Global Labeling Conference

Conference March 14-15

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Overview

DIA's *Global Labeling Conference* is designed for professionals in medical product labeling and related disciplines as they work to develop and manage clear and accurate labeling information for the safe and effective use of prescription drugs, biologics, and medical devices. The efforts of these professionals are key to providing essential information needed by providers, patients, and payers to make decisions about product access, prescription, and use. Influences such as digital technology, patient centricity, evolving product classes, and changing regulations require the use of informed, systematic approaches throughout the labeling cycle to ensure the development and availability of current, compliant information in all regions where products are marketed.

This conference provides a forum for exchange among regulators and industry peers to update their knowledge of key local and global labeling policies and to examine the impact of changes on regulatory compliance. Most importantly, through interactive discussions with expert panels and peer-to-peer exchange, participants will share approaches, processes, and tools to ensure the availability of effective labeling content meeting the needs of patients, consumers, and prescribers.

Event Goals and Offerings

- Gather insights to hot topics impacting labeling professions in life sciences research and development
- Hear directly from global regulators on regulatory plans, priorities, and updates to incorporate into your everyday work and processes
- Identify how advanced technologies and innovation can be applied to impact function and processes within labeling

Why You Can't Miss It

- · Gain access to the latest advancements in labeling
- Get firsthand global regulatory updates and insights from regulators and labeling experts
- · Learn how to streamline your labeling processes
- Connect with professionals from around the world and learn how labeling practices are being embraced and adapted
- Stay ahead of the curve and ensure your organization remains competitive in the evolving labeling landscape
- Enhance your skills and knowledge

Who Should Attend

Professionals involved in:

- Labeling
- Regulatory Affairs/Drug Review and Approval Process
- Clinical Safety/Pharmacovigilance
- Pharmacoepidemiology
- Medical Affairs and Communications
- Medical Writing
- Clinical Research and Development
- Product Research and Development Alliances
- Quality Control/Quality Assurance
- Marketing/Advertising/Promotion



602 Office Center Drive Suite 120 Fort Washington, PA 19034 USA

#Labeling24 | DIAglobal.org As of February 29, 2024

Schedule At-A-Glance

DAY ONE | THURSDAY MARCH 14

7:30AM-5:05PM	Conference Registration Main Lobby, outside North/	Main Lobby, outside North/South Ballrooms	
7:30-8:30 AM	Networking Breakfast	North Ballroom	
8:30-8:45AM	Welcome and Opening Remarks	South Ballroom	
8:45-10:00AM	Session 1: Global Regulatory Updates	South Ballroom	
10:00-10:40AM	Refreshments, Exhibits, and Networking Break Sponsored by Clemser	North Ballroom	
10:05-10:35AM	Hosted Session/Non-CE: Case Study Spotlight hosted by Glemser® How artificial intelligence is being applied to generate FHIR outputs	Cavalier A	
	Please note that this is an exhibitor sponsored event and is not eligible for CE credit.		
10:40-11:55AM	Session 2: End-to-end Labeling Part 1: The Development Phase	South Ballroom	
11:55AM-12:55PM	Luncheon, Exhibits, and Networking Break	and Networking Break North Ballroom	
12:55-2:10PM	Session 3: eLabeling: Regulatory Environment, Early-stage Developments, and Global Adoption	South Ballroom	
2:10-2:50PM	Refreshments, Exhibits, and Networking Break Sponsored by Clemser North Ballroo		
2:15-2:45PM	Hosted Session/Non-CE: Case Study Spotlight hosted by IQVIA® Ensuring Labeling Harmonization Amidst a Legal Entity Change	Cavalier A	
	Please note that this is an exhibitor sponsored event and is not eligible for CE credit.		
2:50-4:05PM	Session 4: Panel Discussion: Impact of Company Size on Labeling Innovation	South Ballroom	
4:05-5:05PM	Networking Reception	North Ballroom	

DAY TWO | FRIDAY, MARCH 15

7:30AM-4:15PM	Conference Registration Ma	in Lobby, outside North/SouthBallroom
7:30-8:30AM	Networking Breakfast	North Ballroom
8:30-10:00AM	Session 5: Patient Centric Labeling: Putting the Patient at the Heart of the Label	South Ballroom
10:00-10:40AM	Refreshments, Exhibits, and Networking Break	North Ballroom
10:05-10:35AM	Hosted Session/Non-CE: Case Study Spotlight hosted Life Science Solutions	by Perigord Cavalier A
	Please note that this is a sponsored event and is not elig	ible for CE credit.
10:40-11:55AM	Session 6: End-to-end Labeling Part 2: The Implementa	ation Phase South Ballroom

11:55AM-12:55PM	Luncheon, Exhibits, and Networking Break	North Ballroom	
12:55-2:10PM	Session 7: eLabeling: Patient Interactions, Advanced e-Labeling Initiatives, and Public/Private Consortia Insights	South Ballroom	
2:10-2:50PM	Refreshments, Exhibits, and Networking Break	North Ballroom	
2:15-2:45PM	Hosted Session/Non-CE: Case Study Spotlight hosted by Doctor Evidence: The Label and Beyond – How to Accelerate Strategy, Planning and Approval with AI-enabled Technology	Cavalier A	
	Please note that this is a sponsored event and is not eligible for CE credit.		
2:50-4:05PM	Session 8: Unveiling Precision: AI, ML, and NLP in Regulatory Labeling	South Ballroom	
4:05-4:15PM	Closing Remarks	South Ballroom	
4:15PM	Conference Adjourns	South Ballroom	

Learning Objectives

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

- Gain insights from global regulatory health authorities
- Discuss best practices and learnings when implementing a broader target product labeling (TPL) process
- Recognize global adoption trends of e-labeling initiatives and describe the best practices and challenges for implementation
- Identify themes and trends in the labeling organizations of small and large companies
- Apply recent patient centric labeling initiatives
- Recognize regional requirements for compliant management of iterative product information
- Discuss regulator interactions, early-stage developments, and global adoption patterns for e-labeling
- Explain the use of AI and ML to support the work of labeling professionals
- 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

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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 10.5 contact hours or 1.05 continuing education units (CEU's). Type of Activity: Knowledge



ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, APRIL 19, 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 Friday, April 19, 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 <u>www.cpemonitor.net</u>

Continuing Education Credit Allocation

March 14, 2024 – Global Labeling Conference – Day 1: 5 contact hours or .5 CEUs Type of Activity: Knowledge, 0286-0000-24-044-L04-P

March 15, 2024 – Global Labeling Conference – Day 2: 5.5 contact hours or .55 CEUs Type of Activity: Knowledge, 0286-0000-24-045-L04-P

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 both 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 **Friday, March 29**.

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

- 1. Attend one or both 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 CE credit, available on Friday, March 29
- 4. ACPE credit must be claimed by April 19

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.

To view DIA's Disclosure and Grievance Policies, visit DIAglobal.org/CE

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- Select My Transcripts then Manage My Transcripts

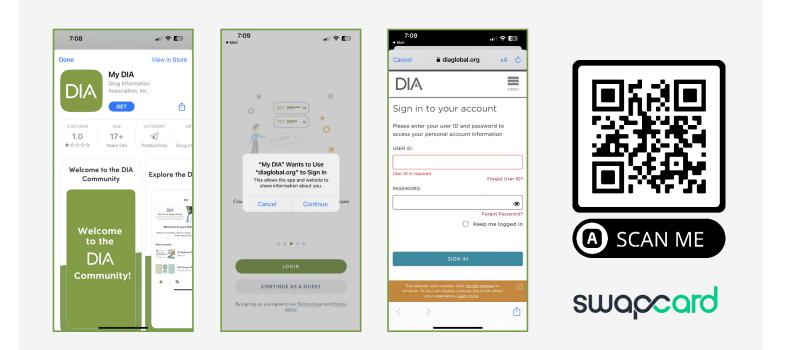
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You will be directed to login to our My DIA Account in order to access the mobile app. Follow the instructions on screen, or please see the registration desk/contact <u>NAEvents@diaglobal.org</u> if you need additional assistance.



Thank you for joining us at this DIA Conference!

We want to thank you with a 10% off discount code for DIA's Global Annual Meeting!

Use code **DIA24Thanks** at checkout!