

Global Labeling Conference

Short Course: April 3 | Virtual Conference: April 7-8 The Westin Arlington

PROGRAM CHAIR

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Overview

DIA's Global Labeling Conference brings together medical product labeling professionals to address the challenges of developing and managing clear. accurate, and compliant labeling information for prescription drugs, biologics, and medical devices. As digital technology, patient needs, and regulatory landscapes evolve, this conference provides a platform for industry and regulatory experts to share knowledge, best practices, and tools for creating effective labeling that meets the needs of patients, providers, and payers worldwide.

Event Goals and Offerings

- Gain insights into hot topics impacting labeling professions in life sciences research and development
- Hear 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 functions and processes within labeling

Why You Can't Miss It

- Gain insights into hot topics impacting labeling professions in life sciences research and development
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Who Should Attend

Forum Designed For:

- 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
- Packaging
- Patient Advocacy
- Supply Chain

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

VIRTUAL SHORT COURSE | THURSDAY, APRIL 3

Global Labeling – The Basics of Core Datasheet

10:00AM-2:00PM *Short Course requires an additional registration fee. You do not need to be

registered for the Conference to attend.

DAY ONE MONDAY, APRIL 7 ROOM		
7:30AM-5:35PM	Meeting Registration	Ballroom Foyer
7:30-8:15AM	Networking Breakfast	Ballroom Foyer
8:15-8:30AM	Welcome and Opening Remarks	F. Fitzgerald Ballroom CDE
8:30-10:00AM	Session 1: Last One Mile for e-labeling: Accelerating Health Innovation with e-labeling and Healthcare Interoperability	F. Fitzgerald Ballroom CDE
10:00-10:45AM	Refreshments, Exhibits, and Networking Break	Ballroom Foyer
10:05-10:35AM	Non-CE: Case Study Spotlight by Dr. Evidence – How BioNTech Uses AI-Enabled Labeling Intelligence to Drive Global Strategy	F. Fitzgerald Ballroom B
10:45AM-12:00PM	Session 2: Patient Centric Labeling for Shared Decision-making in Healthcare	F. Fitzgerald Ballroom CDE
12:00-1:00PM	Luncheon, Exhibits, and Networking Break	Ballroom Foyer
1:00-2:15PM	Session 3: Ensuring Excellence in Safety Labeling: Strategies, Collaboration, and Global Best Practices	F. Fitzgerald Ballroom CDE
2:15-3:00PM	Refreshments, Exhibits, and Networking Break	Ballroom Foyer
2:20-2:50PM	Non-CE: Case Study Spotlight by Glemser – Structured Content Al and ePI Conversions	F. Fitzgerald Ballroom B
3:00-4:15PM	Session 4: End-to-End (E2) Labeling Process, Concepts, and Initiatives	F. Fitzgerald Ballroom CDE
4:20-5:35PM	Session 5: Packaging Label Insights	F. Fitzgerald Ballroom CDE
5:35-6:35PM	Networking Reception	Ballroom Foyer
DAY TWO TUESDAY, APRIL 8		ROOM
7:30AM-3:45PM	Meeting Registration	Ballroom Foyer
7:30-8:15AM	Networking Breakfast	Ballroom Foyer
8:15-9:30AM	Session 6: Professional Development for Labeling: Building Skills for Cross-Functional and Digital Success	F. Fitzgerald Ballroom CDE
9:30-10:15AM	Refreshments, Exhibits, and Networking Break	Ballroom Foyer
9:35-10:05AM	Non-CE: Case Study Spotlight by Basil Systems – Unleash Oncology: Fast-Track Market Access with Unified Labeling	F. Fitzgerald Ballroom B

10:15-11:30AM	Session 7: Human Factors Testing to Core Device Label - Case Study	F. Fitzgerald Ballroom CDE
11:30AM-12:30PM	Luncheon, Exhibits, and Networking Break	Ballroom Foyer
12:30-1:45PM	Session 8: Will Artificial Intelligence (AI) Transform Drug Labeling Processes?	F. Fitzgerald Ballroom CDE
1:45-2:30PM	Refreshments, Exhibits, and Networking Break	Ballroom Foyer
1:50-2:20PM	Non-CE: Case Study Spotlight by RWS – Navigating Complex Labeling with Structured Content & Al-driven Knowledge Portal	F. Fitzgerald Ballroom B
2:30-3:30PM	Session 9: Rare Diseases: Cell and Gene Therapy Considerations for Developing the Label and Your Stakeholders	F. Fitzgerald Ballroom CDE
3:30-3:45PM	Closing Remarks	F. Fitzgerald Ballroom CDE
3:45PM	Conference Adjourns	

Learning Objectives

- Discuss global labeling regulations and trends, including updates from key regions and emerging initiatives, such as e-labeling and healthcare interoperability
- Explain ways to ensure labeling compliance with regulatory requirements by applying best practices that uphold labeling accuracy, safety, and consistency across global markets
- Recognize the role of advanced technologies, such as AI, ML, and NLP in streamlining labeling processes and improving
 efficiency
- Discuss how to incorporate patient perspectives and health literacy principles into labeling practices to improve accessibility and understanding among diverse patient populations
- State techniques to optimize end-to-end labeling through effective governance, traceability, and lifecycle alignment from development to compliance
- Recognize ways to address specialized labeling challenges, such as CGT and rare diseases, by leveraging new guidelines and stakeholder collaboration
- Describe areas to build upon key professional development skills, including leadership, compliance, and adaptability

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 15.25 contact hours or 15.25 continuing education units (CEU's). Type of Activity: Knowledge. <u>ACPE Credit Requests MUST BE SUBMITTED by Monday, May 19, 2025</u>

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 Monday, May 19, 2025, 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 MONDAY, MAY 19, 2025.

Statement of Credit

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, 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 Tuesday, April 22, 2025.

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 ACPE credit, available on Tuesday, April 22, 2025
- 4. ACPE credit must be submitted by Monday, May 19, 2025

Continuing Education Credit Allocation

April 3, 2025 – Global Labeling – The Basics of Core Datasheet: 3.5 contact hours or .35 CEUs, UAN: 0286-0000-25-011-L04-P Type of Activity: Knowledge

April 7, 2025 – Global Labeling Conference – Day 1: 6.75 contact hours or .675 CEUs, UAN: 0286-0000-25-012-L04-P Type of Activity: Knowledge

April 8, 2025 – Global Labeling Conference – Day 2: 5 contact hours or .5 CEUs, UAN: 0286-0000-25-013-L04-P Type of Activity: Knowledge

Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. *Presentations will be available for six months post conference.

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- Select My Account from the menu
- Select My Transcripts then Manage My Transcripts

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- Select **My Account** from the menu
- Choose My Presentation

DIA Disclosure Policy

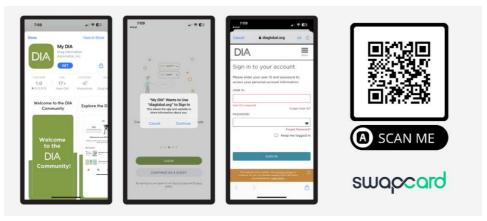
It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved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

Planning Committee

 $\ensuremath{\mathsf{DIA}}$ staff members have no relevant financial relationships to disclose.

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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.