you must attend one or all three days of the conference, (in their entirety) sign in at the DIA registration desk each day, 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 21, 2024**.

If you are claiming CE credit for this event you must:

1. Attend one 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 or CME credit, available on **Wednesday, February 21, 2024**

4. ACPE credit must be claimed by **March 20, 2024**

## PACE and DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

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

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This educational activity may contain discussion of published and/or investigational uses of agents that are not indicated by the FDA. The planners of this activity do not recommend the use of any agent outside of the labeled indications. The opinions expressed in the educational activity are those of the faculty and do not necessarily represent the views of the planners. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

## Disclaimer

Participants have an implied responsibility to use the newly acquired information to enhance patient outcomes and their own professional development. The information presented in this activity is not meant to serve as a guideline for patient management. Any procedures, medications, or other courses of diagnosis or treatment discussed or suggested in this activity should not be used by clinicians without evaluation of their patient's conditions and possible contraindications and/or dangers in use, review of any applicable manufacturer's product information, and comparison with recommendations of other authorities.

## Planning Committee

DIA staff members have no relevant financial relationships to disclose.

The PACE planners and others have no relevant financial relationship(s) to disclose with ineligible companies. The DIA planners and others have no relevant financial relationship(s) to disclose with ineligible companies.

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- Choose **My Presentation**

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# Want to view the detailed agenda? Download DIA's Mobile App!

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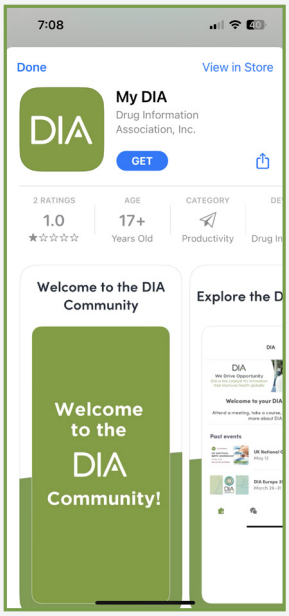


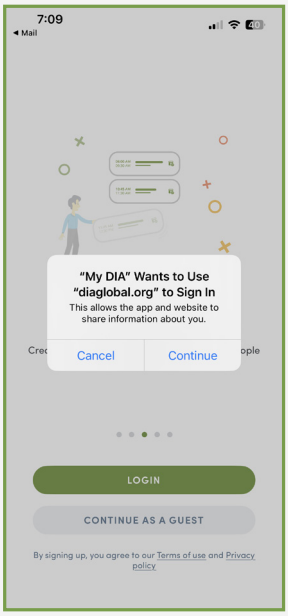


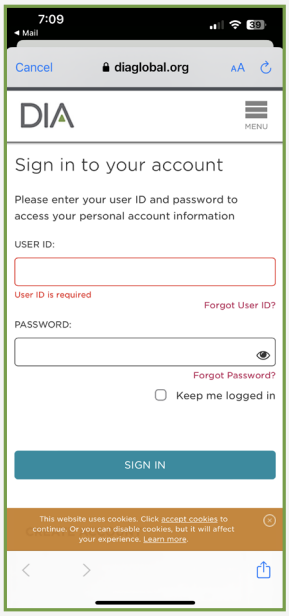


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