Medical Affairs and Scientific Communications 2016 Annual Forum

Core Curriculum: March 20 | Tutorials (AM): March 21 | Forum: March 21-23 | Gaylord Palms Resort and Convention Center | Kissimmee, FL

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Senior Medical Writer and Consultant
Whitsell Innovations, Inc.

This program has been developed in collaboration with the Medical Communications, Medical Writing and Medical Science Liaison Communities.

Overview

This is a must-attend annual forum for Medical Communication, Medical Information, Medical Science Liaison, and Medical Writing Professionals. Nowhere else can you network with all these professionals in one location. This content is developed to meet the needs of those who work in biopharmaceutical industry-based medical scientific communications by including three central tracks covering:

- Medical Communications
- Medical Writing: Regulatory and Publication
- Medical Science Liaisons

Who Should Attend

Professionals involved in:

- 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

KEYNOTE SPEAKER:

Suzanne Schrandt, JD
Deputy Director of Patient Engagement
PCORI

- Five breakout tracks focused on medical information, medical science liaisons, medical call centers, and medical writing (regulatory and publication)
- Cross-functional general sessions dedicated to all track areas
- Presentation of best practices via podium pearls and posters
- Presentation of original research from fellows and residents in training on Tuesday, 5:00-6:00PM, in Exhibit Hall C
- Exhibit Hall and numerous networking opportunities

Message from Program Co-Chairs

On behalf of the Programming Committee and DIA Board of Directors, we are pleased to invite you to the DIA Medical Affairs and Scientific Communications 2016 Annual Forum. Our program is dedicated to providing the necessary information and tools for medical scientific communications professionals to navigate the dynamic health care environment. Experts from industry and regulatory agencies will be presenting at our sessions across the three central tracks (Medical Writing, Medical Communications, and Medical Science Liaisons) as well as cross functional plenary sessions. Suzanne Schrandt, JD, Deputy Director of Patient Engagement at the Patient-Centered Outcomes Research Institute (PCORI), will be our Keynote Speaker. Ms. Schrandt's advocacy work includes educating patients and health care providers on managing chronic diseases.

You can also register for one of four preconference tutorials and Core Curriculum. The Core Curriculum, Tutorials, and Forum will offer continuing education credits for pharmacists and nurses. There will also be opportunities to network and discuss best practices during the Resident and Fellow Poster Reception, the Podium Pearls, and the Networking Receptions. Lastly, vendors and exhibitors will be available to highlight their latest products. We look forward to a great meeting and to seeing you in sunny Florida!

Eileen Girten, MS
Principal Medical Writer
inVentiv Health Clinical

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

Darryl Z. L'Heureux, PhD, MPharm, MSc
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Mary Sendi, PharmD
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Schedule At-A-Glance

- Tracks A and B: Medical Communications
- Track C: Medical Science Liaisons
- Track D: Medical Writing Regulatory
- Track E: Medical Writing Publications

CORE CURRICULUM | SUNDAY, MARCH 20

8:30AM–4:30PM	Core Curriculum: The Fundamentals of Medical Communications

TUTORIALS AND DAY ONE | MONDAY, MARCH 21 | THEME: DEVELOP

7:30AM–6:00PM	Registration
8:30AM–12:00PM	Tutorial 1: Medical Communications: Compliance in 2016
8:30AM–12:00PM	Tutorial 2: Promotional and Medical Review Committee 101
8:30AM–12:00PM	Tutorial 3: Fundamentals, Challenges, and Opportunities – A Tutorial for Medical Science Liaisons
8:30AM–12:00PM	Tutorial 4: Clinical Statistics for Nonstatisticians
1:00–1:30PM	Welcome and Opening Remarks
1:30–3:00PM	Keynote Address
3:00–3:30PM	Refreshment Break, Exhibits, and Networking
3:30–5:00PM	Session 1: FDA Update and Potpourri
5:00–6:00PM	Networking Reception

DAY TWO | TUESDAY, MARCH 22 | THEME: INNOVATE

7:30AM–6:00PM	Registration
7:30–8:30AM	Continental Breakfast, Exhibits, and Networking
8:00–8:30AM	DIA Publications Session
8:30–10:00AM	Session 2: Policy and Medicine
10:00–10:30AM	Refreshment Break, Networking, and Exhibits
10:30AM–12:00PM	Session 3: Breakout Sessions
	Session 3 Track A/B: Innovating in Medical Communications — Moving from Ideas into Real Experiences
	Session 3 Track C: Integrated Health Systems and the Evolution of the ML Role
	Session 3 Track D: The Broad Global Impact of EMA's Transparency Policy
	Session 3 Track E: Ethical and Accurate Data in Publications
12:00PM–1:30PM	Luncheon, Exhibits, and Networking
12:00PM–1:30PM	Resident, Fellow, and Preceptor Lunch: A Time for Reflection
1:30–3:00PM	Session 4: Breakout Sessions
	Session 4 Track A: Hot Topics in Medical Communications
	Session 4 Track B: Contact Center Strategy: Positioning Your Center for Success
	Session 4 Track C/E: Demonstrating and Communicating the Value of Medicines Through Health Economic and Outcomes Evidence
	Session 4 Track D: Best Practices for Regulatory Quality Review
3:00–3:30PM	Refreshment Break, Exhibits, and Networking
3:30–5:00PM	Session 5: Breakout Sessions
	Session 5 Track A: Evolution of Standard Response Documents and Other Communications
	Session 5 Track B: Hot Topics for Contact Centers
	Session 5 Track C: MSL Career Paths: Enjoying the Journey and Determining the Destination
	Session 5 Track D: Innovations in Sharing of Clinical Trial Results
	Session 5 Track E: Hot Topics in Bioethics - It's All Shades of Gray
5:00–6:00PM	Resident and Fellow Poster Reception

DAY THREE | WEDNESDAY, MARCH 23 | THEME: ADVANCE

7:00AM–4:30PM	Registration
7:00–8:00AM	Continental Breakfast, Exhibits, and Networking
8:00–9:30AM	Session 6: Breakout Sessions
	Session 6 Track A/B: Tools and Applications for Data Analytics and Insights in Medical Information
	Session 6 Track C: Value of the Medical Science Liaison Role (MSL) Across the Product Life Cycle - From Early Trial Execution to Patent Expiry
	Session 6 Track D: Saying the Unsaid: Sponsor and Vendor Relationships and Negotiations
	Session 6 Track E: Good Publication Practice 3: Ethical and Transparent Publication Practice
9:30–10:00AM	Refreshment Break, Exhibits, and Networking
10:00–11:30AM	Session 7: Breakout Sessions
	Session 7 Track A/B: Podium Pearls
	Session 7 Track C: Technology and Making the Life of a Medical Science Liaison Easier
	Session 7 Track D: Biosimilars: What the Communicator Should Know About This Growing Field
	Session 7 Track E: What Happens to Patients as They Use a Test Therapy: eCOA and Substantial Evidence of Clinical Benefit
11:30AM–1:00PM	Luncheon, Exhibits, Networking, and Session 8: Poster Pearls
12:30–1:00PM	DIA Publications Session
1:00–2:30PM	Session 9: Breakout Sessions
	Session 9 Track A: Globalization of Medical Communications and Contact Center – What Can We Learn from Orphan Drug, Rare Disease, and Specialty Company Experiences
	Session 9 Track B: Making Patients the Priority
	Session 9 Track C: Globalization of the MSL Role: Best Practices from Around the World
	Session 9 Track D/E: Career Track Options for Medical Writers – Transferability of Skills Sets
2:30–3:00PM	Refreshment Break, Exhibits, and Networking
3:00–4:30PM	Session 10: New Drugs of 2015 Review and Closing Remarks
4:30PM	Conference Adjourns

Continuing Education

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 24.75 contact hours or 2.475 continuing education units (CEU's).

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**.

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- Choose MENU, found in the upper left corner
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The evaluation closes on Wednesday, April 13, 2016.

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Continuing Education Credit Allocation

CORE CURRICULUM

Pharmacy 6.5 contact hours or .65 CEUs, UAN: 0286-0000-16-031-L04-P, Type of activity: Knowledge; Nursing 6.5 contact hours; IACET .7 CEUs

TUTORIALS

Tutorial 1: ***Medical Communications: Compliance in 2016:*** Pharmacy 3.25 contact hours or .325 CEUs, UAN: 0286-0000-16-032-L04-P, Type of activity: Knowledge; Nursing 3.25 contact hours; IACET .3 CEUs

Tutorial 2: ***Promotional and Medical Review Committee 101:*** Pharmacy 3.25 contact hours or .325 CEUs, UAN: 0286-0000-16-033-L04-P, Type of activity: Application; Nursing 3.25 contact hours; IACET .3 CEUs

Tutorial 3: ***Fundamentals, Challenges, and Opportunities – A Tutorial for Medical Science Liaisons:*** Pharmacy 3.25 contact hours or .325 CEUs, UAN: 0286-0000-16-035-L04-P, Type of activity: Knowledge; Nursing 3.25 contact hours; IACET .3 CEUs

Tutorial 4: ***Clinical Statistics for Nonstatisticians:*** Pharmacy 3.25 contact hours or .325 CEUs, UAN: 0286-0000-16-036-L04-P, Type of activity: Knowledge; Nursing 3.25 contact hours; IACET .3 CEUs

FORUM

Pharmacy up to 15 contact hours or 1.5 CEUs; Nursing up to 15.5 contact hours; IACET 1.6 CEUs

Forum Pharmacy Credit Breakdown

Type of activity: Knowledge

Keynote Address and Session 1: ***FDA Update and Potpourri:*** 3 contact hours or .3 CEUs, UAN: 0286-0000-16-037-L04-P

Session 2: ***Policy and Medicine:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-038-L04-P

Session 3A/B: ***Innovating in Medical Communications – Moving from Ideas Into Real Experiences:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-039-L04-P

Session 3C: ***Integrated Health Systems and the Evolution of the ML Role:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-040-L04-P

Session 3E: ***Ethical and Accurate Data in Publications:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-041-L04-P

Session 4A: ***Hot Topics in Medical Communications:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-042-L04-P

Session 4B: ***Contact Center Strategy: Positioning Your Center for Success:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-043-L04-P

Session 4C/E: ***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

Session 4D: ***Best Practices for Regulatory Quality Review:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-045-L04-P

Session 5A: ***Evolution of Standard Response Documents and Other Communications:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-046-L04-P

Session 5B: ***Hot Topics for Contact Centers:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-047-L04-P

Session 5C: ***MSL Career Paths: Enjoying the Journey and Determining the Destination:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-048-L04-P

Session 5D: ***Innovations in Sharing of Clinical Trial Results:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-049-L03-P

Session 5E: ***Hot Topics in Bioethics – It's All Shades of Gray:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-050-L01-P

Session 6A/B: ***Tools and Applications for Data Analytics and Insights in Medical Information:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-051-L04-P

Session 6C: ***Value of the Medical Science Liaison Role Across the Product Life Cycle – From Early Trial Execution to Patient Expiry:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-052-L04-P

Session 6E: ***Good Publication Practice 3: Ethical and Transparent Publication Practice:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-053-L04-P

Session 7A/B: ***Podium Pearls:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-054-L04-P

Session 7C: ***Technology and Making the Life of a Medical Science Liaison Easier:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-055-L04-P

Session 7D: ***Biosimilars: What the Communicator Should Know About This Growing Field:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-056-L01-P

Session 7E: ***What Happens to Patients as They Use a Test Therapy eCOA and Substantial Evidence of Clinical Benefit:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-057-L01-P

Session 9A: ***Globalization of Medical Communications and Contact Center – What Can We Learn from Orphan Drug, Rare Disease, and Specialty Company Experiences:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-058-L01-P

Session 9B: ***Making Patients the Priority:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-059-L05-P

Session 10: ***New Drugs of 2015 Review and Closing Remarks:*** 1.5 contact hours or .15 CEUs, UAN: 0286-0000-16-060-L01-P

Continuing pharmacy education credits are **NOT AVAILABLE** for the following sessions:

- *Welcome and Opening Remarks*
- *DIA Publications Sessions*
- *3D: The Broad Global Impact of EMA's Transparency Policy*
- *6D: Saying the Unsaid: Sponsor and Vendor Relationships and Negotiations*
- *8: Poster Pearls*
- *9C: Globalization of the MSL Role: Best Practices from Around the World*
- *9D/E: Career Track Options for Medical Writers – Transferability of Skills Sets*

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Track Descriptions

Medical Communications Track

This track will explore various topics within the medical communication and medical information fields, highlighting the need for a comprehensive understanding of medical content and the regulatory and compliance environment which directly affects daily activities. Speakers will share methods for adapting to the needs of the changing health care landscape and the variety of evolving stakeholders that rely on the information provided by companies. Other topics will detail how to find the most effective ways to utilize customer input to enhance medical information services and to share the customer insights in an effective, action-driven manner to business partners. Sessions in this track will give you a comprehensive understanding of the essential federal guidance documents and laws for appropriate communications to patients and health care providers. You will also gain a better understanding of best practices within the job function and a broader awareness of the regulatory environment. Lastly, you will learn how to work better as part of interdisciplinary teams, practice evidence-based medicine evaluation, and effectively use innovations in technology.

Medical Science Liaison Track

This track will feature a wide range of topics for MSL professionals, including insight into the MSL role across the product life cycle, perspectives on the MSL career path, and globalization of the MSL role. There will also be a joint session with the Medical Writing track on the topic of Health Economics Research Outcomes. You will learn best practices and for ensuring continued success within the MSL role, ways to advance the development of MSL operations, and solutions for engaging field-based medical teams within the industry.

Medical Writing Track

This track will be subdivided into two tracks: Medical Writing Regulatory and Medical Writing Publications. Included within these sub-tracks will be sessions on biosimilars and the communicator, GPP3, EMA Policy 70, ethical and accurate data in publications, bioethics, health economics and outcomes research, sponsor/vendor relationships, and career development. This track is a great opportunity to develop, innovate, and advance your medical writing career.

8:30AM–4:30PM

Core Curriculum: The Fundamentals of Medical Communications

Session Chair:

Jihwon Im, PharmD
Associate Director
Managed Care Medical Communications
Genentech, Inc., A Member of the Roche Group

Polling: Use the DIA App

Instructors:

Justine Alderfer, PharmD
Director, Organized Customer Support
Medical Information
Pfizer North America

Wynter Balcerski, PharmD
Senior Manager
Oncology Medical Information Services
Sanofi U.S.

Kristin Goettner, PharmD
Director
Medical Information
Janssen Scientific Affairs, LLC

Ellen Whipple, BS Pharm, PharmD
Medical Information Specialist (Oncology)
Med Communications, Inc.

Margaret May, MLS, AHIP
Literature Research Analyst
US Medical Affairs
Genentech, Inc., A Member of the Roche Group

Janelle Saulter, PhD
Master Medical Scientist
Medical Affairs
Allergan

Ankur Shah, PharmD
Associate Director
Medical Information
Incyte Corporation

This activity is specifically designed to meet the needs of individuals new to biopharmaceutical industry-based medical communications. You 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 will gain the most from attending.

Learning Objectives:

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

- Describe how the regulatory environment influences medical communications practice
- Identify critical steps that a medical communications professional should take when receiving an unsolicited inquiry, including evaluating the available data and sources of information
- Describe the important elements of writing a concise and clear standard response letter
- Recognize key biomedical literature resources used for answering medical information inquiries, including strategies and techniques for finding literature to answer medical information questions
- Discuss medical information roles and responsibilities at medical congresses
- Recognize the differences and similarities between the roles of medical communications and medical science liaisons, including ways to share information and resources and share best practices and ideas for collaboration to enhance productivity and value for both organizations
- Discuss ways that medical communications professionals can support the needs of managed care customers including understanding the background, content, and purpose of the AMCP Formulary Dossier
- Describe the distinct scientific value that medical communications provides on promotional review committees

8:30–9:00AM

Welcome and Introductions

Session Chair:

Jihwon Im, PharmD

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

9:00–10:00AM

Session 1: Part 1
An Introduction to the Regulatory Environment and Medical Communications Practices

Session Chair:

Kristin Goettner, PharmD

This presentation will describe how the US regulatory environment impacts medical communications within the pharmaceutical industry. An introduction to key concepts in medical communications practice based on FDA statutes, regulations, policies, and guidance will be provided. In addition, useful regulatory resources that are accessible in the public domain will be shared.

10:00–10:15AM Refreshment Break

10:15–10:45AM

Session 1: Part 2
Best Practices for Handling Unsolicited Medical Inquiries

Session Chair:

Ankur Shah, PharmD

Identify 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, and the importance of fair balance and documenting responses.

10:45–11:15AM

Session 1: Part 3
Unsolicited Request Case Scenario Round Table Discussions

11:15–11:45AM

Session 1: Part 4
Literature Searching for Medical Communications Professionals

Session Chair:

Margaret May, MLS, AHIP

Literature searching is a vital skill for medical communications professionals. This talk will provide an overview of key biomedical literature resources used for responding to medical inquiries. You will walk away with practical tips that can be applied in your daily work.

11:45AM–12:45PM Luncheon

12:45–2:30PM

Session 2

This session will delve deeper into the challenging aspects of different areas of our industry practices. Topics will include medical writing, scientific congress support, and collaborations with medical science liaisons.

Tips for Effective Medical Writing

Ellen Whipple, BS Pharm, PharmD

Medical Congress Planning and Medical Information Booth Support

Wynter Balcerski, PharmD

MSL Collaborations

Janelle Saulter, PhD

2:30–2:45PM Refreshment Break

2:45–4:00PM

Session 3

This session will delve deeper into the challenging aspects of different areas of our industry practices. Topics will include AMCP formulary dossier communications, and promotional review.

AMCP Dossier and the Managed Care Perspective

Justine Alderfer, PharmD

Promotional Review Committee Overview

Jihwon Im, PharmD

4:00-4:30PM

Q&A with Core Curriculum Faculty

4:30PM

Core Curriculum Adjourned

MONDAY, MARCH 21

Theme: DEVELOP

7:30AM–6:00PM Registration

8:30AM–12:00PM

Tutorial 1: Medical Communications: Compliance in 2016

Instructors:

Monica Kwarcinski, PharmD
Executive Director, Medical Services
Purdue Pharma, LP

Mark DeWyngaert, PhD, MBA
Managing Director
Huron Consulting Group

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.

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

8:30AM–12:00PM

Tutorial 2: Promotional and Medical Review Committee 101

Instructors:

Ivy Chang, PharmD
Associate Director, Medical Communications
Genentech, Inc., A Member of the Roche Group

Kristin Goettner, PharmD
Director
Medical Information
Janssen Scientific Affairs, LLC

Kristi Sanford, JD
Head
US Medical Operations
UCB, Inc

Amy C. Van Sant, PharmD, MBA
Director
Medical Information
Ashfield Healthcare, LLC

Promotional review is a critical component to successful marketing of products. Promotional review committees (PRCs) ensure that a company's advertising and promotional materials and activities meet regulatory, legal, and scientific requirements, and internal policies and guidelines. Medical information/communications can play a key role in ensuring scientific rigor and accuracy and clinical relevancy of the content. Topics relevant for medical communications professionals performing promotional review will be covered. The tutorial may be a follow on to the topics covered in Core Curriculum or a refresher for the experienced promotional material reviewer, and will include table breakouts for in-depth reviews of promotional materials such as mock-ups and those cited by FDA.

Learning Objectives:

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

- Apply principles of promotional materials review and learnings from FDA warning letters when reviewing and commenting on promotional materials
- Determine acceptability of data/references used to support promotional claims
- Explain how promotional materials play a role in Corporate Integrity Agreements (CIAs)
- Describe an oversight review process for promotional materials and understand how PRC team members prepare for an oversight/escalation meeting

8:30AM–12:00PM

Tutorial 3: Fundamentals, Challenges, and Opportunities – A Tutorial for Medical Science Liaisons

Instructors:

J. Lynn Bass, PharmD, RPh
Director, Medical Affairs
Jazz Pharmaceuticals

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

The DIA Medical Science Liaison (MSL) tutorial is presented for individuals who have primarily served in the MSL role for less than two years and who wish to gain additional knowledge regarding career enhancement and best practices in this role. This tutorial would also be appropriate for individuals who are considering a future role as a an MSL. The tutorial leaders bring greater than 15 years of experience in a variety of MSL related roles - individual contributor roles, management experience, and MSL trainer roles.

The tutorial will consist of four modules including:

1. Techniques on Improving Key Opinion Leader (KOL) Identification and Expanding KOL Relationships
   - How do you determine who to see and where do you find them?
   - What compliance hurdles should you be aware of when speaking with KOLs?
2. Keys to Building Internal Business Partner Relationships
   - Who are your internal stakeholders and how do you work compliantly with this partner?
   - What do they want to know, and how do you best communicate with them on Clinical/Competitive Intelligence?
   - How can you network with internal colleagues (medical and commercial)?
3. Business Acumen (Pharma 101)
   - How to manage the day-to-day administrative tasks of the MSL role without frustration
   - Geography management best practices
   - How do you cram 60 hours into a 40 hour workweek?
   - Appropriate communication (internally and externally)
4. Career Development
   - What are other potential roles/positions for someone with a MSL background? When do you put your career before your job?

Learning Objectives:

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

- Describe the current challenges MSLs face when starting a career as a MSL
- Examine best practices to be a successful MSL, ranging from identification of thought leaders, to partnering with internal business colleagues
- Discuss how to implement techniques to better manage a career as a MSL and beyond

8:30AM–12:00PM

Tutorial 4: Clinical Statistics for Nonstatisticians

Instructor:

James B. Whitmore, PhD
Vice President, Biometrics
Juno Therapeutics

Statistics plays an important role in the design, collection, analysis, and interpretation of clinical and nonclinical information. While focusing on the basic statistical concepts relevant to clinical research, this tutorial will answer common questions and addresses topics such as confidence intervals, hypothesis testing, interim analysis, and methods for analyzing survival data and establishing noninferiority. Interactive discussions will emphasize thinking critically about data, making valid inferences, and understanding how statistics is an essential element of clinical investigations and medical communications. With limited use of computational formulas, this tutorial will increase the level of statistical knowledge of nonstatisticians so that collaborative efforts of statisticians and nonstatisticians on cross functional teams can be improved.

Learning Objectives:

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

- Recognize concepts such as variability, bias, confidence intervals, hypothesis testing, and P-values and their applications to current projects
- Identify techniques for time-to-event data and interim analyses
- Discuss the statistician's collaborative role in the design, analysis, and interpretation of clinical data
- Demonstrate how to establish clinical superiority, noninferiority, and equivalence
- Effectively speak to coworker and management using statistical terms

1:00–1:30PM Forum Opens

1:00–1:30PM

Welcome and Opening Remarks

Raleigh Malik, PhD
Senior Scientific Liaison
DIA

Darryl L'Heureux, PhD, MSPharm, MSc
Medical Writing Manager
Bristol-Myers Squibb

Mary K. Sendi, PharmD
Director - Team Lead
Pfizer Medical Information
Pfizer, Inc.

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

Eileen Girten, MS
Principal Medical Writer
Inventiv Health Clinical

1:30–3:00PM

Keynote Address

Suzanne Schrandt, JD
Deputy Director of Patient Engagement
PCORI

3:00–3:30PM Refreshment Break, Exhibits, and Networking

3:30–5:00PM

Session 1: FDA Update and Potpourri

Session Chair:

J. Lynn Bass, PharmD, RPh
Director, Medical Affairs
Jazz Pharmaceuticals

Will the new FDA Commissioner usher in a new era for the FDA? How will new guidances, released by the FDA, affect personnel in the medical communications, medical science liaisons, and medical writing roles? What effect does the Presidential election have on the FDA in the future? How do recent rulings regarding off-label discussions impact medical and scientific affairs? How are PRC/MLR Review and social media engagement affected by these rulings?

These topics and others have been at the forefront of the industry dialogue over the last year and beyond. In this session, you will gain perspectives on these and additional hot topics from the FDA. The session lays the foundation for the remainder of the forum by presenting an overview of the current regulations, enforcement actions, recent developments, and insights from the FDA and Department of Justice, which directly affect individuals in the medical communications, medical science liaisons, and medical writing roles.

Darshan Kulkarni, PharmD, MS, JD
Principal Attorney
The Kulkarni Law Firm

Learning Objectives:

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

- Identify the trends reflected in the latest enforcement actions and policies issued by the FDA
- Discuss how new FDA guidances will affect the roles of medical communications, medical science liaisons, and medical writing staff

5:00–6:00PM Exhibitor and Networking Reception

6:30PM

Dinner On The Town

Make plans to form new connections, network with peers, and dine with colleagues! There are three restaurants to choose from (Old Hickory Steakhouse, MOOR, and Villa De Flora) for you to meet, eat, and network. Sign up at the DIA registration table.

(Restaurants are located on site; Dinner cost is own your own.)

TUESDAY, MARCH 22

Theme: INNOVATE

7:30AM–5:00PM Registration

7:30–8:30AM Continental Breakfast, Exhibits, and Networking

8:00–8:30AM

DIA Publications Session

Judy Connors, MA
Associate Director, Editorial Services
DIA

Add "published author" to your accomplishments! Judy Connors, Associate Director of Editorial Services and Managing Editor of DIA's official peer-reviewed journal, *Therapeutic Innovation & Regulatory Science* (TIRS), will discuss the submission and peer-review process for this publication. Other publication opportunities with DIA, including article submission to our digital association news magazine, the *Global Forum*, and content development for the DIA website will also be discussed.

8:30–10:00AM

Session 2: Policy and Medicine

Session Co-Chairs:

Live Streaming for Virtual Conference

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 discussed.

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

Industry Perspective

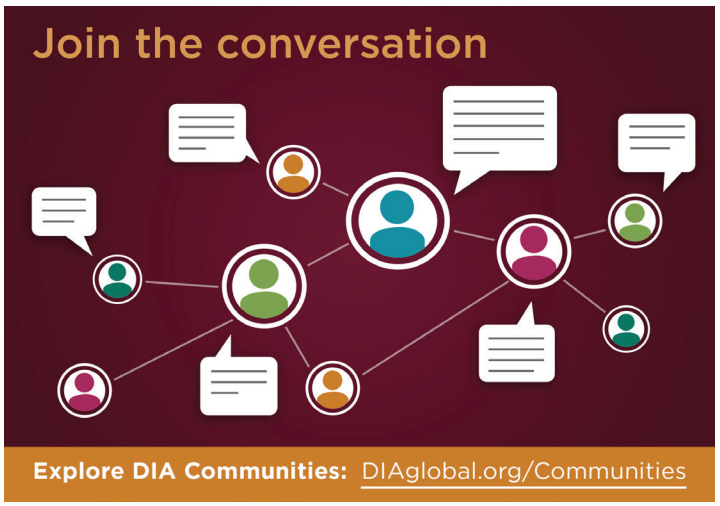
Jamie E. Haney, JD
General Counsel – Lilly Diabetes
Senior Director and Assistant General Counsel
Eli Lilly and Company

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

10:00–10:30 AM Refreshment Break, Exhibits, and Networking



10:30AM–12:00PM **Session 3: Breakout Sessions**

Track A/B: Medical Communications

Innovating in Medical Communications – Moving from Ideas into Real Experiences

Polling: Use the DIA App

Session Co-Chairs:

Michelle Clausen, PharmD
Director
Medical Information-Channel Innovation
Pfizer, Inc.

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

How does innovation occur inside and outside of pharmaceutical companies? Learn broadly how to encourage innovation and examples of how one company is creating environments for colleagues to focus on innovation. Examples will also be shared for a company's medical information group's innovations in medical communications with leveraging social media and digital resources.

Learning Objectives:

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

- Discuss innovation concepts and innovation in other industries
- Relay examples of how to encourage innovation in the workplace
- Describe examples of innovations in medical communications – from idea to execution

Jamie Showrank
Global IT Innovation Manager
Bayer Business Services, GmbH

Gregory Cohen, MBA
Associate Director, Global Strategic Marketing - Multichannel Engagement Lead
UCB, Inc.

Track C: Medical Science Liaisons

Integrated Health Systems and the Evolution of the ML Role

Session Chair:

Rebecca A. Vermeulen, RPh
Head Medical Liaison, Global Medical Affairs
Genentech, Inc., A Member of the Roche Group

This session will focus on the evolution of health systems and the integration of networks that provide care for patients. Presentations will review market dynamics and consolidation of systems that are impacting the role of the medical liaison and the interface they have with a broadening group of key stakeholders. Particular topics include the changing customer landscape, defining value to meet customer needs, and engagement models that are necessary for the industry to serve as a trusted resource for customers.

Learning Objectives:

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

- Describe changes in the health care landscape including consolidation of health systems
- Explore implications for engaging key stakeholders involved in the care of patients
- Develop solutions for engaging field based medical teams within the industry

Randy Miller, PharmD
Director, Field Based Medicine (MSL) Operations
Boehringer Ingelheim Corporation

Robert Albarano
Managing Director
Campbell Alliance

Track D: Medical Writing Regulatory

The Broad Global Impact of EMA's Transparency Policy

Session Chair:

Robert A. Paarlberg, MS
Principal
Paarlberg & Associates LLC

The European Medicines Agency's (EMA) Publication Policy 0070 enables public access to clinical overviews, clinical summaries and clinical study reports included in a Marketing Authorization (MA) or Postmarketing Authorization. Clinical data that were submitted under the centralized procedure after January 1, 2015, (including clinical trials conducted outside the EU or EEA that were included in the MA) will be posted on the EMA website. Under Policy 0070, companies must balance public health interests while ensuring the privacy of patients identified in regulatory submissions.

This session will provide an early assessment of Policy 0070, highlight some potential challenges encountered in the de-identification of patient data, and discuss the challenges in writing a clinical study report with disclosure in mind.

Learning Objectives:

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

- Discuss the current status of EMA Publication Policy 0070
- Recognize the potential risks of jeopardizing personal privacy by disclosing specific clinical trial patient data
- Discuss how clinical study reports can be written with disclosure in mind
- Describe the challenges of redacting commercially confidential information and anonymization of personal data in clinical study reports

EMA's Clinical Data Transparency Policy – Where Are We?

Robert A. Paarlberg, MS
Principal
Paarlberg & Associates LLC

Options for Data Sharing: Industry Implementation

Helle Gawrylewski, MA
Senior Director, Medical Writing and Alliance Management
Janssen Research & Development, LLC

Best Practices for Writing Clinical Study Reports for Disclosure

Ann M. Winter-Vann, PhD
Senior Medical Writer and Consultant
Whitsell Innovations, Inc.

Track E: Medical Writing Publications

Ethical and Accurate Data in Publications

Session Chair:

Jennie G. Jacobson, PhD
Consultant, Scientific Communications
Eli Lilly and Company

Accurate data is vital for communication of scientific results, and is the result of concerted effort throughout the writing process. To ensure quality communication of results, writers must present representative data in a fair and balanced manner. Data annotations must be complete, sufficiently detailed, easy-to-use, and traceable in the event of an audit. Data quality reviewers must be mindful of the broad spectrum of potential errors within scope of their review. This session will provide practical information on these topics to enable improvement in data accuracy of publications.

Learning Objectives:

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

- Describe best practices for ethical and accurate presentation of data in publications
- Discuss processes for data annotation and audit preparedness
- Compare strategies for reviewing publications for data accuracy

Lies, Damn Lies, and Statistics: Keeping Publications Honest

Robin Whitsell
President
Whitsell Innovations, Inc.

It's Midnight...Do You Know Where Your Data Are?

Arlene Kray, PharmD, PhD
Manager, Medical Writing
inVentiv Clinical, LLC

Data Quality Reviews: Eternal Vigilance is the Price of Accuracy

Jennie G. Jacobson, PhD
Consultant, Scientific Communications
Eli Lilly and Company

12:00–1:30PM Luncheon, Exhibits, and Networking

12:00–1:30PM

Resident, Fellow, and Preceptor Lunch: A Time for Reflection

Resident, Fellow, and Preceptor Development Session

This is a special session for Residents, Fellows, and their preceptors, and will be held in a private room during the luncheon. No fee is required.

Session Chair:

Alicia Alexander Cadogan, RPh, PharmD
Director, Oncology Medical Information
Pfizer, Inc.

After the Core Curriculum, the forum takes off at a rapid pace. The topics are intense, and the pace of the information can be a bit rapid for someone early in their career, such as residents and fellows. This special development session has been designed to allow the trainees to reflect on the subject matter of the forum thus far, and to engage in discussion on what they have learned, what they did not follow, and what they would like to better understand. Experienced faculty will highlight key learning points that you may have missed from the previous sessions, and will provide tools that you can apply to the remaining sessions to ensure you are maximizing your learning opportunities, and can act upon what you have learned when you are back in the workplace.

Preceptors are encouraged to participate to better understand what challenges the trainees may have with the content, and to help them identify what actions they can take when back in the workplace.

You are encouraged to ask questions that will allow you to act upon what you have learned at the forum.

Learning Objectives:

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

- Discuss the most important messages from the previous meeting sessions
- Identify key learning points from the upcoming sessions
- Apply the information that is most relevant to their particular situations

Alicia Alexander Cadogan, RPh, PharmD
Director, Oncology Medical Information
Pfizer, Inc.

Michael Toscani, PharmD
Research Professor
Rutgers Institute for Pharmaceutical Industry Fellowship

1:30–3:00PM **Session 4: Breakout Sessions**

Track A: Medical Communications

Hot Topics in Medical Communications

Polling: Use the DIA App

Session Chair:

Ivy Chang, PharmD
Associate Director, Medical Communications
Genentech, Inc., A Member of the Roche Group

If you are a new medical information/communications professional, how will you grow your career? What should your career path look like and how can you get promoted? Is people managing right for you? MSL vs Medical Information career options and other paths to longevity in pharma will be discussed.

Pharma Collaboration for Transparent Medical Information (PhaCT-MI) is a collaboration of medical information departments across the pharmaceutical industry. If PhaCT-MI becomes the one source for HCPs seeking medical information, what is the impact on the future of medical information, individual companies? What are some considerations in providing medical information, particularly off-label information, to non-HCPs?

During this session, speakers will share their unscripted perspectives and opinions on these topics.

Learning Objectives:

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

- Describe ways for new professionals to grow a career in medical information
- Discuss the future of medical information and how to meet non-HCPs' medical information needs

Lesley Fierro, PharmD, MS
Fellowship Consultant
Rutgers University

Dominick Albano, PharmD, MBA
Vice President, Global Medical Information
Pfizer, Inc.

Jeff Mathews, MPH
Senior Director, Medical Communications
Vertex Pharmaceuticals

Sonie M. Lama, PharmD, MS
Post-Doctoral Fellow in Medical Information/Medical Science Liaison
Bristol-Myers Squibb Company

Track B: Medical Communications

Contact Center Strategy: Positioning Your Center for Success

Session Chair:

David Bowers, PharmD
Director
Medical Communications
PPD

Medical information contact centers face a constantly evolving landscape with a growing number of internal and external challenges. In this dynamic environment, the successful contact center must have a strategic approach that is nimble and efficient without compromising increasingly stringent regulatory standards and internal and external customer expectations.

You will hear valuable benchmarking data of strategic approaches used across the medical information industry as well as case studies of strategies used by pharmaceutical companies to successfully navigate major challenges to their contact centers, such as mergers, product launches, and recalls.

Learning Objectives:

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

- Discuss current strategic practices used by contact centers across the pharmaceutical industry
- Describe successful strategies adopted by leading medical information centers to address major challenges
- Identify tactics that can be adopted to improve the ability of your contact center to navigate the current landscape

Call Centers: Effectively Manage the "Highs" to Avoid "Lows"

Tom Wells, PharmD, MBA
Associate Vice President
Medical Information Services
Sanofi US

Mergers, Acquisitions and Divestitures, Oh My! - Championing Change Within the Moving Pharma Landscape

Anne Arvizu, PharmD, FASCP, CPC
Director, Global Medical Information
Baxalta US Inc.

Track C/E: Medical Science Liaisons/Medical Writing Publications

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

Live Streaming for Virtual Conference

Session Co-Chairs:

Donna Wartski
Medical Outcomes Specialist
Pfizer Inc.

Darryl L'Heureux, PhD, MSPharm, MSc
Medical Writing Manager
Bristol-Myers Squibb

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 Marrone, PharmD
Real World Outcomes Liaison
Eli Lilly and Company

Customer Insight

Richard Montgomery
Contracts and Operations Manager – Pharmacy
Adventist Health System

Track D: Medical Writing Regulatory

Best Practices for Regulatory Quality Review

Session Chair:

Michael Church, MA
Senior Director, Strategic
inVentiv Health Clinical

This session will examine the quality review process for regulatory documents. Best practices will be described for annotating, increasing the efficiency of the reviews, and ensuring the accuracy of the information. In addition, we will look at the process from a management perspective: effective resourcing practices when faced with large projects and accelerated timelines, managing "rolling" reviews, and maintaining a process that minimizes the risk of audit findings.

Learning Objectives:

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

- Discuss best practices for completing a quality review of a regulatory document
- Describe the types of tools used in quality review
- Define a strategy for effective annotation
- Evaluate complex projects and formulate resourcing and timeline strategies
- Identify potential audit risks and what can be done to minimize the risks

Managing the Quality Review Process

Michael Church, MA
Senior Director, Strategic
inVentiv Health Clinical

Quality Review of Regulatory Documents – Processes and Outcomes

Vicki Vick
Medical Writer II
inVentiv Health

Drafting Regulatory Documents to Minimize Quality Review Findings

Ann M. Winter-Vann, PhD
Senior Medical Writer and Consultant
Whitsell Innovations, Inc.

3:00–3:30 PM Refreshment Break, Exhibits, and Networking

3:30–5:00PM **Session 5: Breakout Sessions**

Track A: Medical Communications

Evolution of Standard Response Documents and Other Communications

Polling: Use the DIA App

Session Chair:

Juhi Jaisinghani, PharmD
Medical Information Therapeutic Manager
Novo Nordisk Inc.

The content of standard response documents (SRD) and the channel by which health care professionals (HCPs) prefer to receive this information is rapidly evolving with the changing payer landscape and improvements in technology. This session will explore how organizations are implementing changes to SRD content and enhancing delivery of medical information to HCPs. Topics will include information on incorporation of outcomes research data into SRDs, and development of novel communication formats and channels such as infographics, visuals, podcasts, and online chats.

Learning Objectives:

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

- Identify strategies to incorporate outcomes research into standard response documents
- Describe new formats and channels to communicate medical information to health care professionals
- Review learnings and recognize how to apply the findings to your organization

Evolution of Medical Information (MI) Standard Response Documents (SRDs) to Address the Needs of Payors-Incorporation of Outcomes Research (OR)

Joyce P. Fairclough, PharmD
Senior Manager, Medical Information Services
Sanofi

Novel Formats for Providing Medical Information: Alternatives to Standard Response Documents

Justine Alderfer, PharmD
Director, Organized Customer Support
Medical Information
Pfizer, Inc.

Implementing and Utilizing Chat Channel for Customers

Michael Boudreau
Consultant – Business Integrator
Eli Lilly and Company

Track B: Medical Communications

Hot Topics for Contact Centers

Session Chair:

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

We face many challenges every day in the medical information contact center. Do you feel like these challenges are unique to you, or wonder if others are facing some of the same things? This session will begin with the presentation of common challenges we experience: how to manage the collaboration between compliance and the customer experience, ensuring the best customer experience from the first interaction to the last, and finally, a look into one contact center's journey to a new solutions contact center that realized the customer's needs and adapted their organization to meet those needs. We will also have time for your questions or sharing of your best practices.

Learning Objectives:

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

- Identify behaviors and skills needed to maintain regulatory compliance while meeting customer needs
- Discuss the importance of consistent responses regardless of how the customer reaches the contact center
- Discuss the importance of frontline agent empowerment
- Discuss the usefulness of surveys and customer feedback and how that information may change the Contact Center processes
- Recognize what information can be provided and how in this new era of patient centricity

Managing the Collaboration Between Compliance and the Customer Experience

Holli L. Simmons
Director, The Lilly Answers Center
Lilly

Ensuring a Positive Customer Experience from Start to Finish

Katherine Thomas
Associate Director of Operations
PPD, Inc.

Journey to a New Solutions Contact Center

Christopher Bess, RN, BSN
Associate Director
UCBCares
UCB, Inc.

Track C: Medical Science Liaisons

MSL Career Paths: Enjoying the Journey and Determining the Destination

Polling: Use the DIA App

Session Chair:

Edmund J. Cunningham, PharmD
Director, Medical Science Liaisons
Regional Lead
Sunovion Pharmaceuticals, Inc.

Few careers offer the opportunity to make a difference to a population's health, while leveraging scientific knowledge in a dynamic environment quite like the MSL role. However, the challenge for many MSLs – and their managers – is determining a long-term career path that is fulfilling and aligns with an individual's skills and interests. This session will explore the MSL career path from the viewpoint of the MSL, MSL manager, and recruiter. Topics will include considerations for advancement within the MSL role, leveraging diverse MSL roles and responsibilities to identify new areas of opportunity, transitioning to an MSL management role, and promoting a culture of engagement.

Learning Objectives:

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

- Describe the core qualifications and skills required for continued success in an MSL role
- Discuss potential avenues for further professional development within the MSL position
- Examine the current landscape for MSL management opportunities including defining the areas of development for transitioning to a management role
- Define opportunities to engage in new career challenges and continuous improvement within the MSL role and other related roles

Suzanne Giordano, PhD
Executive Director
Head, Medical Science Liaisons
Sunovion Pharmaceuticals, Inc.

Michael Pietrack
Executive Vice President
TMAC Direct

Track D: Medical Writing Regulatory

Innovations in Sharing of Clinical Trial Results

Session Chair:

Eileen Girten, MS
Principal Medical Writer
Inventiv Health Clinical

In November 2014, a Notice of Proposed Rule Making was published by the US Department of Health and Human Services for Section 801 of the US Food and Drug Administration and Amendments Act of 2007 (FDAAA) and proposes to expand the types of clinical trials that require registration and reporting of results to ClinicalTrials.gov. The final rule is expected to be published in 2016. We will discuss what the current law and the proposed changes, if implemented, mean for medical writers.

Learning Objectives:

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

- Describe the proposed changes to Section 801 of FDAAA
- Discuss some of the public comments in response to the NPRM
- Recall current experiences with results reporting from the ClinicalTrials.gov perspective
- Discuss helpful hints and best practices to medical writers involved in clinical trial disclosure

Reporting Results to ClinicalTrials.gov and Changes Proposed in Rulemaking

Rebecca J. Williams, PharmD, MPH
Assistant Director, ClinicalTrials.gov, National Library of Medicine
National Institute of Health (NIH)

Helle Gawrylewski, MA
Senior Director, Medical Writing and Alliance Management
Janssen Research & Development, LLC

Track E: Medical Writing Publications

Hot Topics in Bioethics – It's All Shades of Gray

Session Chair:

Art Gertel, MS
President and Principal Consultant
MedSciCom, LLC

Clinical trials and study subject protections present challenges as we attempt to address bioethical situations encountered in an ever-changing context. We stand at the intersection of evolving science, technology, globalization, and societal perspectives. This session will address emerging topics in the field of bioethics, with a particular focus on those that involve clinical research. The objective is to familiarize yourself with some difficult challenges and dynamic tensions that exist within the realm of human subject research, and how you may use this understanding to better inform the concepts embodied in protocols and strategic documents.

Learning Objectives:

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

- Describe some of the challenges embodied in contemporary clinical research
- Discuss concepts and considerations in the development of clinical programs and associated documents

Hot Topics in Bioethics – Dynamic Tension

Art Gertel, MS
President and Principal Consultant
MedSciCom, LLC

The Clinician's Perspective – Can the Conflict Between Treatment and Research be Reconciled?

Todd Pesavento, MD
Professor, Clinical Nephrology
The Ohio State University

Patient Perspective

Gwen Darien
Executive Vice President of Patient Advocacy
National Patient Advocate Foundation (NPAF)

5:00–6:00PM Resident and Fellow Poster Reception

Resident and Fellow Poster Reception

Session Chair:

Alicia Alexander Cadogan, RPh, PharmD
Director
Oncology Medical Information
Pfizer, Inc.

The residents and fellows will display their projects and will be eager to discuss their work with you. Take advantage of this opportunity to learn from their research, share your perspective, 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.

WEDNESDAY, MARCH 23

Theme: ADVANCE

7:00AM–4:30PM **Registration**

7:00–8:00AM Continental Breakfast, Exhibits, and Networking

8:00–9:30AM **Session 6: Breakout Sessions**

Track A/B: Medical Communications

Tools and Applications for Data Analytics and Insights in Medical Information

Session Chair:

Poonam A. Bordoloi, PharmD
Associate Director, Strategic Medical Communications and Innovation
Celgene Corporation

Pete Guillot, MBA, RAC
President
Centerfirst

Innovative new data analytic tools are being used across all industries to make better use of "big data" by bringing insights and ideas to decision makers. Medical affairs and medical communications organizations create a tremendous amount of valuable data through discussion with health care professionals and other customers. Explore the newest tools used across industries to analyze and report on data insights as well as provide real-life applications of how these tools are being used and implemented in the medical information organization and call center. This session will conclude with a panel discussion of best practices.

Learning Objectives:

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

- Assess which data analytics and reporting tools are the best fit for achieving the objectives of your medical communications organization
- Apply the steps presented in the examples to lead a program for deploying data analytics tools
- Discuss how to improve the quality of the information delivered to your internal and external medical communications customers

Unlocking the Value of MI: Developing a Global MI Reporting Tool

Deniz Namarasli, MD
Global Medical Information Leader
F. Hoffman-La Roche, Ltd, Switzerland

New Data Analytic Tools and Reports for Medical Communications

Zachary Furqueron, MBA
Director/Team Lead Analytics & Reporting Group External Medical
Pfizer

Data Analytic Tools: Innovations, Applications, and Implementation

Paul Grant
Chief Innovation Officer
Creation Healthcare, United Kingdom
(Presentation will be via WebEx)

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Track C: Medical Science Liaisons

Value of the Medical Science Liaison Role (MSL) Across the Product Life Cycle - From Early Trial Execution to Patent Expiry

Session Chair:

Jim R. Wilkinson, PhD
Executive Director, Oncology Regional Medical Liaisons
Global Scientific Affairs
Amgen, Inc.

The value proposition of a function to the organization must be clear, aligned, and consistently communicated to both internal and external stakeholders. In this session, we will discuss the different roles and value the MSL can bring along the product life cycle. Specific examples will be provided of best practices when working with programs pre-approval, around the peri-launch timeframe, and those mature products approaching patent expiry. We will discuss effectively working with study operations and clinical development, CROs, early development, OL engagement, disease state education, ISS/ISTs, product launches, HEOR for mature products, and metrics across the life cycle.

Learning Objectives:

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

- Describe the value of field based medical teams, in the context of different stages of product development, to benefit the whole organization
- Identify best practices in a highly regulated environment and how to flex activities based upon the phase of the supported product or program
- Evaluate specific examples of functional value implemented in the field that support internal, as well as external customers
- Examine the differences between different MSL team models to recognize successes and failures to ultimately become a more effective MSL team

MSL Roles in Clinical Research, Working with Study Operations, and Early OL Identification/Profiling, etc.

Rich Swank, PhD
Executive Director and Head, Regional Medical Liaisons
Global Scientific Affairs
Amgen, Inc.

MSL Roles in Preparing for Product Launch: Disease State Education, OL Engagement, and Launch Measurements of Success

Valerie Stafford-Fox, RN, MSN, MBA
Associate Director, BioOncology Women's Health Medical Science Liaison Team
Genentech Inc., A Member of the Roche Group

Mature Product Support, Life Cycle Management, OL Engagement with Limited New Data, HEOR, and "Right-Sizing" a Team When Approaching for Patent Expiry

Ralph Rewers, PharmD
US Medical Science Liaison, Head
AbbVie

Track D: Medical Writing Regulatory

Saying the Unsaid: Sponsor and Vendor Relationships and Negotiations

Session Chair:

Robin Whitsell
President
Whitsell Innovations, Inc.

In relationships between sponsors and vendors, there is a fine line between being honest versus offensive, between being customer-oriented versus enabling, and between optimism versus overselling. When the sponsor says "tight timelines," does that mean "working nights and weekends"? When the vendor says "we can knock this out" does that mean "we can deliver something that is substandard and expensive"? Communication and candor at the outset of a relationship can help bridge some of this divide and create a better managed project and relationship. What are the questions that could better facilitate the right relationship? This session will present the best and worst case scenarios from the sponsor and vendor side. It will detail lessons learned and present examples of effective communication.

Learning Objectives:

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

- Discuss the perspective of sponsors and vendors in understanding each respective obligations and commitments
- Differentiate between "must haves" and "nice to haves" with sponsor/vendor engagements
- Compare communication approaches in terms of their potential to enhance or harm the understanding between outsourcing partners

The Sponsor Side

Marsha Marquess, PharmD
Manager, Regulatory Medical Writing
Duke Clinical Research Institute

The Vendor Side

Robin Whitsell
President
Whitsell Innovations, Inc.

Track E: Medical Writing Publications

Good Publication Practice 3: Ethical and Transparent Publication Practice

Session Chair:

Diane Moniz Reed, PharmD, CMPP
Head, Oncology Medical Publications
Bristol-Myers Squibb

Good Publication Practice guidelines (GPP3) provides recommendations that contribute to the publication of research results sponsored or supported by pharmaceutical, medical device, diagnostics, and biotechnology companies. These newly updated recommendations are designed to help individuals and organizations maintain ethical and transparent publication practices and comply with legal and regulatory requirements. These recommendations cover publications in peer reviewed journals and scientific congress presentations. This session will present the updated GPP guidelines and discuss best practices in this highly visible area of pharmaceutical data presentation. It will also share some of the most frequently asked questions that have been received by ISMPP.

Learning Objectives:

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

- Discuss why GPP guidelines are relevant to medical writers and all stakeholders involved with industry sponsored presentations and publications
- Describe the key guidelines that are considered industry best practice
- Explain the main elements of the newly-published GPP3 that are particularly important to medical writers
- Describe how to access the key Good Publication Practice guidelines, including GPP3

Good Publication Practice 3: Ethical and Transparent Publication Practice Overview and Panel Discussion

Diane Moniz Reed, PharmD, CMPP
Head, Oncology Medical Publications
Bristol-Myers Squibb

Overview and Panel Discussion

Kim Pepitone, CMPP
Scientific Director
Cactus Communications, Inc.

Eileen Girten, MS
Principal Medical Writer
Inventiv Health Clinical

Christian Klem, PharmD
Sr. Director, Global Scientific Publications & Communications, CV, Metabolics & Kidney Disease
AstraZeneca Pharmaceuticals

9:30–10:00AM Refreshment Break, Exhibits, and Networking

10:00-11:30AM **Session 7: Breakout Sessions**

Track A/B: Medical Communications

Podium Pearls

Session Chair:

Mary K. Sendi, PharmD
Director - Team Lead
Pfizer Medical Information
Pfizer, Inc.

Medical communications professionals will be presenting 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.

Learning Objectives:

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

- Discuss and share best practices, experiences, and innovative processes for medical communications topics related to social media, new technologies, information exchange platforms, and expanding medical information roles

Track C: Medical Science Liaisons

Technology and Making the Life of a Medical Science Liaison Easier

Session Chair:

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

This session will review technology enhancements, which will help the MSL streamline and work more efficiently. Software and Apps developed to help fulfill the MSLs needs with Key Opinion Leaders (KOLs) will be reviewed. The session will also offer tips and tricks to make the MSL more organized in their daily tasks.

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
- Evaluate technology that can be used to best communicate between internal and external customers of the MSL
- Examine tools to help work more efficiently and remain organized in daily MSL tasks

The Way to Better Organization via Technology and Reference Management

David Price, PhD
Medical Liaison Consultant – Strategy and Capabilities
Lilly USA, LLP

Kevin Appareti, MBA
Senior Director
Global Medical Science Liaison
Philips HealthTech

Khanh Bui, PharmD, MBA
Principal Medical Science Liaison-Hematology
Genentech, Inc., A Member of the Roche Group

Track D: Medical Writing Regulatory

Biosimilars: What the Communicator Should Know About This Growing Field

Session Chair:

Lawrence Liberti, MS, RPh, RAC
Executive Director
Centre for Innovation in Regulatory Science (CIRS)

This session is aimed at regulatory writers and publications/medical communications writers who have an interest in preparing communications describing biosimilars products. The objective is to help you recognize differences in communicating about the chemistry, pharmacology, and other characteristics of biosimilars distinct from small molecules and generics.

Learning Objectives:

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

- Recognize the differences between a biosimilars, small molecule, biologic, and generic product
- Describe the special approaches required to communicate regulatory and clinical concepts regarding biosimilars
- Discuss the role of biosimilars in global health care

Biosimilars 101: A Primer

Matthew Frankel, MD, MBA
Executive Director, Medical Affairs Biopharmaceuticals North America,
Sandoz Inc.

Communicating About Biosimilars: Building on Your Experience – Exploring a New Path

Eileen Girten, MS
Principal Medical Writer
Inventiv Health Clinical

Why Biosimilars Matter: Their Global Role in Modern Therapy

Lawrence Liberti, MS, RPh, RAC
Executive Director
Centre for Innovation in Regulatory Science (CIRS)

Track E: Medical Writing Publications

What Happens to Patients as They Use a Test Therapy: eCOA and Substantial Evidence of Clinical Benefit

Session Chair:

Stephen A. Raymond, PhD
Chief Scientist, Scientific Affairs
ERT

Clinical Outcome Assessments include various reports on the status of patients in clinical trials, including diaries and questionnaires completed by patients about themselves as well as assessments made by observers, clinicians, and/or caretakers. Capturing these assessments electronically rather than on paper forms makes information available in real time and also increases the quality of data. After 20 years of experience using more than 800 eCOA "instruments" in thousands of trials, the scientific importance of a patient perspective is established. This session will review aspects of eCOA methods that relate to writing and ethics, particularly the challenges of writing both the content of the survey instruments and the programming of systems for capture, review, monitoring, analysis, and delivery of results. eCOA systems increasingly support oversight of patient conditions, triggering alerts on symptom worsening and trends that warrant attention by site investigators and/or data monitoring boards. What are the ethical implications? Clarity of writing is essential in order for assessments to make sense to those who complete them (content validity). Reviewers who allow claims need to know that the substantial evidence standard has been met. An intriguing case history will illustrate how meeting these challenges enable quantification of improvement in ways that justify market approval and inclusion in formularies.

Learning Objectives:

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

- ·Describe how clarity of writing applies to eCOA instruments, protocols, and project management
- Explain how measurement of feelings, symptoms, and behaviors may fail
- Identify how medical writers and ethicists can ensure that the content captured within eCOA is valid

Writing eCOA: Optimizing Trustworthiness and Sensitivity of Subjective Data

Stephen A. Raymond, PhD
Chief Scientist, Scientific Affairs
ERT

The eCOA Story of a New Drug from First Use in Humans to Post Approval Claims

Jean Paty, PhD
Senior Director and Practice Lead, Endpoint Strategy
Quintiles

11:30AM–1:00PM Luncheon and Professional Poster Pearls

Session 8: Poster Pearls

Medical Communication and Medical Writing Poster Pearls

Session Co-Chairs:

Julia Petses, PharmD
Director
Medical Information Services, Diabetes
Sanofi U.S.

Mary K. Sendi, PharmD
Director - Team Lead
Pfizer Medical Information
Pfizer, Inc.

Eileen Girten, MS
Principal Medical Writer
Inventiv Health Clinical

Darryl L'Heureux, PhD, MSPharm, MSc
Medical Writing Manager
Bristol-Myers Squibb

This session will offer a unique opportunity for any medical communications practitioner to share their successes, challenges, and "pearls of wisdom" on various medical communications topics through poster presentations.

The Medical Communication and Medical Writing Poster Pearls will be presented in the lunch area.

Medical Science Liaisons Podium Pearls

Session Chair:

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

Medical science liaison professionals were invited to present their successes, challenges, and "pearls of wisdom" on various topics through podium presentations. Presentation topics were selected from submitted abstracts for this unique opportunity to share podium pearls. You may bring their lunch to the meeting room for the podium pearls presentations.

12:30–1:00PM

DIA Publications Session

Judy Connors, MA
Associate Director, Editorial Services
DIA

Add "published author" to your accomplishments! Judy Connors, Associate Director of Editorial Services and Managing Editor of DIA's official peer-reviewed journal, *Therapeutic Innovation & Regulatory Science* (TIRS), will discuss the submission and peer-review process for this publication. Other publication opportunities with DIA, including article submission to our digital association news magazine, the *Global Forum*, and content development for the DIA website will also be discussed.

1:00–2:30PM

Session 9: Breakout Sessions

Track A: Medical Communications

Globalization of Medical Communications and Contact Center – What Can We Learn from Orphan Drug, Rare Disease, and Specialty Company Experiences

Session Chair:

Mike Burman, PharmD
Senior Director
Propharma Group

Globalization of medical communications, from content to contact, continues to be a focus for many companies. Case studies will be highlighted from orphan drug, rare disease, and specialty companies to understand their motives, their approach, and most importantly, to identify what we can learn from their experience. Are there best practices and challenges associated with globalization that transcend company size? This session will include time for discussion and participation.

Learning Objectives:

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

- Evaluate reasons and different models for globalizing medical communications
- Identify challenges faced by orphan drug/rare disease companies in globalizing their medical communication organizations
- Apply lessons learned and best practices from orphan drug/rare disease companies to any size or type of company

Globalization Case Study for a Rare Disease Company

Kristen Morris, MSc
Senior Director, Global Medical Affairs
BioMarin Pharmaceuticals, Inc.

Globalization Case Study from a Specialty Company Perspective

Nancy Dougherty
Director Medical Communications and Information, Medical Affairs
Seqirus

Track B: Medical Communications

Making Patients the Priority

Live Streaming for Virtual Conference

Session Chair:

Christi Marsh, PharmD
Director, UCBCares
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 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/offerings, 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 Marsh, PharmD
Director, UCBCares
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"

Track C: Medical Science Liaisons

Globalization of the MSL Role: Best Practices from Around the World

Session Chair:

Geoff Brockway
Director, Global MSL Excellence
AstraZeneca

Medical Science Liaisons (MSL) are continuing to gain prominence in the life sciences field. With the growing importance and profile of this role in the dissemination of balanced, scientific, and medical information, companies are looking for ways to advance the development of MSL operations and achieve consistency across therapy areas and affiliates. Hear from global and local MSL excellence leaders about how they are using leading practices from affiliates to rapidly evolve the upskilling of the MSL role on a global scale.

Learning Objectives:

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

- Discuss how companies are working to advance MSL operations on a global scale
- Describe best practices for promoting skills and excellence for MSL professionals

Lisa Cesario, RPh
Director, Medical Liaison Oncology
Hoffmann-La Roche Ltd.

Debra Israel, MBA
Director, Global Medical Affairs Center of Excellence
Eli Lilly and Company

Track D/E: Medical Writing Regulatory and Publications

Career Track Options for Medical Writers – Transferability of Skills Sets

Session Chair:

Christine Dale, MBA, MS
Independent Contract Writer
XWrite, LLC

This session is aimed at regulatory writers and publications/medical communications writers, with a few years to many years of experience, who are interested in exploring career paths other than the one they are currently on. The objective is to help you recognize transferable skill sets that may identify new career directions/opportunities.

Learning Objectives:

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

- Evaluate personal attributes in order to recognize skill sets relevant to career objectives
- Discuss career options in which those skills could lead to success

Panelists:

Michael Church, MA
Senior Director, Strategic
inVentiv Health Clinical

Lawrence Liberti, MS, RPh, RAC
Executive Director
Centre for Innovation in Regulatory Science (CIRS)

Sara Ewing
President
Accurate Biomedical Communication, LLC

Eileen Girten, MS
Principal Medical Writer
Inventiv Health Clinical

Raleigh Malik, PhD
Senior Scientific Liaison
DIA

Kendra Bolt, PhD, CNIM
Manager of Scientific Communications and Medical Writing
Audentes Therapeutics

Darryl L'Heureux, PhD, MSPharm, MSc
Medical Writing Manager
Bristol-Myers Squibb

Art Gertel, MS
President and Principal Consultant
MedSciCom, LLC

2:30–3:00PM Refreshment Break, Exhibits, and Networking

Thanking our Media Partner: PharmaVOICE

3:00–4:30PM

Session 10: New Drugs of 2015 Review and Closing Remarks

Live Streaming for Virtual Conference

Session Chair:

Craig 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 2015. 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
Remington Professor of Pharmacy
Philadelphia College of Pharmacy, University of the Sciences in Philadelphia

4:30PM

Conference Adjourned

Exhibiting Companies

As of March 14, 2016

- 3vue, LLC
- American Medical Writers Association
- APCER Life Sciences
- Aris Global
- Ashfield Medical Information
- AMWA
- Author-It
- BESTMSLs
- C3i Healthcare Connections
- Cactus Communications
- CenterFirst
- DIA
- DITA Exchange
- Doctor Evidence, LLC
- Dohmen Life Science Services (DLSS)
- Endpoint Technologies, Inc.
- Envision Technology Solutions
- Gilead Sciences, Inc.
- GP Strategies
- Juno Therapeutics
- Mavens
- Med Communications, Inc.
- Medical Vigilance Solutions
- Microsystems
- Online Business Applications
- PhaCT-MI
- PleaseTech Ltd.
- PPD
- ProPharma Group
- Sylogent
- Techsol Corporation
- The Medical Affairs Company
- Truven Health Analytics
- Veeva Systems
- WRB Communications

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Develop. Innovate. Advance.

DIA is the only global organization dedicated to bringing health care product development professionals together in a neutral environment to improve health and well-being throughout the world.