

Medical Affairs and Scientific Communications 2016 Annual Forum Virtual Conference



March 22: 8:30-10:00AM 1:30-3:00PM | March 23: 1:00-2:30PM 3:00-4:30PM

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Overview

For the first time, DIA is offering four sessions virtually from the Medical Affairs and Scientific Communications 2016 Annual Forum. The cross-functional sessions will help you gain further expertise and networking opportunities in your own area as well as different functional areas.

Who Should Attend

- Medical Communications
- Medical Writing
- Medical Liaisons
- Medical Information
- Medical Call Center Environment
- Regulatory Affairs
- Clinical Research
- Professional Education, Training and Development
- Document Management/eSubmissions

Highlights

- Four live-streamed sessions focused on medical information, medical science liaisons, medical call centers, and medical writing (regulatory and publication) delivered in real time.
- Interactive group discussions
- Twitter chats
- Access to session presentations
- Continuing Education

We Hope To See You Next Year!

Medical Affairs and Scientific Communications 2017 Annual Forum

Core Curriculum:
March 12, 2017

Tutorials (AM):
March 13, 2017

Forum: March 13-15, 2017

Hilton El Conquistador Resort
Tucson, AZ



Medical Communications eLearning Certificate Program

Module 1: Crisis Management

Module 2: Database Management

Module 3: Literature Evaluation

Module 4: Literature Searching

Module 5: Medical Inquiries

Module 6: Medical Writing

Module 7: Product Labeling

Module 8: Regulatory Issues

Module 9: Statistics for Medical Communications
Professionals

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Continuing Education

 DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for 6 contact hours or .6 continuing education units (CEU's). Type of activity: Knowledge



ACPE credit requests **MUST BE SUBMITTED by FRIDAY, MAY 6, 2016**

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, May 6, 2016, 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.



DIA has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET).

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer 0.6 CEUs for this program. Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you would like to receive a statement of credit, you must participate in the sessions, sign in (through the designated portal, assigned after registration), and complete the online credit request process through My Transcript. 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 on **Wednesday, April 6, 2016**.

To access My Transcript:

- Visit DIAglobal.org, select "Sign in" and you will be prompted for your user ID and password
- Choose MENU, found in the upper left corner
- Under CONFERENCES select "Continuing Education"
- Select the blue "My Transcript" button followed by "Credit Request" to process your credit request for the forum

It is DIA's 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. Faculty disclosures will be included in the handout materials.

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Continuing Education Credit Allocation

- **Policy and Medicine:** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-038-L04-P
- **Demonstrating and Communicating the Value of Medicines Through Health Economic and Outcomes Evidence:** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-044-L01-P
- **Making Patients the Priority:** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-059-L05-P
- **New Drugs of 2015 Review and Closing Remarks:** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-060-L01-P

8:30–10:00AM

Session 1: Policy and Medicine

Session Co-Chairs:

Kevin Appareti, MBA

Senior Director
Global Medical Science Liaison
Philips HealthTech

Julia Petses, PharmD

Director
Medical Information Services, Diabetes
Sanofi US

The rapid transformation of the US health care landscape creates an environment that is complex and constantly evolving. The regulation of communication is in a state of flux; the amount of activity in this area is greater today than it has been over the past several decades.

It is essential under these circumstances to stay abreast of legislative, judicial, and regulatory developments that may impact how pharmaceutical companies communicate and disseminate off label medical information.

This session will provide an update of current legislative, judicial, and regulatory developments, and the potential implications to our work. Topics such as: 21st Century Cures Act and companion bills, MIWG and PhRMA citizen petitions, Amarin and similar cases, and/or other relevant subjects at the time of the meeting, may be addressed.

Learning Objectives:

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

- Describe and discuss current policy regulating communications
- Explore the trends and directions of these and other activities in order to better prepare and react to changes as they evolve

Industry Perspective

Jamie Haney, JD

General Counsel - Lilly Diabetes Senior Director and Assistant General Counsel
Eli Lilly and Company

What Patient Groups and PhRMA Are Saying About Expanded Off-Label Communication

John Kamp, JD, PhD

Executive Director
Coalition For Healthcare Communication

The Ability to Communicate Truthful, Non-Misleading Speech: Developments in the Courts, Congress, and the Agency

Alan R. Bennett, JD

Senior Counsel
Ropes & Gray

1:30–3:00PM

Session 2: Demonstrating and Communicating the Value of Medicines Through Health Economic and Outcomes Evidence

Session Co-Chairs:

Donna Wartski

Medical Outcomes Specialist
Pfizer Inc.

Darryl Zachary L'Heureux, PhD, MPharm, MSc

Principal Writer
MedSciTech Writing

The reimbursement landscape has elevated the importance of health economics and outcomes research (HEOR) within the pharmaceutical industry. Demands from payers, population health decision makers, and payment models that incentivize quality have placed higher demands on the data provided and the importance of market access. In addition to clinical attributes such as safety and efficacy, there is an increased demand for evidence supporting the real-world use of a drug, including patient experience, medication adherence, comparative effectiveness, and cost implications. It is essential for medical communicators working on any HEOR-related work to understand the role of that work within the context of the value proposition. Furthermore, field medical colleagues such as medical liaisons and outcomes liaisons play an important role in communicating this information to payers to inform their formulary decisions and quality initiatives.

Learning Objectives:

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

- Review the external regulatory and health care landscape
- Describe the scope of health pharmacoeconomic research and the differences from clinical trials
- Discuss why health outcomes and pharmacoeconomics data are important to payer customers and how they use this information
- Examine effective medical communication techniques and tools utilized by field medical colleagues

Demonstrating Value of Medicines Through Health Economic and Outcomes Evidence

Eleni Samaras Allen, PharmD

Senior Manager
REMS Program Management (RPM)
Amgen Inc.

Communicating the Value of Medicines to Payer Customers

Christopher M. Marrone, PharmD

Real World Outcomes Liaison
Eli Lilly and Company

Customer Insight

Richard Montgomery

Contracts and Operations Manager-Pharmacy
Adventist Health System

1:00–2:30PM

Session 3: Making Patients the Priority

Session Chair:

Christi C Marsh, PharmD, RPh

Director, UCB Cares
UCB, Inc.

In this patient-focused session, we will explore insights from a new solution center and how to measure time to impact to value with a patient-focused mindset. Two patient advocates will share their insights on how to engage patients as partners. There will be a discussion on the challenges of navigating through a chronic illness as well as important resources that are available to help patients. Key points will include the importance of finding community and support groups for patients, earlier involvement of patients in research and development, and caregiver needs and resources.

Learning Objectives:

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

- Discuss the patient's perspective, the top concerns and needs upon diagnosis of a chronic disease
- Explain how advocacy and support groups are a vital part of helping awareness as well as healing and connection to solutions for patients and caregivers
- Discuss new ways to use our communications knowledge and platforms to identify some new solutions in which patients want or need from pharmaceutical companies
- Recall how patients have benefited from partnering with industry programs/offers, the limitations and gaps that still exist, and possible opportunities in the future
- Describe how the evolution of customer surveys and feedback have been adapted to offer value to patients including quality of answers, evolving response documents, improved time to therapies, and access to other resources for patient therapy

Customer Interactions: Time to Impact to Value, Insights from a New Solution Center and Patient Focused Mindset

Christi C Marsh, PharmD, RPh

Director, UCB Cares
UCB, Inc.

Patients as Partners

Bill Wilkins

Owner/Founder
Wilkins Foundation For Parkinson's Disease

Chris Maxwell

Patient, Pastor, Author, Speaker, and Spiritual Director
Author of "Changing My Mind"

3:00–4:30PM

Session 4: New Drugs of 2015 Review

Session Chair:

Craig J. Klinger, RPh

Consultant
Medical Liaison Strategy and Capabilities – Trainer
Lilly USA, LLC

Update your knowledge on new drugs that have been approved or have been given new indications or line extensions by the FDA in 2016. A unique New Drug Comparison Rating (NDCR) system will be reviewed to allow you to understand the features of new drugs and explain their role among currently available therapies.

Learning Objectives:

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

- Identify the indications and routes of administration of the new therapeutic agents
- Describe the important pharmacokinetic properties and the unique characteristics of the new drugs
- Restate the most important adverse events and precautions of the new drugs
- Compare the new drugs to the older therapeutic agents to which they are most similar in activity
- Assess information regarding the new drugs that should be communicated to patients

Daniel A Hussar, PhD, MS

Remington Professor of Pharmacy
Philadelphia College of Pharmacy, University of the Sciences In Philadelphia

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DIA 2016

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DIA 2016 is packed with 175+ educational offerings over 22 tracks on today's hottest topics. It is our largest interdisciplinary event, bringing together a global network of 7,000+ life sciences professionals from industry, academia, regulatory and government agencies, and patient and philanthropic organizations from around the globe, to foster innovation in the discovery, development, and life cycle management of health care products.



Just Announced – DIA 2016 Co-Chairs:

Hans-Georg Eichler, MD, MSc

Senior Medical Officer, European Medicines Agency



Gigi Hirsch, MD

Executive Director, MIT Center for Biomedical Innovation

Featured Sessions:

- Disease Interception: Shifting the Paradigm from Treatment to Prevention of Disease
- Expedited Reviews and Other Pathways to Speed up Access to Medicines
- Lessons Learned from Eight Years of Drug Development Tool/Novel Methodology Qualification
- Regulatory Science Considerations Applying to Novel Biologics and Bifunctional Biologics Development
- Infectious Disease Containment and Lessons Learned

Featured Highlights

- Global regulatory presence with representatives from FDA, EMA, PMDA, Health Canada, and more
- NEW Engage and Exchange Sessions: Engage with fellow attendees in a new, collaborative learning environment
- Increase your knowledge while allowing for small group interaction with DIA 2016 Preconference Tutorials
- Hear from the top thought-leaders in drug development discuss topics such as 21st Century Cures, biologics/biosimilars, patient engagement, mobile/wearable technology, big data, personalized medicine, approval pathways, pricing, reimbursement and access, plus much more



**Agenda
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