25th Annual
Medical and Scientific Communications 2014
Annual Forum
Core Curriculum: March 9 | Tutorials (AM): March 10
Forum: March 10-12 | Orlando, FL

OVERVIEW:
We are celebrating the 25th Anniversary of this Annual Forum, and the accomplishments of introducing new areas of content over the years to help pharmaceutical based Medical Scientific Communications professionals arm themselves with the knowledge and skills to navigate in the ever-evolving health care arena.

At this forum, attendees will gain further expertise in their own area and/or learn about different functional areas. Attendees have the flexibility to attend sessions from any of the three central tracks. Not only can you gain further expertise and networking opportunities in your own area but different functional areas too, including medical information, medical communications, medical call center, and medical writing. Nowhere else can you network with all these professionals in one location.

FORUM HIGHLIGHTS:
• Three Central Tracks: Medical Communications, Medical Writing Regulatory and Publication, and Medical Science Liaisons
• Five breakout tracks focused on medical information, medical science liaisons, medical call centers, and medical writing (regulatory and publication)
• Preconference tutorials including Core Curriculum
• Cross-functional general session dedicated to all areas including medical information, medical science liaisons, medical communications, medical call center, and medical writing
• Presentation of best practices via podium pearls and posters
• Presentation of original research from fellows and residents in specifically focused forum for fellows and residents in training
• Exhibit Hall with 23 Exhibiting Companies

This program has been developed in collaboration with three DIA Communities: Medical Communications, Medical Science Liaisons, and Medical Writing.

Register at diahome.org/MSC2014
CONTINUING EDUCATION

The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 22.5 contact hours or 2.25 continuing education units (CEU’s).

ACPE Credit Requests
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. 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.

Corexcel is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center’s Commission on Accreditation. Corexcel designates this activity for a maximum of 25.75 contact hours.

Drug Information Association has been accredited as an Authorized Provider by the International Association for Continuing Education and Training (IACET), 1760 Old Meadow Road, Suite 500, McLean, VA 22102; +1.703.506.3275.

As an IACET Authorized Provider, Drug Information Association offers CEUs for its programs that qualify under the ANSI/IACET Standard. Drug Information Association is authorized by IACET to offer up to 2.6 CEUs for this program. Participants must attend the entire program <core curriculum, tutorial, conference, if applicable> 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 attend the forum, core curriculum, and/or tutorials, if applicable, scan your name badge at each session, core curriculum and/or tutorial you attend, and complete the online credit request process through My Transcript. To access My Transcript, please go to www.diahome.org, select “Login to My DIA” and you will be prompted for your user ID and password. Select “My Transcript” (left side bar) and “Credit Request” to process your credit request. 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, March 26, 2014.

Please Note: If you do not scan your badge at each session you attend, you will not be able to request continuing education credits for that portion of the program.

It is Drug Information Association policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any real or apparent conflict(s) of interest 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 course materials.

TO ACCESS PRESENTATIONS:

• Visit diahome.org
• Login to My DIA
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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.
Continuing pharmacy education credits are NOT AVAILABLE for the following tutorial/sessions:

- Tutorial 2: Interpreting and Reporting Descriptive Statistics, Confidence Intervals, and Hypothesis Tests
- Welcome and Opening Remarks
- OPENING PLENARY
- 2A-B: Sunshine Act and Implications to Medical Communications
- 2C-D: Professionalism and Certification in Medical Writing
- 3C-D: Always Keeping a Ball in the Air: Project Management in Medical Writing
- 4B: The 4 Cs of Quality Monitoring: Coaching, Compliance, Calibration, and Continuous Improvement
- 4C: Lessons Learned from Preparing Responses to Post-Filing Regulatory Queries from Regional Health Authorities (FDA, CHMP, PMDA)
- 4D: What’s up on the Hill?—What Medical Communications Professionals Need to Know (Sunshine Act and Corporate Integrity Agreement) – Roundtable Discussion
- Buffet Lunch/Roundtable Discussions
- Resident, Fellow, and Preceptor Development Session
- Global MSL Functions
- 5A: Adapting and Refining Technologies within Medical Information to Drive Innovation
- 5C: Medical Writing Outsourcing Models
- 5E: Win-Win Solutions and Best Practices – A Soft Skills Showcase
- 6C: Strategic Review of Documents
- 6D: Global Publication Planning
- 6E: Own Your Career
- 7A-B: Podium Pearls
- 8D: Best Practices in Publications
- 8E: Unique Value: How to Differentiate and Measure
- 9: Luncheon/Professional Poster Session
- Resident, Fellow, and Preceptor Development Session
- Global MSL Functions
- 10C: Global Developments in Clinical Trial Transparency and Their Impact on Clinical Trial Disclosure and Publication Writing
- OPENING PLENARY
- 11: Closing Plenary and Closing Remarks

Unless otherwise disclosed, the statements made by speakers represent their own opinions and not necessarily those of the organization they represent, or that of the Drug Information Association. Speakers, agenda, and CE information are subject to change without notice. Recording of any DIA educational material in any type of media, is prohibited without prior written consent from DIA.

To view DIA’s Grievance Policy, please visit the CE page on DIA’s website at www.diahome.org/CE.
SUNDAY, MARCH 9

7:00–8:00 AM CORE CURRICULUM REGISTRATION AND CONTINENTAL BREAKFAST

8:00 AM–4:45 PM CORE CURRICULUM

CHAIR:

Jihwon Im, PharmD
Principal Scientist
Managed Care Medical
Medical Communications
Genentech, A Member of the Roche Group

FACULTY:

Michael Cuozzo, PharmD
Senior Medical Director
Medical Affairs and Medical Information Services
Incyte

Rebecca Falcone, PharmD
Senior Manager
US Medical Information Services
Sanofi

Ellen Guthrie, BS Pharm, PharmD
Medical Information Specialist & Virtual Scientific Manager
Oncology
Med Communications
AstraZeneca

Kurt T. Kreiter, PhD
Director
Medical Information and Congress Strategy
Global Medical Affairs
Biogen Idec

Jackie Morton, MLS
Research Information Specialist
Amgen Libraries
Amgen, Inc.

Jennifer Totten, PharmD
Senior Specialist
Scientific Communications
Forest Research Institute

Danielle Ziernicki, PharmD
Director
Global Regulatory Policy and Intelligence
Janssen Research & Development LLC

Core Curriculum Learning Objectives:

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

• Identify activities that Medical Communication professionals participate in that provide global value to both internal and external customers, as part of working in interdisciplinary teams

• Describe how the regulatory environment influences Medical Communications practices

• Identify regulatory resources available and how to apply them to your day-to-day work

• Identify critical steps that a Medical Communications professional should take when receiving an unsolicited inquiry, including evaluating the available data and sources of information

• Determine the important elements of planning for a scientific presence at a medical congress, including the provision of medical information and the optimal use of technology at this type of venue

• Recognize the importance of the payer environment by evaluating AMCP/EBM dossier requirements

• Describe the distinct scientific value that Medical Communications provides on promotional review committees and how to balance the provision of marketing support while avoiding common pitfalls in that role

• Describe the important elements of writing a concise and clear standard response letter

• Provide an overview of literature searching techniques and resources

This activity is specifically designed to meet the needs of individuals new to biopharmaceutical industry-based Medical Communications. Attendees will learn and discuss skill sets that provide value to both internal and external customers. Those who have been in their functional role for less than one year would gain the most from attending.

Follow #DIAMSC for real-time updates.
8:00-9:30AM CORE CURRICULUM – SESSION 1

8:00-8:30AM WELCOME AND INTRODUCTIONS

Jihwon Im, PharmD

Following opening remarks, the Core Curriculum faculty will introduce themselves to the attendees and provide descriptions of their career paths leading to their current roles in Medical Communications. The faculty will then describe their current responsibilities, allowing the audience to begin to see similarities and differences in the practice of Medical Communications across the industry.

8:30-9:30AM REGULATORY ENVIRONMENT AND MEDICAL COMMUNICATIONS PRACTICES

Danielle Ziernicki, PharmD

This session introduces the current regulatory environment that influences the activities of a US-based Medical Communications professional. An overview of the pharmaceutical industry and DDMAC regulations will be reviewed, along with the rationale for many of the activities common in Medical Communications departments which will include a case study presentation.

9:30–9:45AM BREAK

9:45-11:30AM CORE CURRICULUM – SESSION 2

9:45–10:30AM HELPFUL TRICKS OF THE TRADE 1: ADVANCED LITERATURE SEARCHING AND EVALUATION

Jackie Morton, MLS

Literature searching is a vital skill for Medical Communications professionals. This session will review “tricks of the trade” for searchers of medical literature. Attendees will walk away with a new trick that can be applied immediately in their daily work.

10:30-11:30AM HELPFUL TRICKS OF THE TRADE 2: REGULATORY RESOURCES IN THE PUBLIC DOMAIN

Danielle Ziernicki, PharmD

There are multiple regulatory resources available for Medical Communications professionals, many of them for free. This session will review resources available in the public domain and how they can help you successfully deliver results. An interactive case presentation will be discussed by the faculty and attendees.

11:30AM-12:30PM LUNCH

12:30-4:15PM CORE CURRICULUM – SESSION 3 AND 4

These two sessions will delve deeper into the challenging aspects of six different areas of our industry practices. This includes activities such as identifying the critical steps that a Medical Communications professional should take when receiving an inquiry, evaluating the sources of information/data available when preparing a response, the importance of fair balance and documenting responses. Topics will also include formulary dossier communications, global activities, promotional review, activities at scientific congresses, and medical writing considerations.

12:30-2:15PM SESSION 3

Best Practices for Handling Medical Inquiries

Michael Cuozzo, PharmD

Standard Response Letter Writing 101

Ellen Guthrie, BS Pharm, PharmD

Global Considerations for Medical Communications

Kurt Kreiter, PhD

2:15-2:30PM BREAK

2:30-4:15PM SESSION 4

Strategic Role of Medical Communications at Medical Congresses

Rebecca Falcone, PharmD

AMCP Dossiers and the Managed Care Perspective

Jennifer Totten, PharmD

Promotional Review Committee Overview

Jihwon Im, PharmD

4:15-4:45PM Q&A WITH CORE CURRICULUM FACULTY
TUTORIAL #1

Medical Communications: Compliance in 2014

Chair:

Monica Kwarcinski, PharmD
Executive Director, Medical Services
Purdue Pharma L.P.

The compliance obligations within the pharmaceutical industry continue to increase each year. Now more than ever it is critical that Medical Communication departments have policies and procedures that address such things as medical inquiry and response documentation, staff training, and monitoring/audit programs. Whether you have been in Medical Communications for a few months or a few decades this tutorial will provide an overview of what policies, procedures and programs Medical Communications departments should consider implementing to help ensure compliance and mitigate risk. This will be an interactive tutorial with opportunity for discussion and questions from the audience.

Faculty

Monica Kwarcinski, PharmD
Executive Director, Medical Services
Purdue Pharma L.P.

Mark A. DeWyngaert, PhD
Managing Director
Huron Life Sciences

Tutorial Learning Objectives:
At the conclusion of this tutorial, participants should be able to:

- Discuss compliance hot topics in Medical Communications such as medical inquiry documentation, response development and documentation, Sunshine Act reprint reporting requirements, staff training, and sales force facilitated inquiries
- Describe what policies and procedures the Office of Inspector General (OIG) is requiring Medical Communications departments to have in place based on recent Corporate Integrity Agreements (CIA)
- Identify the factors to consider when developing, implementing, and maintaining QA, compliance, and training programs
- Describe how to mitigate risk in Medical Communications

TUTORIAL #2

Interpreting and Reporting Descriptive Statistics, Confidence Intervals, and Hypothesis Tests

Faculty

Tom Lang, MA
Principal
Tom Lang Communications and Training International

This tutorial begins by defining a variable and progresses step-by-step through levels of measurement, how each level is reported with descriptive statistics, and how these statistics are applied and misapplied in biomedical research. Building on these concepts, the reasoning behind estimates, confidence intervals, and hypothesis testing is presented. Participants learn the strengths and weaknesses of P values, estimates, and measures of precision when reporting research results.

Tutorial Learning Objectives:
At the conclusion of this tutorial, participants should be able to:

- Define the three most common levels of measurement used in biostatistics
- Define and describe the proper use of the most common descriptive statistics used in biomedical research
- Explain what a 95% confidence interval is and why it is valuable in reporting research
- Discuss the hypothesis tests and related concepts

**Please note: Lunch is not provided by DIA.**
MEDICAL AND SCIENTIFIC COMMUNICATIONS 2014 ANNUAL FORUM

1:00-1:30pm WELCOME AND OPENING REMARKS

Barbara Lopez Kunz
Global Chief Executive
DIA

Program Co-Chairs:

Sara Doshi, PharmD
Manager
Global Medical Information
Eli Lilly and Company

Darryl L'Heureux, PhD
Medical Writer
CSL Behring

J. Lynn Bass, PharmD
Director
Medical Scientists
Jazz Pharmaceuticals

1:30-3:00pm OPENING PLENARY – SESSION 1

Keynote Address

Chair:

Sara Doshi, PharmD
Manager
Global Medical Information
Eli Lilly and Company

Keynote Speaker:

Daniel Kraft, MD
Founder and Executive Director, Exponential Medicine (formally FutureMed)
Medicine Track Faculty Chair, Singularity University
Founder & CEO, IntelliMedicine, & Bioniq HealthInventor of the MarrowMiner
Frequent TED and TEDMED Speaker

3:00-3:30pm REFRESHMENT BREAK/EXHIBITS

BELS EXAM Offered at Medical & Scientific Communications Annual Forum

March 9 | 1:00-5:00PM
Hyatt Regency Grand Cypress | Orlando, FL

The Board of Editors in the Life Sciences (BELS) is a not-for-profit organization founded in 1991 for the purpose of evaluating the proficiency of manuscript editors in the life sciences. Proficiency is determined by means of a written test, and the credential Editor in the Life Sciences (ELS) is awarded to successful candidates.

Applications and registrations must be complete by February 16.

For more information about applying for candidacy and registering for the exam, please visit www.bels.org

Follow #DIAMSC for real-time updates.
Key for all breakout sessions throughout the entire forum. Please note that you are free to attend breakout sessions in any track based upon your level of interest and the topics that are offered.

3:30-5:00PM  BREAKOUT SESSIONS 2

MEDICAL COMMUNICATIONS TRACK 2A-B

Sunshine Act and Implications to Medical Communications

CHAIR:
Monica Kwarcinski, PharmD
Executive Director
Medical Services
Purdue Pharma L.P.

While the first reporting period under the Physician Payments Sunshine Act has past, industry continues to grapple with this new compliance obligation. This session will describe the obligations, challenges, and impact the Sunshine Act has had on industry medical information departments, medical science liaisons, medical writers as well as industry sponsored publications. This will be an interactive session with opportunity for discussion and questions from the audience.

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

• Describe key element of the Physician Payments Sunshine Act
• Describe the specific obligations under the Sunshine Act that affect Medical Communication, Medical Science Liaisons, and Medical Writing departments within industry
• Discuss examples of reprint values and the basis of those values
• Identify challenges and considerations for Medical and Scientific Communications departments related to the Sunshine Act

FACULTY:
Monica Kwarcinski, PharmD
Executive Director
Medical Services
Purdue Pharma L.P.
Kathleen Guindon, RN, MS, DM/OL
Senior Medical Liaison
Genentech, a Member of the Roche Group
Mina Patel, PhD
Senior Director
Medical Communications
Global Medical Affairs
Vertex Pharmaceuticals Incorporated

MEDICAL WRITING REGULATORY AND PUBLICATION TRACKS 2C-D

Professionalism and Certification in Medical Writing

CHAIR:
David B. Clemow, PhD
Senior Clinical Research Scientist
Lilly USA, LLC

Medical writing as a career continues to mature and is recognized more than ever as a critical role for drug development and health communication companies. The profession is growing quickly globally, particularly in India and Asia-pacific. There is now a large pool of well-experienced writers. Medical writing can be a life-long career, and it is increasingly guided by professionally defined competencies and related knowledge, skills, and abilities. Formal training for medical writers is on the increase, and there are even academic programs now available. The days of waking up one day and deciding to be a medical writer the next are long gone. Instead of positions being filled by people making career changes, job recruiters now specifically search for qualified candidates to fill open positions. Ongoing development and skills acquisition is important. Several associations exist to support professional medical writers and editors, including but not limited to the American Medical Writers Association (AMWA), Board of Editors in the Life Sciences (BELS), and the International Society for Medical Publication Professionals (ISMPP). Each of these groups now has or will have professional certification programs. These topics will be discussed, with a focus on certifications available for medical writer’s and the place they hold in their professional development. The session will conclude with a panel discussion on certification for medical writers.

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

• Assess medical writing professional landscape to aid in career growth
• Identify competencies of importance to medical writer hiring managers
• Recognize how professional association certification programs fit within medical writing career development

FACULTY:
David B. Clemow, PhD
Senior Clinical Research Scientist
Lilly USA, LLC
Leslie E. Neistadt, ELS
Board of Editors in the Life Sciences
Saint Louis University
Laine Capaccio, CMPP
Director
Credentialing
International Society for Medical Publication Professionals (ISMPP)
MEDICAL SCIENCE LIAISONS TRACK 2E

Part I: “Real World Data” What is it, How is it Being Used and How Does It Impact the MSL role?

Co-chairs:
Edith Eby, PharmD
Executive Director
Medical Relations & Governance
Pfizer Inc

Rebecca Vermeulen, RPh
Senior Director
BioOncology Medical Science Liaisons
Genentech, A Member of the Roche Group

This session will describe the importance of Real World Data (RWD) to help translate the value for MSL teams. Given the importance of RWD and impact on patient care decision making, this session will define RWD and how it integrates into the care of patients. Session participants will also discuss and evaluate the legal and regulatory challenges that must be addressed to communicate information effectively. How it used by the industry and health care providers as well as the impact on evolving the MSL role

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

• Describe the importance of Real World Data (RWD) and express the value for patient care management
• Evaluate the legal and regulatory challenges associated with providing and communicating information effectively

Faculty:
David Purdie
Head
Quality of Care and Patient Access
Genentech, A Member of the Roche Group

Laura Puzniak
Director
Regional Medical and Research Specialist
Vaccines & Infectious Diseases
Pfizer Inc

5:00-6:00pm NETWORKING RECEPTION AND 25TH ANNIVERSARY CELEBRATION

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MEDICAL COMMUNICATIONS TRACK 3A

Drug Information Compendia: Evaluating Drug Monograph Content, Impact on Patient Care and Understanding Transparency

Chair:
Julia Petses, PharmD
Director
Medical Information Services
Oncology/Hematology
Sanofi

Health care professionals use drug information compendia as a resource for prescribing medications safely and effectively and for clinical decision making based on evidenced based medicine. Drug compendia also impact coverage and access because they are used by public and private payers to make coverage decisions for both on-label and off-label therapeutic uses. Accuracy and quality of information may vary among compendia. Medical Communications departments play an important role in the process of reviewing the information provided in compendia, including scientific exchange of clinical data and assessing interpretation of prescribing information by drug compendia editorial staff. This session will provide participants with an overview of drug information compendia, strategies for monitoring, and communicating with compendia, how clinical data are evaluated and rated, and transparency of drug monograph reviews.

Learning Objectives:
At the conclusion of this session, participants should be able to:
• Recognize the differences among drug information compendia
• Identify strategies on communicating with compendia, including submitting requests for clinical review
• Explain the impact on patient access and payer coverage decisions and which payer types use which drug compendia
• Describe conflict of interest and transparency, in processes/policies for creating or updating drug monographs

Faculty:
Sonia Raikar, PharmD
Senior Medical Services Specialist
Purdue Pharma L.P.

Amy Schroeder, RPh
Senior Consultant, Oncology Strategies
DK Pierce & Associates, Inc.

Iris Tam, PharmD
Director
Managed Care Medical Communications
Genentech, A Member of the Roche Group

MEDICAL COMMUNICATIONS TRACK 3B

Technology in the Medical Information Contact Center: Innovation and Best Practices

Chair:
David Bowers, PharmD
Director
Medical Communications
PPD

In our highly regulated industry, adopting innovative technologies can be daunting. Managers may struggle with simple questions, such as, what new technology is available? What are other companies doing? This session will explore the adoption of new technology among pharmaceutical Contact Centers. Results from a recent survey of technology practices within the industry will be reviewed. Case studies will be shared to provide real world examples of how innovative technologies have been successfully adopted within the Contact Center.

Learning Objectives:
At the conclusion of this session, participants should be able to:
• Recognize innovative technologies that are being adopted within Medical Information Contact Centers
• Discuss current trends and technology solutions used within the industry
• Define strategies used by other pharmaceutical companies to successfully implement new technologies

Faculty:
Suzana Giffin, PharmD
Executive Director
Medical Information
Amgen

Maureen L. Baldwin MSN, RN
Associate Director
Medical Customer Interface
Medical Information
Pfizer Inc
### MEDICAL WRITING REGULATORY AND PUBLICATION TRACKS 3C-D

**Always Keeping a Ball in the Air: Project Management in Medical Writing**

**Chair:**
**Robin Whitsell**  
President  
Whitsell Innovations, Inc.

The authoring of regulatory and publication documents require organizing the interdependencies of deliverables and establishing timelines. A delay in one deliverable can easily result in significant downstream effects that may ultimately delay submission and impact the overall business plan. The medical writer must effectively build relationships between team members and manage the overall process by setting timelines and leading individuals to succeed in their tasks. Project management tools can help facilitate this communication, manage timelines, and identify rate-limiting steps to minimize delays.

In this session, we will present ideas on:
- Identify how medical writers are integrated into companies and recognize the key interactions with other functional areas (eg, statistics, pharmacology, data management, clinical, operations, etc). Discuss best practices of how in-house medical writers and external writing support are coordinated.
- Discuss different project management models used in industry. Identify different medical writing tools (Gantt charts, metrics, work flow diagrams, etc) and describe best practices in project management in medical writing. Do team dynamics determine which tool/approach to select?
- Recognize how to be a more impactful as a leader/project manager. Medical writers are often project managers who are forced to lead with various levels of influence and authority over their teams.

**Learning Objectives:**
At the conclusion of this session, participants should be able to:
- Discuss best practices for team implementation
- Define tools, metrics, and how to apply these to specific teams
- Describe how to maximize a team’s impact through project management

**Faculty:**
**Amy Holbrook, MS**  
Lead Medical Writer  
Takeda Pharmaceuticals International Co.

**Cynthia Gates, PhD**  
Senior Medical Writer  
Biogen Idec

### MEDICAL SCIENCE LIAISONS TRACK 3E

**Part II: The Integration of Real World Data Into Patient Care Management and the Industry**

**Co-chairs:**
**Edith Eby, PharmD**  
Executive Director  
Medical Relations & Governance  
Pfizer Inc

**Rebecca Vermeulen, RPh**  
Senior Director  
BioOncology Medical Science Liaisons  
Genentech, A Member of the Roche Group

This session will evaluate how to evolve MSL teams to incorporate RWD into team structure and communications. Participants will also be able to analyze specific examples of how RWD can make a difference in patient care management while evaluating pitfalls and issues that need to be addressed.

**Learning Objectives:**
At the conclusion of this session, participants should be able to:
- Evaluate how to model MSL teams to evolve and incorporate RWD into team structures
- Describe how to manage issues in sharing RWD so that teams can make a demonstrate impact for patient care

**Faculty:**
**Verna Welch**  
Senior Director, Team Leader  
Institutional Outcomes Research Scientists  
Pfizer Inc

**Ralph Rewers, PharmD**  
Director  
Oncology Field Medical  
US Medical Oncology  
Bristol-Myers-Squibb

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**10:00-10:30am**  
**REFRESHMENT BREAK/EXHIBITS**

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**MEDICAL COMMUNICATIONS TRACK 4A**

**Hot Topics: Innovations in Medical Communications**

**Chair:**

**Poonam A. Bordoloi, PharmD**
Senior Manager
Medical Information Services
Internal Medicine and BioSurgery
Sanofi

This interactive session will review several hot topics of interest to Medical Information (MI) professionals. Have you ever wondered how other companies respond to ingredient and complex formulation questions? How is all the information organized and how much detail is provided to the customer by the Contact Center or the MI specialist? What about the open-space concept? Several companies are trending towards open workspace including MI groups. Does this really work?

In January, the FDA issued draft guidance providing us with yet another glimpse of how social media and online promotion come together. The new guidance is titled: Fulfilling Regulatory Requirements for Postmarketing Submissions of Interactive Promotional Media for Prescription Human and Animal and Drugs and Biologics. How will this guidance affect the responsibilities and activities specific to MI groups? What about devices? We are sure this topic will generate some great dialogue.

During this session, you will have the opportunity to hear from a distinguished panel of experienced Medical Communications professionals and have the opportunity to share best practices. You are invited to attend and participate in a lively discussion that will leave you with great ideas to think about when you return back to your “workspace”.

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

- Define key documents and contacts required to create appropriate standard response documents for complex ingredient and formulation questions
- Evaluate and assess the types of responses provided to health care professionals and consumers
- Compare and contrast the positives and negatives of the open workspace concept
- Assess the recently issued FDA draft guidance and discuss the use of interactive technologies

**Faculty:**

**Juan C. Nadal, MD**
Vice President
Medical Communication
Medical Affairs
Bayer HealthCare Pharmaceuticals

**Thomas Faria, PharmD**
Senior Director
Global Medical Information
Celgene Corporation

**Robert Lewis, PharmD**
Director
Medical Information
Regeneron Pharmaceuticals, Inc.

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**MEDICAL COMMUNICATIONS TRACK 4B**

**The 4 Cs of Quality Monitoring: Coaching, Compliance, Calibration, and Continuous Improvement**

**Chair:**

**Maureen L. Baldwin MSN, RN**
Associate Director
Medical Customer Interface
Medical Information
Pfizer Inc

Medical Communications Call Centers are generally the first line of contact for consumers and health care professionals seeking product information from your company. What process do you have in place to ensure that the staff members are handling the calls appropriately? This session will briefly review quality monitoring (QM) programs and assessment methods. Actual recorded telephone calls will be provided for review and discussion by the group. You are also encouraged to share your QM tool and/or your QM program. The panel will provide quality monitoring insights and answer your questions.

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

- Identify quality monitoring measures and information technology used in Contact Centers
- Discuss the importance of calibration sessions with your team or outsourced vendor
- Explain quality improvement strategies for enhancing performance of the Contact Center staff, Coaching versus compliance

**Faculty:**

**Maureen L. Baldwin MSN, RN**
Associate Director
Medical Customer Interface
Medical Information
Pfizer Inc

**Pete Guillot, MBA, CPA, CIA, RAC**
President
Center First Consulting, LLC

**Kathleen Meyer Ritz**
Global Medical Information Customer Centers
Bristol-Myers Squibb

**David Bowers, PharmD**
Director
Medical Communications
PPD

Follow #DIAMSC for real-time updates.
**MEDICAL WRITING REGULATORY TRACK 4C**

**Lessons Learned from Preparing Responses to Post-Filing Regulatory Queries from Regional Health Authorities (FDA, CHMP, PMDA)**

**Chair:**
Darryl L’Heureux, PhD  
Medical Writer  
CSL Behring

Despite the advances made in harmonizing regulatory filing requirements, significant variation exists in the regulatory review of marketing applications across different regions. In addition to differences in the regulatory review process itself, regulatory agencies differ in terms of their qualitative approach to the review of data (which is sometimes influenced by cultural differences), posing challenges to sponsors responding to post-filing regulatory queries. This session intends to describe these differences, and to share lessons learned from the preparation of responses to post-filing queries from different national health authorities (FDA, CHMP, PMDA). Experiences on drug, biologic, and device programs will be discussed.

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

- Distinguish the various regulatory review processes employed by some of the key regulatory agencies (FDA, CHMP, PMDA)
- Identify different review strategies across regions and plan the regulatory responses based on specific expectations from the relevant health authority
- Interpret the communication and negotiation styles of different health authorities
- Identify best practices for preparing responses to queries on global marketing applications

**Faculty:**
Kai-Yu Jen, PhD  
Senior Regulatory Writer  
Global Regulatory Writing  
Biogen Idec

Liz Miller, MS  
Principal Medical Writer  
Global Medical Writing  
Biogen Idec

Terry Martin, MA  
Associate Director  
Medical Writing  
Biogen Idec

**MEDICAL WRITING PUBLICATION TRACK 4D**

**What’s up on the Hill?—What Medical Communications Professionals Need to Know (Sunshine Act and Corporate Integrity Agreement) – Roundtable Discussion**

**Chair:**
Kim Pepitone  
Scientific Director  
Cactus Communications

Different government bodies are responsible for the regulations and/or guidelines around the Sunshine Act ([Sunshine] CMS), corporate integrity agreements ([CIAs] OIG), and social media (FDA). It is important to know which body is responsible for issuing what regulation or guideline in order to know where to look for relevant information and be able to stay current.

There are important operating principles around Sunshine, CIAs, and social media with respect to medical publications. Lack of knowledge of the details can risk one’s ability to be compliant, and can result in government-levied fines and/or other punitive actions.

It is important to know the difference between a regulation and a guideline or draft guideline, and how that difference relates to the work performed by medical publication and communication professionals.

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

- Identify the government bodies responsible for the regulations and/or guidelines pertaining to Sunshine Act, CIAs, and social media.
- Define the requirements and operating principles for Sunshine, CIAs, and social media as relates to medical publications and know the risks for failure to comply
- Differentiate the regulations from the guidelines and draft guidelines that pertain to Sunshine, CIAs, and social media in the context of developing medical publications

**Faculty:**
Kim Pepitone  
Scientific Director  
Cactus Communications

Frank J. Rodino, MHS, PA  
President and Founder  
Churchill Outcomes Research, LLC

Robin Whitsell  
President  
Whitsell Innovations, Inc.

Teresa Peña, PhD  
Senior Global Director Publications  
Global Medical Affairs  
AstraZeneca

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MEDICAL SCIENCE LIAISONS TRACK 4E

Technology Showcase – Using Technology to Strengthen the Customer Interface

**Chair:**
Craig Klinger, RPh
Medical Liaison Consultant
Strategy and Capabilities – Trainer
Lilly USA, LLC

As field-based medical, MSLs are in constant need to provide information to both internal and external customers. This session will review hardware, software, and Apps developed to help fulfill the MSLs needs. We will explore apps which allow the MSL access to medical content during a customer interaction as well as provide fulfillments for information per unsolicited requests from HCPs. We will also explore the potential of using cloud-based technology to facilitate version control, how the Google environment can help facilitate communications between the MSL and external and internal customers. We will also explore how technology can leverage how the MSL can provide support to their HCP customers.

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

• Identify apps, software, and other resources currently available to aid in providing medical information to customers

• Demonstrate the process used to develop or evaluate new apps and software for your organization and how to implement them appropriately

• Evaluate technology that can be used to best communicate between internal and external customers of the MSL

**Faculty:**
Jeff Gaus
Chief Executive Officer
Prolifiq Software

Kevin Henderson, PharmD, MBA
Commercial Rotational Development Program (CRDP) Associate
Genentech, A Member of the Roche Group

Additional Speaker Invited

12:00-1:30pm    BUFFET LUNCH/ROUNDTABLE DISCUSSIONS/EXHIBITS

Back by Popular Demand – 2014 Medical Communications Workshop Networking Lunch Discussions

**Chair:**
Jim Wilkinson, PhD
Executive Director
Medical Communications
Scientific Affairs
Amgen

Attendees will have the opportunity to either dine on their own or grab their buffet lunch and participate in networking roundtable discussions. These networking sessions will each be led by a facilitator having experience within a core Medical Affairs functional area that is specific to that table topic discussion (see topics to the right).

These informal networking sessions are designed to enable all roundtable participants to discuss topics of relevance to them, specific to their job functions and activities, and encourage information sharing from the perspectives of large, midsize, small, and specialty companies including the device and diagnostics industries. Facilitators will help to guide discussions, but the true catalysts of conversation will be the participants! Please join your colleagues and engage in what will sure to be a variety of insightful networking sessions.

**Roundtable Discussion Topics (2 roundtables/topic):**

Career development, talent management, career options, etc.

1. Communicating the value proposition of your team, department or organization to internal stakeholders and senior management

2. Personal skills development for career growth - what technical and soft skills are valued most in your field or organization? What resources are available?

3. Career options for your degree and experience – discussion on potential pros and cons of different roles and responsibilities within industry

Follow #DIAMSC for real-time updates.
Resident, Fellow, and Preceptor Development Session

This is a special session for Residents and Fellows only. No fee required to attend. Will be held in separate room during lunch.

Chair:
Alicia Alexander Cadogan, PharmD
Director, Team Lead, Oncology
Pfizer Medical Information
Pfizer Inc

Pharmaceutical Industry-based Drug Information Residency and Fellowship programs are an important step towards ensuring that the future of Medical Communications in the pharmaceutical industry is in capable hands. There is no governing structure to standardize these programs, and as a result the experience and training received can vary greatly in content and expectations. Although the trainees must be engaged and committed to meet their goals, the preceptor is critical to the success of the programs, and critical to the preparedness of the trainee upon completion of their experience. For this DIA session, we invite Residents, Fellows, and their preceptors to join us as we explore the training experience from the perspective of both the trainee and the preceptor. We will discuss some optimal preceptor activities, share success stories and challenges, and explore the possibility of working together through DIA to provide more structure to this important career development path.

Session Objectives:
At the conclusion of this session, participants should be able to:
• Discuss how to assess a resident or fellow’s competencies gained during the training program
• Identify the roles and responsibilities of program’s preceptors
• Identify best practices for the preceptor – trainee relationship that optimize educational outcomes
• Recognize how the DIA can strengthen and cultivate preceptor – trainee relationships through partnership

Faculty:
Evelyn Hermes-DeSantis, PharmD, BCPS
Clinical Professor
Ernest Mario School of Pharmacy
Rutgers, The State University of New Jersey

12:30-1:30pm
MSL – GLOBAL MSL FUNCTIONS (RETURN TO SESSION ROOM)

Chair:
Carrie C. Murray, MSN, NP
Director, Global MSL Excellence
Bayer HealthCare Pharmaceuticals

Participants in this session are invited to participate in a discussion of the MSL function worldwide. Experienced MSL leaders will share their experiences in implementation of permanent as well as contract MSL teams to meet the needs of diverse markets.

Learning Objectives:
At the conclusion of this session, participants should be able to:
• Identify strategies to maximize communication in a global MSL community
• Explain the need for flexibility organizational structures and job requirements for MSLs worldwide
• Recognize the potential upsides and pitfalls of global MSL alignment through an understanding of pros and cons of global reporting lines, communication channels, and performance recognition

Faculty:
Ian Bancroft
Owner
Tardis Medical Consultancy

Nikolas Karkanias, PhD
Director, Field Based Medical Effectiveness
Pfizer Inc

Earn CMPP credits for attending select sessions*. This is your opportunity to attain additional credits towards your CMPP recertification. Please be sure to visit www.ismpp.org/recertification for a full list of pre-approved activities.

*Sessions reviewed and determined credit-eligible by ISMPP

Follow #DIAMSC for real-time updates.
**MEDICAL COMMUNICATIONS TRACK 5A**

**Adapting and Refining Technologies within Medical Information to Drive Innovation**

**Chair:**

**Leena Jindia, MS, PharmD**
Director
Medical Information
Janssen Scientific Affairs, LLC

This session will explore the elements of innovation within Medical Information critical for meeting the evolving needs of our technologically advanced customers. New tools and systems utilized to deliver Medical Information will be presented. Speakers will discuss enhancements to the Medical Information websites such as unique awareness campaign involving third-party external partnerships and globalization to drive consistency. Furthermore, we will review innovative electronic methods for capturing customer inquiry in a rapid manner.

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

- Identify and explore technologies such as instant messaging and video chat being used within Medical information
- Discuss strategies for globalization of the medical information site – One medical Voice website
- Explain the medical information website awareness via external third party partnerships
- Discuss an innovative electronic way to handle unsolicited request for Medical Information

**Faculty:**

**Natalie Groves**
Senior Manager
Pfizer Inc

**Monica Mody**
Director
Medical Information, Oncology
Bristol-Myers Squibb

**Marie-Ange Noue, PhD**
Project Manager
Drug Safety / Medical Information
Deputy Local Drug Safety Officer
EMD – Living Innovation
EMD Serono

**MEDICAL COMMUNICATIONS TRACK 5B**

**What If?**

**Chair:**

**Pete Guillot, MBA, CPA, CIA, RAC**
President
Center First Consulting, LLC

Health care professionals rely on pharmaceutical contact centers for accurate, timely, and accessible information. Preparing for and delivering on these customer needs is ultimately the responsibility of the organization’s senior leaders. Medical Communications senior leaders use a broad range of skills from long-range strategic planning to day-to-day operations management to help ensure their organizations are prepared to meet the evolving needs of the health care community. This session is designed to hear directly from Medical Communications senior leaders on what strategic planning and operational techniques they use and how long-term planning can help prepare for the organization for operational excellence. Audience participation will be a key component of this session, and participants are encouraged to come to the session with questions for our panel of senior leaders.

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

- Recognize how strategic planning can help in preparing Medical Communications team organize and prepare for future product launches, patent expirations, company mergers, outsourcing, etc.
- Identify specific strategic planning tools for addressing the quality, performance, and financial responsibilities of the Medical Communications organization
- Describe the benefits of effective strategic planning and what pitfalls to avoid
- Recognize how a strong planning process helps lead to strong operational quality and performance

**Faculty:**

**Vivian Broach, PharmD**
Vice President
Operations – Medical Communications
PPD

**Suzana Giffin, PharmD**
Executive Director
Medical Information
Amgen

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**Join DIA – Biopharmaceutical Professionals LinkedIn Group**

Follow #DIAMSC for real-time updates.
Medical Writing Outsourcing Models

Chair:
Christine T. Ong, PharmD
Director
Medical Writing and Scientific Communications
AccelaRx LLC

Regulatory medical writing continues to be an intrinsic function within the framework of the drug development matrix environment. As the industry vacillates between maintaining in-house staff and outsourcing medical writing to CROs, pharmaceutical and biotechnology companies need to develop appropriate business models to ensure success in the authoring and review of regulatory documents. Often, “mixed” models incorporate both in-house and outsourced writers and appropriate metrics must be created. Methodology in vendor selection and vendor oversight must be established and consistent practices in vendor management must be integrated across the therapeutic teams. This session will identify key elements that need to be identified in the sponsor-CRO relationship and discuss best practices in vendor management.

Learning Objectives:
At the conclusion of this session, participants should be able to:
• Identify and recognize the risks and benefits of different medical writing outsourcing models
• Discuss criteria and metrics in selection and evaluation of outsourced medical writers
• Discuss best practices and elements necessary for successful partnership from both a sponsor and a CRO perspective

Faculty:
Christine T. Ong, PharmD
Director
Medical Writing and Scientific Communications
AccelaRx LLC

Darryl L’Heureux, PhD
Medical Writer
CSL Behring

Health Economics Outcome/Comparative Effectiveness Research

Chair:
Robert Matheis, PhD
Executive Director
Global Scientific Communications
Celgene Corporation

Globally, there is a growing emphasis on ensuring the effectiveness and quality of health care products, services, and technologies in order to provide the highest quality care in the most efficient manner possible. As a result, health care decision makers now rely on multiple sources of evidence in health technology assessments (HTA) that determine patient access to treatment. These environmental trends provide important opportunities for medical writers and publication professionals to ensure that the necessary types of evidence and publications are developed in a manner that supports evidence based medicine approach to health care decision making. Indeed, trends toward comparative effectiveness research (CER) and the utilization of health economics and outcomes research within HTA and evidence synthesis requires the development of new capabilities among professionals involved in the development and writing of medical publications. The purpose of this session will be to review environmental trends in HTA, provide an overview on how to interpret HEOR/CER data, provide suggestions for how to evolve publication plans to incorporate HEOR/CER, and discuss specific techniques for writing high impact, relevant publications that address HTA requirements. Perspectives from a pharmaceutical publication professional, a medical writer, and journal editor will all be provided.

Learning Objectives:
At the conclusion of this session, participants should be able to:
• Discuss and articulate the global changes in how health technology assessment is conducted and the impact on evidence needed
• Describe the basic HEOR concepts
• State the concepts of evidence synthesis and quality assessment in publications

Faculty:
Susan Pacconi
Senior Manager
Global Scientific Communications
Celgene Corporation

Caitlin Rothermel, MA, MPHc
Principal
MedLitera

Laura T. Pizzi, PharmD, MPH
Professor
Department of Pharmacy Practice
Jefferson School of Pharmacy

Follow #DIAMSC for real-time updates.
WIN-WIN SOLUTIONS AND BEST PRACTICES –
A SOFT SKILLS SHOWCASE

Chair:

Vickee Altman, MEd, BSN, RN
MSA National MSL Manager
Roche Diagnostics

The Challenge: Breaking “not-so-good” news, moving a stalled conversation, controlling a conversation monopolizer, delivering an effective five minute message, communicating with a difficult KOL, colleague, employee, or boss.

The Solution: A panel of experienced MSLs will share best practices based on personal insights and real life experiences. Using an interactive forum they will focus on how to effectively communicate, one of our biggest challenges. The workshop will incorporate professionally developed concepts, panel and workshop participant personal experiences, and interactive dialogue. Session will include a discussion of “virtual” communication opportunities; types, pros, cons.

The Takeaway: Knowledge and awareness of peer best practices and winning solutions.

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

- Identify strategies for effective thought leader KOL interactions
- Integrate knowledge of behavioral strengths, challenges, and differences with improving communication styles, enhancing teamwork, and reducing team conflict
- Differentiate effective communication techniques
- Describe the structure of an environment that supports self and team growth
- Formulate a list of virtual communication options

FACULTY:

Vickee Altman, MEd, BSN, RN
MSA National MSL Manager
Roche Diagnostics

Carrie C. Murray, MSN, NP
Director
Global MSL Excellence
Bayer HealthCare Pharmaceuticals

J. Lynn Bass, PharmD
Director
Medical Scientists
Jazz Pharmaceuticals

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

Deborah Hails PhD, RN
National Director
Medical Science Clinical Liaisons
Biogenic Idec, Inc.

3:00-3:30PM
REFRESHMENT BREAK/EXHIBITS

Follow #DIAMSC for real-time updates.
3:30-5:00 PM BREAKOUT SESSIONS 6

MEDICAL COMMUNICATIONS TRACK 6A-B

Voice of the Customer (VOC), How do You Measure it and What do You Do with it?

Chair:
Nicole Corder, RPH, MBA
Director
The Lilly Answers Center
Lilly USA, LLC

The customer experience should be our primary focus when providing support through our Medical Information and/or Contact Center services. This session will explore how organizations are measuring our success through the Voice of the Customer. Topics will include information how customer feedback was collected and outcomes to improve services. Learn how to improve your group's customer experience and share insights with peers across medical information and Contact Center services.

Learning Objectives:
At the conclusion of this session, participants should be able to:
• Evaluate strategies for implementing a customer feedback mechanism
• Identify key insights to measure
• Analyze and respond to customer feedback
• Evaluate learning's to implement your VOC opportunity

Faculty:
Juhi Jaisinghani, PharmD
Medical Information Scientist
Clinical Development
Medical & Regulatory Affairs
Novo Nordisk Inc.

Holli Simmons
Director
The Lilly Answers Center
Lilly USA, LLC

MEDICAL WRITING REGULATORY TRACK 6C

Strategic Review of Documents

Chair:
Darryl L’Heureux, PhD
Medical Writer
CSL Behring

Document review is a critical component of drug development and must be executed from early clinical development to regulatory submission to postmarketing surveillance. The type of information and complexity that is found in these documents will vary with in the life cycle and range from single reports to a complex summation of all the known safety and efficacy data of the molecular entity. Different strategies may be implemented for reviewing documents but a common thread is woven throughout these review cycles. This session will discuss the need to understand the scope of the review, best practices to manage reviewers, and choice of appropriate vendors, tools, and platforms for the strategic review.

Learning Objectives:
At the conclusion of this session, participants should be able to:
• Identify different strategies and new methods for document review
• Discuss staged reviews with focus on timely distribution to subject matter experts and timing to development stage
• Utilize different tools (review instructions, checklists, content maps, work flow diagrams, and timelines) to enhance productivity of review cycles and document decision making

Faculty:
Darryl L’Heureux, PhD
Medical Writer
CSL Behring

Ann Winter-Vann, PhD
Senior Medical Writer and Consultant
Whitsell Innovations, Inc.
**MEDICAL WRITING PUBLICATION TRACK 6D**

**Global Publication Planning**

**Chair:** Donald Samulack, PhD  
President, U.S. Operations  
Cactus Communications Inc.

GLOBAL can mean many things when it comes to publication planning. Each company approaches “global” in different ways, and for different infrastructural reasons. The inference of “global” is that one size does not fit all. This session will address many aspects of global publication planning strategies, from different points of view, while keeping individual stakeholders in mind. Specific references will be made to the medical writing, publication, and stakeholder landscape of China.

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

- Identify specific needs of global affiliates with respect to the publication plan
- Identify the functional needs of different stakeholders and local opportunities
- Discuss the fact that GLOBAL means many things, and that individual company infrastructure determines the design and scope of a global publication plan
- Recognize that the global affiliate of a publication planning team needs a share of voice to be able to be effective in their respective geography

**Faculty:**

Donald Samulack, PhD  
President, U.S. Operations  
Cactus Communications Inc.

Eric Yu, PhD  
Medical Publications Manager  
Shanghai Roche Pharmaceuticals Ltd.

**MEDICAL SCIENCE LIAISONS TRACK 6E**

**Own Your Career**

**Chair:** Robert J. Moss, PharmD  
Senior Regional Scientific Manager  
AstraZeneca Pharmaceuticals LP

The MSL role may be a stepping stone for some or a career bonanza for others. This session explores avenues to career development through the experiences shared by MSLs who have taken a nontraditional path to success. Topics will include developing and maintaining your professional network, uncovering resources for career growth, becoming an information champ, learning from successes and failures, and uncovering your passion. Learn more about yourself and take ownership of your career through this insightful session.

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

- Discuss several avenues to career success as an MSL
- Discuss resources available to manage your career
- Identify important dynamics of the career development process
- Recognize the characteristics and attributes that may help you take the next step in your career

**Faculty:**

Robert J. Moss, PharmD  
Senior Regional Scientific Manager  
AstraZeneca Pharmaceuticals LP

Vanessa Johnson, MS  
Regional Director, Therapeutics MSLs  
US Medical Affairs  
Bayer HealthCare Pharmaceuticals

Kristen Mack, PharmD, CMPP  
Associate Director  
Medical Publications  
Global Medical Affairs  
Biogen Idec

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**5:00-6:00PM  RESIDENT AND FELLOW POSTER RECEPTION**

**Chair:** Alicia Alexander Cadogan, PharmD  
Director, Team Lead, Oncology  
Pfizer Medical Information  
Pfizer Inc

The residents and fellows will display their projects and will be eager to discuss their work with you. Please take advantage of this opportunity to learn from their research, share your perspective on their work, and discuss the results and impact on our business with them. Projects will cover a wide range of topics and represent many pharmaceutical companies. One project will be selected as the winner for having the biggest potential impact on how we practice Medical Communications.

**6:30PM  DINNER ON THE TOWN**

Sign up for dinner with your colleagues at your choice of several restaurants (transportation cost provided by DIA, however dinner cost is on your own).

Follow #DIAMSC for real-time updates.
MEDICAL COMMUNICATIONS TRACK 7A-B

Disruptive Innovation in Medical Information

Chair:
Mary Sendi, PharmD
Director
Medical Information
Pfizer Inc

Wikipedia describes Disruptive Innovation as “an innovation that helps create a new market and value network, and eventually goes on to disrupt an existing market and value network (over a few years or decades), displacing an earlier technology.” Disruptive innovation can be exhilarating and uncomfortable.

How is disruptive innovation applicable to Medical Information/Communications? Why should Medical Information/Communications departments consider disruptive innovation?

This session will explore the adoption of disruptive innovation among global medical information/communications departments. Case studies will be shared to provide real world examples of how disruptive innovation is advancing strategic direction and operational efficiencies such as how medical information is being processed, packaged, and communicated to health care professionals.

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

- Recognize disruptive innovation that is being adopted within medical information/communications departments
- Discuss disruptive innovation trends within the industry
- Define disruptive innovation strategies used by other pharmaceutical companies to successfully inform future operational models

Faculty:
Caroline Suh, PharmD
Director
Oncology Global Medical Information
Oncology Global Development & Global Medical Affairs
Novartis Pharmaceuticals Corporation

Mark Tacelosky, PharmD
Associate Director
Medical Information
Pfizer Inc

Sabine Lischka-Wittmann
Senior Manager
Medical Information & Medical Liaison
Lilly Deutschland GmbH

MEDICAL WRITING REGULATORY AND PUBLICATION TRACKS 7C-D

Ethics in Medical Writing

Chair:
Tolu Taiwo, PharmD, MBA
Director
Medical Information
Horizon Pharma, Inc.

Ethical issues confront health care practitioners (HCPs) in clinical trials and post-approval patient care, yet information is scant on addressing these issues and the written word. Health care professionals preparing manuscripts for publication or those practicing in pharmaceutical Drug Information Centers (DICs) often rely on the company’s regulatory department or legal team to deal with such concerns. This session will identify ethical matters that arise in medical writing that discloses information in published journal articles or responds to unsolicited medical information inquiries relative to drugs in development or in the market. It will offer strategies for accurate and truthful reporting whilst maintaining the integrity of the sponsor and assuring optimal release of information that is useful to the medical community.

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

- Describe ethical issues commonly encountered in publication
- Recognize industry and regulatory agency expectations for disclosure about products in development or the marketplace
- Identify with regulatory agency requirements and international guidelines for disclosure
- Identify and avoid writing pitfalls, such as inflated language, unintended plagiarism, or unsubstantiated claims
- Identify what constitutes an ethical issue in responding to an unsolicited DI request
- Define and design a strategy to create a written response that is devoid of ethical bias
- List best practices from Pharmaceutical Drug Information colleagues on ‘the what’, ‘the why’ and ‘the how’ of ethical issues in Standard Response Document (SRD) creation and maintenance

Faculty:
Janet Gough, MA
Consultant
Systems, Documentation, and Training

Tolu Taiwo, PharmD, MBA
Director
Medical Information
Horizon Pharma, Inc.
Scope of MSL Proactive Engagements

Chair:
Ramineh Zoka, PharmD, MS
Senior Director
Medical Science Liaison
Medical Affairs
Janssen Services, LLC

During this session, a panel of experts will discuss the opportunities through which Medical Science Liaisons may be able to proactively engage their customers. The focus will be on proactive scientific communication and input gathering from customers. The speakers will also provide an overview of regulatory guidelines and how various companies have approached such exchange.

Learning Objectives:
At the conclusion of this session, participants should be able to:
• Recognize the possible opportunities that MSLs may proactively discuss appropriate evidence-based information with their customers
• Identify how MSLs, as part of an interdisciplinary team, may support company scientific programs through input gathering and communication of such feedback within their company

Faculty:
Maura Norden, JD
Associate
Food and Drug Practice
Sidley Austin LLP

Sheetal Patel, PharmD
Regulatory Compliance Lead
Johnson & Johnson U.S. Pharmaceuticals Group HCC

Randy Miller PharmD, RPh
Director
Field Based Medicine Operations
Boehringer Ingelheim Pharmaceuticals, Inc.

9:30-10:00AM REFRESHMENT BREAK/EXHIBITS

Leader in Patient Engagement to Give Keynote Address

KEYNOTE SPEAKER:
Monday, June 16 | 2:30PM PT

Jamie Heywood
Co-Founder and Chairman
PatientsLikeMe
Founding Director
ALS Therapy Development Institute

This year marks the 50th Anniversary of the DIA Annual Meeting, the largest multidisciplinary event that brings together a global network of life sciences professionals. DIA 2014 50th Annual Meeting is packed with 260 + education offerings over 18 tracks on today’s hottest topics:
• 3-D Printing
• Big Data
• Career Transformation
• Disruptive Technologies
• Drug Shortages
• Observational Studies
• Patient Engagement
• Patient Recruitment Strategies
• PDUFA V
• Pediatrics
• Personalized Medicines
• Regenerative Medicine
• Risk-based Monitoring
• Social Media Strategies
• Strategic Partnerships
• Sunshine Act

Come celebrate with us in San Diego this June!

Register Now at diahome.org/DIA2014
### MEDICAL COMMUNICATIONS TRACK 8A-B

**Podium Pearls**

**Chair:**

**Stacey Fung, PharmD**  
Associate Director, Medical Communications  
Genentech, A Member of the Roche Group

In this session, Medical Communications Professionals were invited to present their successes, challenges, and “pearls of wisdom” on various topics through podium presentations. Six presentation topics were selected from submitted abstracts for this unique opportunity to share podium pearls.

#### A Full-Service Collaborative Partnership Between a Pharmaceutical Company and a Vendor to Support Medical Information Services

**Amy Dixon, PharmD**  
Medical Writer, Global Medical Writing  
PPD Inc.

#### Assessment of How MI Letters are Used and Evaluated by Internal Medical Stakeholders within MI Contact Center Team and MSLs

**Allison Little, PharmD**  
Senior Medical Information Specialist  
UCB, Inc.

#### Response from Online Drug Information Compendia following Submission of Content Corrections by a Pharmaceutical Company

**Sonia Raikar, PharmD**  
Senior Specialist  
Medical Services  
Purdue Pharma L.P.

#### Global Pilot Program to Evaluate Medical Information Call Center Quality

**Arlene Santhouse, PharmD**  
Director  
GMCC CRM Americas  
Bristol-Myers Squibb

#### Sunshine Act: Impact on Medical Information (MI) process to handle reprint requests-Challenges, Opportunities & Lessons learned

**Ellen Shulman, PharmD**  
Medical Information Manager  
Pfizer Inc

**Pharmaceutical Company Medical Information Customer Preferences and Use of Services**

**Elissa Vine**  
Manager  
Medical Information  
Janssen Inc.

### MEDICAL WRITING REGULATORY TRACK 8C

**Safety Reporting: What Writers Need to Know**

**Chair:**

**Eileen Girten, MS**  
Senior Medical Writer  
inVentiv Health Clinical

Harmonization efforts have led to standard safety reporting formats, such as the Development Safety Update Report (DSUR), Periodic Safety Update Report (PSUR), and the recent Periodic Benefit-Risk Evaluation Report (PBRER). This session will summarize the evolution of the PSUR to the PBRER, compare and contrast the PBRER/PSUR to the DSUR, and provide practical approaches to preparing DSURs/PSURs/PBRERs.

**Learning Objectives:**

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

- Identify the challenges to preparing DSURs/PSURs/PBRERs
- Identify best practices for preparing safety documents

**Faculty:**

**Angela B. Thompson**  
Principal Medical Writer  
inVentiv Health Clinical

**Valerie P. Perentesis, PharmD**  
Senior Director  
Aggregate Reports & Product Safety Evaluations  
Group Lead, Global Medical Safety  
Janssen Research & Development, L.L.C.
### MEDICAL WRITING PUBLICATION TRACK 8D

**Best Practices in Publications**

**Chair:**

**Martin Delahunty**  
Associate Director,  
Academic Journals & Pharma Solutions  
Nature Publishing Group

In recent years, the barrier to free access to clinical research has been a particularly hot topic with various individuals and groups calling for mandatory open access publishing. From a journal publishers' perspective, the Web now means that we live in a world without borders or boundaries. Within this rapidly changing and challenging environment, this session will share a publisher's insight into the future of medical publishing where: research and data will be more interconnected; articles will become more organic and evolve relative to user interaction and open peer review; and data repositories will serve as platforms to enable text and data mining.

**Learning Objectives:**

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

- Describe and illustrate with examples and data
- Discuss and identify opportunities for improvement of these relationships
- Explain and describe with examples, new publishing innovations

**Faculty:**

**Martin Delahunty**  
Associate Director  
Academic Journals & Pharma Solutions  
Nature Publishing Group

**Speaker Invited**

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### MEDICAL SCIENCE LIAISONS TRACK 8E

**Unique Value: How to Differentiate and Measure**

**Chair:**

**Randy Miller PharmD, RPh**  
Director  
Field Based Medicine Operations  
Boehringer Ingelheim Pharmaceuticals, Inc.

This session is focused on providing insights into key value drivers for MSL programs that have demonstrated success and unique value to internal and external stakeholders. The panel will address both current and future drivers, focusing on evolving areas where MSLs can provide unique value in our rapidly changing healthcare system and commercial marketplace.

**Learning Objectives:**

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

- Evaluate MSL activities and tactics that are unique to the MSL role where internal and external stakeholders have found the greatest value
- Discuss the challenges in differentiating the value of MSLs as teams face an increasing presence of new and unique field facing teams (clinical trial liaisons, outcomes, advocacy, nurse educators, others) in response to the changing commercial and regulatory landscape
- Identify the potential opportunities, challenges, and threats impacting differentiation and sustainability of the MSL function
- Describe how MSLs can add value across the continuum and engage with emerging customer segments to achieve success
- List the key competencies that can differentiate an MSL, now and in the future

**Faculty:**

**Randy Miller PharmD, RPh**  
Director  
Field Based Medicine Operations  
Boehringer Ingelheim Pharmaceuticals, Inc.

**Hilary Mandler, PharmD**  
Director  
Global MSL Operations  
Shire PLC

**David Jencen, PhD**  
Principal  
Jencen Field Medical Consulting LLC

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**Poster Pearls**

Chair:  
**Stacey Fung, PharmD**  
Associate Director, Medical Communications  
Genentech, A Member of the Roche Group

This session will offer a unique opportunity for any Medical Communications practitioner (e.g., information specialist, medical liaison, manager) to share their successes, challenges, and “pearls of wisdom” on various Medical Communications topics through poster presentations.

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**Medical Science Liaisons Track Posters**

Chair:  
**J. Lynn Bass, PharmD**  
Director  
Medical Scientists  
Jazz Pharmaceuticals

In this session, Medical Science Liaison professionals were invited to present their successes, challenges, and “pearls of wisdom” on various topics through poster presentations.

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**2014 Medical Science Liaisons (MSL) Networking Lunch Discussions**

Chair:  
**J. Lynn Bass, PharmD**  
Director  
Medical Scientists  
Jazz Pharmaceuticals

Attendees will have the opportunity to either dine on their own or grab their buffet lunch and participate in networking roundtable discussions. These networking sessions will each be led by a facilitator having experience within a core MSL functional area that is specific to that table topic discussion (see topics to the right/below).

These informal networking sessions are designed to enable all roundtable participants to discuss topics of relevance to them, specific to their job functions and activities, and encourage information sharing from the perspectives of large, midsize, small, and specialty companies including the device and diagnostics industries. Facilitators will help to guide discussions, but the true catalysts of conversation will be the participants! Please join your colleagues and engage in what will sure to be a variety of insightful networking sessions.

**Roundtable Discussion Topics:**

1. MSL Communications - Proactive vs Reactive
2. MSL Training - A discussion of Best Practices
3. Stakeholder Engagement - How are you aligning your activities to support Scientific Platforms/Plans?
4. Collecting and Evaluating Field Intelligence
5. Initiating a Career as a MSL
## MEDICAL COMMUNICATIONS TRACK 10A-B

### Crystal Ball Management: Preparing for Expected and Unexpected Events

**Chair:**

**Timothy E. Poe, PharmD,**
Director  
TEP Consulting, LLC

The management of handling the complexities of day to day operation of Medical Information and Contact Centers may lead us to think we need a crystal ball to manage this business. In this session we will discuss a framework for this thought process and discuss the architecture of successful planning, including communication with cross functional partners. Case studies will be presented to illustrate some of the “events” that require planning and actions to minimize customer and patient impact. Included will be mergers and acquisitions, joint ventures, product recalls/withdrawals, product shortages and inclement weather/natural disasters. This will be an interactive session where the audience will be asked to participate by sharing best practices.

**Learning Objectives:**

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

- Recognize the benefits of good planning as it impacts your customers and patients
- Describe the architecture of successful planning for expected and unexpected events and demonstrate how to apply these capabilities when the unexpected happens
- Describe the ideal positioning of Medical Communications and Contact Center within the organization by discussing good working relationships, identify boundaries between functional groups and ways to overcome them, and how good positioning solidifies the “crystal ball”

**Faculty:**

- **Juan C. Nadal, MD**  
  Vice President  
  Medical Communication  
  Medical Affairs  
  Bayer HealthCare Pharmaceuticals
- **Jason Roebuck**  
  Associate Director  
  Medical Communications Operations  
  PPD

## MEDICAL WRITING REGULATORY TRACK 10C

### Global Developments in Clinical Trial Transparency and Their Impact on Clinical Trial Disclosure and Publication Writing

**Chair:**

**Eileen Girten**  
Senior Medical Writer  
inVentiv Health Clinical

Recent proposed changes to clinical trial disclosure requirements are under assessment. These developments relate to the access and disclosure of clinical trial data. This session will explain today’s clinical trial disclosure requirements and illustrate how a pharmaceutical company is addressing clinical trial disclosure requirements within its publication procedures. In addition, this session will discuss best practices in clinical trial disclosure and publication writing.

**Learning Objectives:**

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

- Recognize the current clinical trial disclosure requirements
- Apply examples from a pharmaceutical company to their current practice
- Discuss best practices for clinical trial disclosure and publication writing

**Faculty:**

- **Barbara Godlew, RN, BA**  
  President  
  The FAIRE Company
- **Peter Fairfield, MBA**  
  Global Scientific Communications Technical Lead  
  Commercialization  
  Eli Lilly and Company
MEDICAL WRITING PUBLICATION TRACK 10D

Publications in a Brave New World

Chair:
Chad Wagner, RPh
Director
Consumer Experience and Digital Channels
Eli Lilly and Company

Health care professionals (HCPs) have more options than ever when seeking scientific information. While traditional sources of information are still relevant, new sources are proliferating. These new sources are predominantly digital in nature and are forcing us to re-evaluate how we create and share scientific information. In this session we will take a deeper look at the digital behaviors of HCPs and how those behaviors are causing change with traditional publishers. We will also examine the emergence of non traditional publishers and how they are disrupting how information is delivered.

LEARNING OBJECTIVES:
At the conclusion of this session, participants should be able to:
- Discuss the HCP behaviors in digital channels when seeking scientific content
- Identify how to better tailor content to align with customer behaviors, how to place that content in relevant places, and how to measure the impact
- Discuss how traditional publishers are adapting and evolving, and how new forms of access are emerging
- Describe emerging tactics to measure relevance of publications in a digital world

FACULTY:
Chad Wagner
Director
Consumer Experience and Digital Channels
Eli Lilly and Company

James Avallone
Director
Physician Research
Manhattan Research, Decision Resources Group

MEDICAL SCIENCE LIAISONS TRACK 10E

Building an MSL Team

Chair:
Edmund J. Cunningham, PharmD
Director
Specialty Care MSLs
Medical Affairs
Eisai Inc

As the industry evolves, many organizations’ needs have turned to an increased focus on supporting the clinical development of compounds and launch products. Medical Science Liaisons (MSLs) serve a critical role in this paradigm as scientific experts in the field, communicating the science behind the company’s products and developing scientific contacts with key opinion leaders (KOLs) in the therapeutic area. Many organizations recognize the need for MSL capabilities and the importance of either establishing new MSL teams or increasing their MSL resources to meet their needs. This session discusses concepts involved in building effective MSL teams, including identifying the capabilities that are needed, determining the appropriate number of MSL team members, developing the necessary infrastructure to support MSL effectiveness in alignment with an organization’s needs, and effectively hiring an MSL team.

LEARNING OBJECTIVES:
At the conclusion of this session, participants should be able to:
- Discuss the strategic considerations associated with building an MSL organization, including the strategic scientific focus and anticipated MSL customer base
- Identify methods of determining appropriate MSL resourcing based on staffing models, as well as the technical needs and scope of MSL responsibilities
- Describe the approaches and considerations involved with effectively recruiting an MSL team
- Define the additional considerations involved with building an MSL team, including the necessary infrastructure to support an MSL team, ongoing training, metrics, and contingency planning

FACULTY:
Stacey Benefiel, PharmD
Senior Director, MSL Operations
TriNet Pharma

Edmund J. Cunningham, PharmD
Director, Specialty Care MSLs
Medical Affairs
Eisai Inc

Stephen Dodge, PharmD, MBA
Executive Director, Medical Affairs-Health Systems
Merck & Co., Inc.

Bryan Vaughan
Managing Member
TriNet Pharma

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2:30-2:45PM  REFRESHMENT BREAK

2:45-4:00PM  CLOSING PLENARY AND CLOSING REMARKS – SESSION 11

Chair:
J. Lynn Bass, PharmD
Director
Medical Scientists
Jazz Pharmaceuticals

Closing Plenary Speaker:
Jeffrey K. Francer, JD
Vice President & Senior Counsel
PhRMA

Closing Remarks:

Program Co-Chairs:
Jim Wilkinson, PhD
Executive Director
Medical Communications
Scientific Affairs
Amgen

Tolu Taiwo, PharmD, MBA
Director
Medical Information
Horizon Pharma, Inc.

Carrie C. Murray, MSN, NP
Director, Global MSL Excellence
Bayer HealthCare Pharmaceuticals

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