DIA

Medical Affairs and Scientific Communications Forum

Primer: March 18 | Short Courses: March 19 | Forum: March 19-21
Omni Ranchos Las Palmas Resort and Spa | Rancho Mirage, CA

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Overview

The *Medical Affairs and Scientific Communications Forum* is a cross-functional forum for knowledge sharing and integrated thought leadership, for the purposes of gaining further expertise and networking opportunities in a specific area of work, as well as related functional areas. The sessions are developed to meet the needs of those who work in pharmaceutical-based medical affairs and scientific communications.

Highlights

- Full-day Primer course on March 18 to prepare you for the full Forum
- Three Preconference Short Courses to expand your learning opportunities
- Four breakout sessions within three educational tracks covering medical communications, medical writing, and medial science liaisons
- Multiple networking opportunities with your peers, speakers, and exhibitors
- **NEW!** DIA*fit* yoga classes on Tuesday and Wednesday morning to start your morning off on the right foot
- Podium Pearls Presentations on best practices
- Two poster sessions highlighting original research from fellows, residents in training, and professionals
- Exhibit Hall with 30+ exhibiting companies

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

Stay Connected!

Connect to the Complimentary Forum WiFi

Network: **Omni Meeting**

User Name: **dia**

Password: **dia2018**

Featured Tracks

Medical Communications Track

Hear from industry experts on the latest approaches in medical communication, from the creation of patient-centric medical information deliverables to managing digital channels. The program is designed for medical information and communication professionals by medical information and communication professionals. This is your opportunity to gain insight into the latest challenges and opportunities impacting med info/com professionals!

Medical Writing Track

This is the forum to network and learn from colleagues in and supporting Medical Writing. Industry experts will share the latest approaches in medical regulatory and publication writing. Topics discussed this year include health economics outcomes research publication considerations, clinical data disclosure requirements for submission, and implementation of common protocol templates.

Medical Science Liaison Track

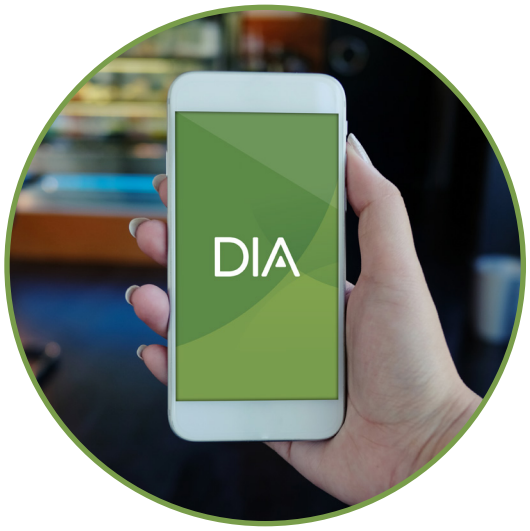
Medical Science Liaisons will find a comprehensive and cohesive agenda curated and peer-reviewed by recognized thought leaders in the MSL community. The high-quality, non-biased content is developed by MSLs for MSLs in DIA's global neutral forum. This is your opportunity to interact with – and be – an MSL thought leader.

Download the DIA Global Mobile App!

It is designed to enhance your meeting experience and provide valuable information in one place: agenda and speaker information, presentations, connect with attendees and exhibitors, participate in live session polling, and more!

Search "DIA Global" in your app store.

Your initial password is 'global'. If you have previously used this app, please use your existing password or reset your password.



SAVE THE DATE!

Medical Affairs and Scientific Communications Forum

March 17-20, 2019
Loews Sapphire Falls Resort
Orlando, FL

Learn More at DIAglobal.org/MASC19

Dear Colleagues,

We are pleased to welcome you to DIA's *Medical Affairs and Scientific Communications Forum*!

This forum is unique in setting the stage for an open, collaborative discussion of important topics and tools for medical scientific communications professionals to navigate the dynamic and quickly changing healthcare environment. Experts across the three central tracks, Medical Writing, Medical Communications, and Medical Science Liaisons, will be presenting. We are truly three meetings in one, with plenaries planned to create a cross-functional experience for knowledge sharing, integrated thought leadership, and proactive networking.

We will kick off with a full day Primer on Sunday and three half day Short Courses on Monday morning (note these courses require an additional fee). The main forum will begin in the afternoon on Monday and will feature our first keynote address by Paul Grant. We will lead into our first round of breakout sessions and end the day with an amazing welcome reception to be held outside on the roof terrace.

Tuesday we start the day with our second keynote address by Pam Cyrus, MD, Vice President and Head of Medical Governance, Pharmaceuticals, at Bayer!

We hope you will take advantage of the many opportunities to actively engage in discussions and with each other. Be sure to join us Tuesday evening for the Residents and Fellows Poster Session/ Networking Reception followed by a Dinner on the Town. Wednesday don't miss the luncheon featuring professional posters and our closing professional development session!

Best Regards,

The 2018 Medical Affairs and Scientific Communications Forum Program Committee

Schedule At-A-Glance

Track 1: Medical Communications **Track 2**: Medical Writing **Track 3**: Medical Science Liaisons

PRIMER COURSE | SUNDAY, MARCH 18		ROOM
8:00AM-5:00PM	Medical Communications Primer Registration **This course requires an additional registration fee*	Ballroom Foyer
8:30AM-5:00PM	**Medical Communications Primer:** The Fundamentals of Medical Communications	Salon ABC
DAY ONE | MONDAY, MARCH 19		**ROOM**
8:00-9:00AM	Short Course Registration **Courses require an additional registration fee*	Ballroom Foyer
8:00-8:30AM	Networking Breakfast for Short Course Attendees	Ballroom Foyer
8:30AM-12:00PM	**Short Course 1:** Medical Communications: Compliance in 2018 **Short Course 2:** Advertising, Promotion, and Scientific Content Review Process **Short Course 3:** Wearing Multiple Hats with Style: How to Effectively Manage Your Medical Writing Projects	Salon FG Salon A Salon C
10:00AM-12:00PM	**MSL Community Round Table**	Salon H
11:00AM-5:05PM	Forum Registration	Ballroom Foyer
12:40-1:00PM	DIA Mobile App Tutorial	Salon DE
1:00-1:30PM	**Welcoming Remarks**	Salon DE
1:30-2:30PM	**Session 1:** Keynote Address: Future Capability and the World of Tomorrow	Salon DE
2:30-3:00PM	Refreshment and Networking Break in the Exhibit Hall	Fiesta Ballroom
3:00-4:00PM	**Session 2:** Breakout Sessions **Track 1**: I Don't Need a Trophy, Grandpa! Rethinking the Myths of the Generation Gaps **Track 2A:** Medical Writing: Are You Calling Me Transparent? Insights into Clinical Trial Transparency: Layperson Summaries and the Plain Language Initiative **Track 2B:** The International Committee of Medical Journal Editors' Authorship and Data Sharing Statement Requirements: What and Why **Track 3:** Seeking Optimization of the MSL Role in an Industry of Disruptive Forces	 Salon E Salon D Salon ABC Salon FG
4:05-5:05PM	**Session 3:** Breakout Sessions **Track 1/3:** It Takes a Village: Collaboration for One Medical Voice **Track 2A:** The Trouble with IgG: Immunogenicity in the Clinical Development of Biologics **Track 2B:** Improving the Reporting of Clinical Trials	 Salon E Salon D Salon ABC
5:05-6:30PM	Networking Reception	Starlight Terrace
DAY TWO | TUESDAY, MARCH 20		**ROOM**
6:00-7:00AM	**DIAfit: Good Morning Sunrise Stretch with Light Yoga**	Salon H
7:00AM-5:30PM	Registration	Ballroom Foyer
7:00-8:00AM	Networking Breakfast in the Exhibit Hall	Fiesta Ballroom
8:00-9:00AM	**Session 4:** Keynote Address: Medical Affairs: Where Are We today and Where Will We be in the Future?	Salon DE
9:00-9:30AM	**Session 5:** DIA Communities Update	Salon DE
9:30-10:00AM	Refreshment and Networking Break in the Exhibit Hall	Fiesta Ballroom
10:00-11:00AM	**Session 6:** Breakout Sessions **Track 1:** Strategic Deployment of MI "Troops" and Capitalizing on New Technologies for MI Collaborations **Track 2:** Alpha and Alphabet: Statisticians and Medical Writers Working Together **Track 3:** Fishing for Insights and Extending the Engagement Beyond the Congress	 Salon E Salon D Salon F

Schedule At-A-Glance

Track 1: Medical Communications **Track 2**: Medical Writing **Track 3**: Medical Science Liaisons

DAY TWO | TUESDAY, MARCH 20		ROOM
11:05AM-12:35PM	**Session 7:** Breakout Sessions	
	Track 1A: One Medical Voice: Ensuring Consistent, Quality Medical Information Responses Globally	Salon E
	Track 1B: The Art and Science of Medical Information Contact Center Staffing	Salon D
	Track 2: Contemplate Your Template: New or Used Options for Protocol Development	Salon ABC
	Track 3: Policy Updates: The Evolution of Customer-Facing Medical Roles	Salon FG
12:35-2:00PM	Networking Luncheon in the Exhibit Hall	Fiesta Ballroom
12:35-2:00PM	**Fellow and Resident Professional Development Session: Personality Types and Leadership Characteristics**	Salon H
2:00-3:30PM	**Session 8:** Breakout Sessions	
	Track 1: Gold! Gold! Gold from Medical Information!	Salon E
	Track 2A: Interstellar: Crossing the Galaxy Between Pharma and Medical Devices/Companion Diagnostics	Salon D
	Track 2B: Brave New World: Planning for Global Submissions in a Post-Disclosure World	Salon ABC
	Track 3: Best Practices for Capturing Key Performance Indicators (KPIs) and Metrics for MSLs	Salon FG
3:30-4:00PM	Refreshment and Networking Break in the Exhibit Hall	Fiesta Ballroom
4:00-5:30PM	**Session 9:** Breakout Sessions	
	Track 1: Mixology: Headaches and Cures for Medical Information Challenges	Ballroom Foyer
	Track 2A: Scientific Communication Strategy	Salon D
	Track 2B: Secrets of the Editorial Office	Salon ABC
	Track 3: Are You Prepared to Ride the Tsunami of Change in Medicine or Will You Drown?	Salon FG
5:30-6:30PM	**Resident and Fellow Poster Reception and Networking**	Fiesta Ballroom
7:00PM	Dinner on the Town	

DAY THREE | WEDNESDAY, MARCH 21		ROOM
6:00-7:00AM	**DIAfit: PIYO Mix (Pilates/Yoga)**	Salon H
7:00AM-2:30PM	Registration	Ballroom Foyer
7:00-8:00AM	Networking Breakfast in the Exhibit Hall	Fiesta Ballroom
8:00-9:30AM	**Session 10:** Breakout Sessions	
	Track 1: Podium Pearls	Salon E
	Track 2: Managing Up, Down, and Across: Effective Medical Writing Management Strategies and Business Practices	Salon D
	Track 3: The Strategic MSL – Applying Business Acumen	Salon FG
9:30-10:30AM	Refreshment and Networking Break in the Exhibit Hall - View Professional Posters!	Fiesta Ballroom
10:30AM-12:00PM	**Session 11:** Breakout Sessions	
	Track 1: Global Warming: Conserve Energy and Unify Partners	Salon E
	Track 2A: Understanding Patient-Reported Outcomes (PROs) in Clinical Trials: The Value of Patient Experience	Salon D
	Track 2B: Personalized Medicine: Gene Therapy	Salon ABC
	Track 3: MSL Training – All Things Considered	Salon FG
12:00-1:30PM	Networking Luncheon in the Exhibit Hall - View Professional Posters!	Fiesta Ballroom
1:30-2:45PM	**To Thine Own Self be True: How Understanding Who You Are and What You Want Will Help You Build and Market Your Brand**	Salon E
1:30-3:30PM	**Career Fair**	Ballroom Foyer
3:30PM	**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 20.75 contact hours or 2.075 continuing education units (CEU's).

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY SUNDAY, MAY 6, 2018

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 Sunday, May 6, 2018, 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.

As an IACET Authorized Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to 2.3 CEUs for this program. Participants must attend the entire forum (primer and/or short courses 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 (primer and/or short courses if applicable), complete the "Verification of Attendance" form located in your forum folder, turn in your form to the registration desk at the conclusion of the forum, and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on **Wednesday, April 4, 2018.**

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

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Continuing Education Allocation

Medical Communications Primer: The Fundamentals of Medical Communications

Pharmacy 7 contact hours or .7 CEUs, UAN: 0286-0000-18-017-L04-P; IACET .7 CEUs

Short Courses

Short Course 1: ***Medical Communications: Compliance in 2018:*** Pharmacy 3.25 contact hours or .325 CEUs, UAN: 0286-0000-18-018-L04-P; IACET .3 CEUs

Short Course 2: ***Advertising, Promotion, and Scientific Content Review Process:*** Pharmacy 3.25 contact hours or .325 CEUs, UAN: 0286-0000-18-019-L04-P; IACET .3 CEUs

Short Course 3: ***Wearing Multiple Hats with Style: How to Effectively Manage Your Medical Writing Projects:*** IACET .3 CEUs

Forum Pharmacy Credit Breakdown

Session 2 Track 1: ***I Don't Need a Trophy, Grandpa! Rethinking the Myths of the Generation Gaps:*** Pharmacy 1 contact hour or .1 CEUs, UAN: 0286-0000-18-020-L04-P

Session 2 Track 2A: ***Medical Writing: Are You Calling Me Transparent? Insights into Clinical Trial Transparency: Layperson Summaries and the Plain Language Initiative:*** Pharmacy 1 contact hour or .1 CEUs, UAN: 0286-0000-18-021-L04-P

Session 2 Track 3: ***Seeking Optimization of the MSL Role in an Industry of Disruptive Forces:*** Pharmacy 1 contact hour or .1 CEUs, UAN: 0286-0000-18-022-L04-P

Session 3 Track 1/3: ***It Takes a Village: Collaboration for One Medical Voice:*** Pharmacy 1 contact hour or .1 CEUs, UAN: 0286-0000-18-023-L04-P

Session 3 Track 2A: ***The Trouble with IgG: Immunogenicity in the Clinical Development of Biologics:*** Pharmacy 1 contact hour or .1 CEUs, UAN: 0286-0000-18-024-L04-P

Session 3 Track 2B: ***Improving the Reporting of Clinical Trials:*** Pharmacy 1 contact hour or .1 CEUs, UAN: 0286-0000-18-025-L04-P

Session 6 Track 1: ***Strategic Deployment of MI "Troops" and Capitalizing on New Technologies for MI Collaborations:*** Pharmacy 1 contact hour or .1 CEUs, UAN: 0286-0000-18-026-L04-P

Session 6 Track 2: ***Alpha and Alphabet: Statisticians and Medical Writers Working Together:*** Pharmacy 1 contact hour or .1 CEUs, UAN: 0286-0000-18-027-L04-P

Session 6 Track 3: ***Fishing for Insights and Extending the Engagement Beyond the Congress:*** Pharmacy 1 contact hour or .1 CEUs, UAN: 0286-0000-18-028-L04-P

Session 7 Track 1A: ***One Medical Voice: Ensuring Consistent, Quality Medical Information Responses Globally:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-029-L04-P

Session 7 Track 1B: ***The Art and Science of Medical Information Contact Center Staffing:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-030-L04-P

Session 7 Track 2: ***Contemplate Your Template: New or Used Options for Protocol Development:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-031-L04-P

Session 7 Track 3: ***Policy Updates: The Evolution of Customer-Facing Medical Roles:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-032-L04-P

Session 8 Track 1: ***Gold! Gold! Gold from Medical Information!:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-033-L04-P

Session 8 Track 2A: ***Interstellar: Crossing the Galaxy Between Pharma and Medical Devices/Companion Diagnostics:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-034-L04-P; IACET .15 CEUs

Session 8 Track 2B: ***Brave New World: Planning for Global Submissions in a Post-Disclosure World:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-035-L04-P

Session 8 Track 3: ***Best Practices for Capturing Key Performance Indicators (KPIs) and Metrics for MSLs:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-036-L04-P

Session 9 Track 1: ***Mixology: Headaches and Hangover Cures:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-037-L04-P

Session 9 Track 2A: ***Scientific Communication Strategy:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-038-L04-P

Session 9 Track 3: ***Are You Prepared to Ride the Tsunami of Change in Medicine or Will You Drown?:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-039-L04-P

Session 10 Track 1: ***Podium Pearls:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-040-L04-P

Session 10 Track 3: ***The Strategic MSL – Applying Business Acumen:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-041-L04-P

Session 11 Track 1: ***Global Warming: Conserve Energy and Unify Partners:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-042-L04-P

Session 11 Track 2A: ***Understanding Patient-Reported Outcomes (PROs) in Clinical Trials: The Value of Patient Experience:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-043-L04-P

Session 11 Track 2B: ***Personalized Medicine: Gene Therapy:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-044-L04-P

Session 11 Track 3: ***MSL Training – All Things Considered:*** Pharmacy 1.5 contact hours or .15 CEUs, UAN: 0286-0000-18-045-L04-P

Sessions not available for Pharmacy Credit:
Short Course 3, Community Round Table, DIA Mobile App Tutorial, Welcoming Remarks, Session 1, Session 2 Track 2B, Session 4, Session 5, Fellow and Resident Professional Development Session, Session 9 Track 2B, Poster Reception, Session 10 Track 2, To Thine Own Self be True

8:00AM-5:00PM

Medical Communications Primer Registration

8:30AM-5:00PM

This course requires an additional registration fee

Medical Communications Primer: The Fundamentals of Medical Communications

Lead Instructor

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

Co-Instructors

Shelby Biagi, PharmD
Scientific Engagement and Communication Lead
UCB, Inc.

Jackie Byun, PharmD
Manager, Medical Information Services
Sanofi

Payal Desai, PharmD
Associate Director, Medical Information
Janssen Scientific Affairs, LLC

Sabrina Lo, PharmD
Senior Scientist, Managed Care Medical Communications
Genentech, a Member of the Roche Group

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

Ankur Shah, PharmD
Director, US Medical Information
Incyte Corporation

Ellen Whipple, Pharm, PharmD
Director, Medical Communications
Med Communications, Inc.

Healthcare professionals and patients look to medical communication and medical information professionals to provide essential, accurate, and unbiased drug information, therefore making medical communications an integral part of the healthcare industry. Because we work in the second most regulated industry, the pharmacy professionals who provide these services need to have a comprehensive understanding of not only the medical content, but also the regulatory and compliance environment which directly affects their daily activities.

This workshop will address many of the common responsibilities of medical communications staff and dig deeper into challenging aspects of each role. This activity is specifically designed to meet the needs of individuals new to biopharmaceutical industry-based medical communications. Many times, their understanding is limited to only their own company's SOPs and "way of doing things." In this activity, you will learn and discuss important skill sets that provide value to both internal and external customers and compare these across companies. These include activities such as identifying the critical steps that a medical communications professional should take when receiving an inquiry, evaluating the sources of information/data, and the importance of fair balance and documenting responses. Topics will also include important elements of writing a standard response letter (formulary dossier communications), promotional review committee best practices, and activities at scientific congresses. Role playing and mock examples will be used to re-enforce principles that emphasize the importance of our role to the industry and to the customers we serve.

You will be presented with real-life scenarios that represent challenges that are common to our roles; groups will be asked to discuss and share their responses to the situations. You will gain a better understanding of best practices within your job function and a broader awareness of the regulatory environment. You will also learn how to work better as part of interdisciplinary teams, practice evidence-based medicine evaluation, and effectively use technology.

At the conclusion of the primer, participants should be able to:

- Describe how the regulatory environment influences medical communications practice
- Identify critical steps 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

DAY ONE | MONDAY, MARCH 19

8:00-9:00AM

Short Course Registration

8:00-8:30AM

Networking Breakfast for Short Course Attendees

8:30AM-12:00PM

Short Courses require an additional registration fee

Short Course 1

Medical Communications: Compliance in 2018

Co-Instructors

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

Mark DeWyngaert, PhD
Managing Director, Life Sciences
Deloitte & Touche, LLP

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 short course 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 course with opportunity for discussion and questions.

At the conclusion of the short course, participants should be able to:

- Discuss compliance hot topics in medical communications such as medical inquiry documentation; response development, review, and dissemination; 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 communication

Short Course 2

Advertising, Promotion, and Scientific Content Review Process

Instructor

Kristi Sanford, JD
Head, US Medical Operations
UCB, Inc.

This course will discuss the basics of advertising and promotion regulation (including scientific content) and then explore how to create an effective and agile system (people, process, technology, and training) to support content development, review, and management. We'll examine how to use risk and brand maturity assessments to reduce review complexity and streamline processes for time sensitive materials.

At the conclusion of the short course, participants should be able to:

- Review the current and evolving regulatory landscape
- Discuss how content review is a integrated system from ideation to content expiration
- Describe how each system element (training, people, process, technology) must work as a whole in an agile and continually improving structure and explore best practices for each
- Discuss how to easily incorporate risk assessments into review processes

Short Course 3

Wearing Multiple Hats with Style: How to Effectively Manage Your Medical Writing Projects

Instructor

Eileen Girten, MS
Principal Medical Writer
PRA Health Sciences

An effective medical writer needs to be skilled in negotiations, collaborations, time management, team building, setting goals, interpersonal skills, and accepting criticism. However, such skills may be overlooked at the expense of focusing on the document types and therapeutic areas. Therefore, it is important to consider and develop such skills to help produce quality deliverables on time and cultivate client-customer relationships. This workshop will incorporate the DIA Medical Writing Competency model and include breakout sessions to brainstorm and discuss approaches to the writing project lifecycle. This workshop is appropriate for medical writers or other individuals who wish to further develop their project management skills.

At the conclusion of the short course, participants should be able to:

- Summarize why project management skills are important for medical communicators
- Identify resources and skills that are helpful for delivering projects for all stakeholders involved
- Examine best practices for managing tasks throughout the project's lifecycle
- Apply techniques for successfully launching, managing, and completing projects

DAY ONE | MONDAY, MARCH 19

10:00AM-12:00PM

MSL Community Round Table

Are you seeking an opportunity to connect with Medical Science Liaisons (MSLs) colleagues? This NEW addition to the agenda will provide you the opportunity to join your MSL colleagues from across the industry for interactive round table discussions with the leaders in our MSL Community. Topics to be discussed will include MSL career paths, evaluating the value of the MSL team to the organization, capturing clinical/scientific insights, and considerations for MSL on-boarding and training. This MSL Community discussion is open to everyone interested in learning and sharing best practices regarding the MSL role.

11:00AM-5:05PM

Forum Registration

12:40-1:00PM

DIA Mobile App Tutorial

1:00-1:30PM

Welcoming Remarks

Sudip Parikh, PhD
Senior Vice President and Manageing Director, Americas
DIA

Medical Writing Track Co-Chair
Eileen Girten, MS
Principal Medical Writer
PRA Health Sciences

Medical Science Liaisons Track Co-Chair
Robin Winter-Sperry, MD
Head, Global Field Based Medical Excellence & Insights
Sanofi Genzyme

Medical Communications Track Co-Chair
David Bowers, PharmD
Director, Professional Contact Center
PPD

1:30-2:30PM

Session 1

Keynote Address: Future Capability and the World of Tomorrow

Keynote Speaker
Paul Grant
Healthcare Engagement Strategist

In the near future, continuous and rapid technological advancements will enhance and challenge our current way of working. How do we reliably plan for the capability we will need as individuals and organizations, to adapt for success in this changing world? What are the core tenets of a data-driven world that will help us flourish in future medical affairs and scientific communications?

2:30-3:00PM

Refreshments and Networking Break in the Exhibit Hall

3:00-4:00PM

Session 2

Breakout Sessions

TRACK 1

I Don't Need a Trophy, Grandpa! Rethinking the Myths of the Generation Gaps

Session Chair
Peter Baumeister, PhD
Senior Manager, Global Scientific Communications
Amgen, Inc.

Gain an overview of the generational differences present in the workplace and how each one is perceived and compare it to empirical evidence. This session will also cover what really motivates each generation in the workplace and present a model for how to bridge the gaps. You will have an opportunity to participate and have fun with this often-discussed topic.

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

- Define the generations present in the current workplace
- Identify the formative events and challenges associated with each generation
- Evaluate the numbers and predictions for each generation
- Recognize the factors that motivate each generation
- Develop a framework for creating and participating in a highly rewarding, trans-generational work environment

Peter Baumeister, PhD
Senior Manager, Global Scientific Communications
Amgen, Inc.

Amber Daughtery, MBA
Senior Training Manager, Global Learning and Performance – R&D
Amgen, Inc.

TRACK 2A

Medical Writing: Are You Calling Me Transparent? Insights into Clinical Trial Transparency: Layperson Summaries and the Plain Language Initiative

Session Chair
David Meats
Global Scientific and Regulatory Documentation
Syneos Health

Discuss the continuously expanding approach to transparency in pharmaceutical development. We will discuss the most current breaking developments in the Clinical Trial Transparency space. In addition, we will cover tips for the development of trial summaries using plain language and what patients and health care providers want from these summaries.

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

- Understand what returning results of clinical trials means to patients and health care providers
- Discuss the current regulation requirements of clinical trial summaries
- Describe the real-world MRCT experiences for the creation and maintenance of clinical trial summaries and returning results to patients and public
- Describe the evolution of patient and public power as stakeholders, and the need to gain the public's trust
- Understand what the future challenges are, and how plan language summaries should be made available

Deborah Collyar
President
Patient Advocates In Research (PAIR)

Theresa Shalaby, MSN, RN, CCRP
Senior Regulatory Writer
Synchrogenix; A Certara Company

TRACK 2B

The International Committee of Medical Journal Editors' Authorship and Data Sharing Statement Requirements: What and Why

Session Chair
Eileen Girten, MS
Principal Medical Writer
PRA Health Sciences

Thousands of medical journals indicate that they follow the ICMJE's recommendations for the conduct, reporting, editing, and publication of scholarly work in Medical Journals. These include criteria for authorship as well as newly announced requirements for the inclusion of data-sharing statements in manuscripts describing the results of clinical trials. This session will analyze the rationale for these requirements and how to meet them.

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

- Describe the ICMJE requirements for manuscript authorship and for data-sharing statements
- Explain the reasons why these requirements have been adopted
- Apply authorship and data sharing statement requirements to plan studies and publications

Darren Taichman
Executive Deputy Editor
Annals of Internal Medicine

TRACK 3

Seeking Optimization of the MSL Role in an Industry of Disruptive Forces

Session Chair
J. Lynn Bass, PharmD
Director, Medical Science Liaisons, Americas
Santen, Inc.

This session will peek into the variety of technological advances and scientific innovation to review how these contribute to the positive disruption currently underway in the MSL role.

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

- Review the benefits and risks of disruptive forces within the current pharmaceutical environment
- Summarize meaningful examples of how these disruptive forces are impacting the MSL role
- Detect how the future of the MSL role will be positively affected

J. Lynn Bass, PharmD
Director, Medical Science Liaisons, Americas
Santen, Inc.

Lori Mouser, PharmD
Global head, Medical Science Liaison
F. Hoffmann-La Roche, Ltd.

DAY ONE | MONDAY, MARCH 19

4:05-5:05PM

Session 3
Breakout Sessions

TRACK 1/3
It Takes a Village: Collaboration for One Medical Voice

Session Co-Chairs
Rebecca Falcone, PharmD
Senior Manager, US Medical Information Services
Sanofi

Jim Wilkinson, PhD
Executive Director, Global Medical Affairs
Amgen, Inc.

This session will highlight the value that collaboration can bring between Medical Information, Field Medical (MSLs), Health Outcomes, and Scientific Communications to provide one medical voice. The importance of collaborations between internal stakeholders to align on external engagements and deliverables will be discussed.

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

- Explain the necessary collaborations between HEOR and Medical Affairs to provide a value story for Payers
- Describe the value of a highly-collaborative global team including MSLs, Medical Information, and Scientific Communications for the creation of MSL strategy, tactical plans, training plans, and medical resources
- Identify best practices for creating a collaborative team

Donna Booth, PharmD
Director, Medical Information, Neurology and Psychiatry
GlaxoSmithKline

Jennifer Slade, PharmD
Senior Director, Global Lead MSLs
Novartis Pharmaceuticals

TRACK 2A
The Trouble with IgG: Immunogenicity in the Clinical Development of Biologics

Session Chair
Darryl L'Heureux, MsC, PhD, Mpharm
Medical Writing Manager
Bristol-Myers Squibb

While proteins have a dynamic role in the body (catalyzing biochemical reactions, forming receptors and channels in membranes, providing intracellular/extracellular scaffolding, and transporting molecules), protein-based therapeutics have a tendency to trigger unwanted immune responses against themselves. This session will discuss immunogenicity, the safety and efficacy implications in clinical development, and the communication of risk to stakeholders.

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

- Identify the use of therapeutic proteins in treatment, immunogenicity response, and regulatory requirements
- Assess risk-based approaches for clinical development and communication to Health Authorities
- Communicate clinical relevance and significance of immunogenicity to both patients and clinicians

Darryl L'Heureux, MsC, PhD, Mpharm
Medical Writing Manager
Bristol-Myers Squibb

Lisa Iacono Sheehan, PharmD
Principal Documentation Lead
Bristol-Myers Squibb

TRACK 2B
Improving the Reporting of Clinical Trials

Session Chair
Jennie Jacobson, PhD
Lead Medical Writer
Fishawack Communications

Clinical trial data presentation in the medical literature is under increasing scrutiny. It must be accurate, balanced, and comprehensive, but also concise. Publications must adhere to a variety of guidelines, including the ICMJE recommendations and GPP3. The panel will lead a group discussion of challenges and solutions for improving reporting of clinical trials.

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

- Assemble authoring teams to improve presentation of clinical trial data by using the ICMJE recommendations and GPP3
- Assess effectiveness of data quality reviews
- Implement best practices shared by the panel and by audience members

Darren Taichman, MD, PhD
Executive Deputy Editor
Annals of Internal Medicine

David Clemow, PhD
Advisor Scientific Communications Strategy, Neuroscience
Eli Lilly and Company

Jennie Jacobson, PhD
Lead Medical Writer
Fishawack Communications

5:05-6:30PM

Networking Reception

DAY TWO | TUESDAY, MARCH 20

6:00-7:00AM

DIAfit: Good Morning Sunrise Stretch with Light Yoga

Instructor
Tracy Meats
Certified Personal Trainer

Start your day with a rejuvenating class to stretch the body and practice mindful breathing.

7:00AM-5:30PM

Registration

7:00-8:00AM

Networking Breakfast in the Exhibit Hall

8:00-9:00AM

Session 4
Keynote Address: Medical Affairs: Where Are We Today and Where Will We be in the Future?

Pam Cyrus, MD
Vice President and Head of Medical Governance, Pharmaceuticals
Bayer

This talk will review trends in medical affairs with a focus on pharmaceutical industry reputation, interaction with thought leaders, patient centricity and big data (real world evidence). It will also suggest the focus for the next several years.

9:00-9:30AM

Session 5
DIA Communities Update

J. Lynn Bass, PharmD
Director, Medical Science Liaisons
Santen, Inc.

David Clemow, PhD
Advisor Scientific Communications Strategy, Neuroscience
Eli Lilly and Company

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

9:30-10:00AM

Refreshments and Networking Break in the Exhibit Hall

DAY TWO | TUESDAY, MARCH 20

10:00-11:00AM

Session 6
Breakout Sessions

TRACK 1
Strategic Deployment of MI "Troops" and Capitalizing on New Technologies for MI Collaborations

Session Chair
Christi Marsh, PharmD
Director, Medical Affairs, Medical Information and Scientific Communication
HEMA Biologics, LLC

We invite you to come learn about FRESH and DIFFERENT ways two experienced medical information (MI) professionals are working in new ways. First from one member who is embedding their MI team members across functions within their organization to deliver value and "delight customers" based on insights. Second, we change gears to hear how an UBER*-like platform can be used to collaborate across drug information professionals to deliver value to customers.

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

- Describe an example approach to aligning medical info teams with corporate strategy
- Demonstrate the differences between insight, observation, and reporting on data and analytics
- Identify what skills MI teams need to find insights
- Establish challenges regarding evidence-based medicine
- Discuss differences and similarities regarding the evolution of the non-industry drug information center

The Secret Sauce of Med Info: Strategic Ingredients for Your Embedding MI Teams and Insights

Michelle Clausen, PharmD
Senior Director, Chief Medical Office-Strategy and Innovation Team
Pfizer, Inc

How are Uber and Medical Information Related? InpharmDTM Using Technologies to Harness Medical Information Expertise Collaboratively

Ashish Advani, PharmD
Clinical Associate Professor, Director of Drug Information Service
Mercer University College of Pharmacy

TRACK 2
Alpha and Alphabet: Statisticians and Medical Writers Working Together

Session Chair
Stephanie Byrde, MS, BSN, RN
Manager, Clinical Pharmacology Scientific Communications
Eli Lilly and Company

Hear from a panel of experienced statisticians: their war stories; insights into what they value in a medical writer; the good, the bad, and the ugly about working with numbers and translating them into the written word; and what statisticians wish every medical writer understood about how to effectively work with statisticians.

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

- Identify key ways in which writers and statisticians can effectively partner
- Recognize and potentially eradicate misunderstandings and miscommunications between the statistics and medical writing functions

Paul Berg, MS
Principal Research Scientist
Eli Lilly and Company

Jenna Elder, PhD
Chief Scientific Officer
PharPoint Research, Inc.

TRACK 3
Fishing for Insights and Extending the Engagement Beyond the Congress

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

We will be covering the importance of uncovering insights from customers during various types of engagements at conferences and how to extend our reach beyond the confines of the forum. We will share novel ideas on how to extend the engagement with key customers so we can ensure we are connected over time to strengthen our relationships. The session will offer different perspectives from Pharma, Professional Societies, and Medical Device. There will be ample time to interact with the audience in sharing best practices and ideas on this topic.

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

- Identify the value of uncovering insights from our key customers
- Build strategies and tactics to extend the engagement beyond the conference venue
- Recognize different perspectives from Professional Organizations, Pharma, and Med Device on this topic

Gathering Insights and Extending Engagement with Customers - Med Device Perspective

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

Gathering Insights and Extending Engagement with Customers - DIA Perspective

Raleigh Malik, PhD
Senior Scientific Liaison
DIA

Gathering Insights and Extending Engagement with Customers - Pharma Perspective

J. Lynn Bass, PharmD
Director, Medical Science Liaisons, Americas
Santen, Inc.

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DAY TWO | TUESDAY, MARCH 20

11:05AM-12:35PM

Session 7
Breakout Sessions

TRACK 1A
One Medical Voice: Ensuring Consistent, Quality Medical Information Responses Globally

Session Chair
Jeff Mathews, MPH
Director, Medical Communications
Gilead Sciences

Discuss ways that MI departments across three pharmaceutical companies are addressing this challenge with a comprehensive content strategy and utilizing technology to create "One Source of the Truth" for their content. The solution is only part of the story, though. This session will also uncover each company's journey, from proof-of-concept through implementation, and discuss the best practices and lessons learned that was acquired along the way.

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

- Describe the importance of developing a MI content strategy and identify the resources necessary to deliver
- Explain how to manage staff and key stakeholders through change
- Cite examples on how to reuse the source of truth
- Identify and compare different technology solutions to develop and share content globally

Content is Like Water: Let it Flow

Cecil Lee, RPh
Knowledge Management Advisor, Global Customer Information
Eli Lilly and Company

Implementation of a Global Content Management System to Pave the Road for a Successful Global Content Strategy

Meera Patel, PharmD
Associate Director, Medical Information
Janssen Pharmaceuticals, Inc.

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

Global Content Management: A Neuroscience and Pain Story Through Word Clouds, Digital, and Non-Digital Interactions!

Rania Gaspo, PhD
Director, Global Therapy Area Lead, External Medical Communications
Pfizer Canada, Inc.

TRACK 1B
The Art and Science of Medical Information Contact Center Staffing

Session Chair
David Bowers, PharmD
Director, Professional Contact Center
PPD

Medical Information contact centers face an array of challenging questions related to staffing, including: Should we staff with nurses, pharmacists, or other staff? How do we build a cost effective model that answers inquiries quickly and effectively with a minimal number of transfers? How do we build a flexible model that can respond to changes in volume and staffing? This will be an interactive session designed to maximize your participation and idea sharing.

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

- Discuss effective staffing models used in the medical information industry
- Recognize key levers that can be adjusted to impact staffing costs of a contact center
- Create strategies to increase flexibility in a contact center

Kathleen Meyer Ritz
Director, Medical Capabilities, Medical Information Contact Centers
Bristol-Myers Squibb

John Warwick, PharmD
Director, Medical Information
Grifols, Inc.

TRACK 2
Contemplate Your Template: New or Used Options for Protocol Development

Session Chair
Robin Whitsell
President
Whitsell Innovations, Inc.

This session will introduce the newly-issued TransCelerate Biopharma Common Protocol Template (CPT) and the NIH-FDA template. The speakers will detail the benefits and limitations of these templates, and factors for consideration when using them. In addition, we will host a case-study on creating your own protocol template, ensuring that content requirements are met, and getting endorsement from your study development team.

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

- Discuss the TransCelerate Biopharma Common Protocol Template (CPT) and the NIH-FDA template
- List the components (regulatory requirements and document architecture) of a well-written protocol
- Analyze the factors that influence your selection of a protocol template

TK Booker Porter, PhD
Senior Manager Gobal Regulatory Writing, Protocol Authoring Lead
Amgen, Inc.

Robin Whitsell
President
Whitsell Innovations, Inc.

Amy Holbrook, MS
Director of Medical Writing
Keryz Biopharmaceuticals

TRACK 3
Policy Updates: The Evolution of Customer-Facing Medical Roles

Session Co-Chairs
Kathryn Bucci, PharmD
Senior Director, Medical Governance Lead
Pfizer, Inc

Ed Cunningham, PharmD
Senior Director, Neurology Medical Science Liaison Lead
Sunovion Pharmaceuticals, Inc.

As the demand for medical information continues to increase, this session will discuss how the interpretation and application of new FDA rules are expected to further evolve the role of customer-facing medical teams.

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

- Prepare an overview of recent court rulings regarding manufacturers' ability to communicate
- Describe the current challenges in FDA rules and how they influence pharma companies
- Explain how companies are interpreting and applying the rules to customer-facing medical
- Describe what the industry can do to advance capabilities and move field-based medical roles forward

Michelle Drozd
Deputy Vice President, Policy and Research
Pharmaceutical Research and Manufacturers of America (PhRMA)

Michael Labson
Partner
Covington & Burling, LLP

12:35-2:00PM

Networking Luncheon in the Exhibit Hall

DAY TWO | TUESDAY, MARCH 20

12:35-2:00PM

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

Fellow and Resident Professional Development Session: Personality Types and Leadership Characteristics

Session Co-Chairs

Alicia Cadogan
Director, Oncology Medical Information
Pfizer, Inc

Evelyn Hermes-DeSantis, PharmD
Director, Drug Information Service, Clinical Professor, Ernest Mario School of Pharmacy
Rutgers, The State University of New Jersey

In today's workplace we find many different personality types. However, sometimes it may feel that we are expected to "fit the mold" when it comes to workplace behavior. Our actions may be driven by company values and corporate culture, leaving one to question what opportunities there are for individuality. Although it may be true that certain personality types are better fit for particular roles than others, it should not prohibit the diversity that is needed for a successful team.

In this session, designed for Fellows, Residents, and their Preceptors, we will discuss a variety of personality types and challenge some preconceived thoughts of where they may best fit in our career arena. We will explore our own personality types and challenge how they align with our career a aspirations. Finally, we will discuss how leadership characteristics are not only for those who lead large groups or manage teams, but are necessary in everyone who contribute to the common goals of the organization.

At the conclusion of the short course, participants should be able to:

- Summarize why project management skills are important for medical communicators
- Identify resources and skills that are helpful for delivering projects for all stakeholders involved
- Examine best practices for managing tasks throughout the project's lifecycle
- Apply techniques for successfully launching, managing, and completing projects

2:00-3:30PM

Session 8

Breakout Sessions

TRACK 1

Gold! Gold! Gold from Medical Information!

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

Sharing the metrics is easy, but what do the metrics mean without context? What are some key performance indicators that can showcase the value of MI? What are insights, how are these identified, and who should be the audience of these? During this session the faculty will share their views and experiences on demonstrating the value of medical information.

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

- Define insights and key performance indicators (KPIs)
- Identify insights from medical information request metrics and customer feedback
- Identify key internal stakeholders with whom to share various metrics, insights, and KPI
- Integrate value of Medical Information through customer insights and KPIs

Representative Invited
Vertex Pharmaceuticals, Inc.

Joyce Fairclough, PharmD
Senior Manager, Medical Information Services
Sanofi

Kim Lee, PharmD
Director, Multiple Myeloma Team Lead, Global Medical Information
Celgene

TRACK 2A

Interstellar: Crossing the Galaxy Between Pharma and Medical Devices/Companion Diagnostics

Session Chair
Robin Whitsell
President
Whitsell Innovations, Inc.

Gain an overview of the regulations surrounding medical devices and companion diagnostics, steps for bringing medical devices to the market, and practical knowledge in writing the associated documents. Speakers will introduce these regulations in the context of similar pharmaceutical regulations. They will detail the required documentation associated with Pre-Market Approval (PMA) and Pre-Market Notification (510(k)s) for medical devices and companion diagnostics. The speakers will also provide an overview of investigational device exemptions (IDE) and a case-study of an IDE filing.

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

- Compare device classifications
- Discuss regulatory documents associated with medical devices and companion diagnostics
- Organize the associated subject matter within a medical device or companion diagnostics submission

Navigating Medical Device Regulations - A Guide to the Galaxy

Robin Whitsell
President
Whitsell Innovations, Inc.

IVD Companion Diagnostics – A "Sirius"ly Bright Star

Cyndi Carr, PhD
Senior Manager, Medical Writing
Ventana Medical Systems, Inc.,
A Member of the Roche Group

Device Classification and Investigational Device Exemptions - Following the Laws of the Universe

Ryan Hietpas, PhD
Consultant, Global Scientific Communications
Eli Lilly and Company

TRACK 2B

Brave New World: Planning for Global Submissions in a Post-Disclosure World

Session Chair
Robert Paarlberg, MS
Principal
Paarlberg & Associates, LLC

This session will be a panel discussion on hot topics in clinical trial disclosure/transparency and how they are impacting company processes and strategies as well as impact on the orphan/rare disease community. Topics to be addressed include: how disclosure requirements are impacting clinical development strategies; commercial confidential information; individual personal data; potential legal implications to patients and companies; and impact on the orphan/rare disease community.

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

- Identify key areas within a company impacted by the ClinicalTrials.gov Final Rule and EMA Policy 0070
- Describe how disclosure/transparency requirements are impacting approaches to protocol and clinical study report writing
- Discuss potential legal implications that disclosure is having in the US and EU
- Describe how disclosure/transparency is impacting orphan/rare disease community

Deborah Collyar
President
Patient Advocates in Research

Mark Barnes, JD
Partner
Ropes & Gray, LLP

Kelly Vaillant
President
Vaillant Consulting, LLC

Rebecca Williams, PharmD, MPH
Assistant Director, ClinicalTrials.gov, NCBI
National Library of Medicine, NIH

TRACK 3

Best Practices for Capturing Key Performance Indicators (KPIs) and Metrics for MSLs

Session Chair
David Price, PhD
Field Medical Strategy and Capabilities Consultant
Eli Lilly and Company

This session will start with a brief overview aimed at providing participants a basic framework on key performance indicators (KPIs) and metrics across the spectrum of Medical Science Liaison (MSL) activities and responsibilities that represent the overall value MSLs bring to customers. Topics include KPIs and metrics related to core aspects of the MSL role, product lifecycle, and MSL program size and longevity. The session will continue through a panelist-led discussion involving questions and participant responses through the DIA App. Panelists will help facilitate and guide the discussion while bridging concepts such as best practices for capturing and communicating KPIs/metrics and aligning MSL KPIs/metrics to medical affairs strategy and objectives.

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

- Review the variety of KPIs and metrics associated with the MSL role
- Discuss how KPIs and metrics differ based on MSL support across the product lifecycle and on the size and longevity of a MSL program
- Recognize the significance of KPIs and metrics that ladder up to medical affairs strategy
- Discuss how to collate the overall value message for MSLs that can be shared with key stakeholders

David Price, PhD
Field Medical Strategy and Capabilities Consultant
Eli Lilly and Company

Ed Cunningham, PharmD
Senior Director, Neurology Medical Science Liaison Lead
Sunovion Pharmaceuticals, Inc.

3:30-4:00PM

Refreshments and Networking Break in the Exhibit Hall

DAY TWO | TUESDAY, MARCH 20

4:00-5:30PM

Session 9
Breakout Sessions

TRACK 1
Mixology: Headaches and Cures for Medical Information Challenges

Session Chair
Maureen Feeney, MBA, PharmD, RPh
Head Global Medical Information
Shire Pharmaceuticals

Medical Information and Communication roles continue to evolve. At the same time, companies face challenges in determining the appropriate level of service in the face of constrained resources. This session will explore the everyday challenges facing medical communication and information professionals and provide practical examples to current challenges.

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

- Develop solutions to manage support across the product lifecycle
- Develop impactful solution and tips to improve customer service
- Apply practical examples to enable more efficient use of existing resources

When to Cut the Cord? Managing Medical Information Support Across Product Lifecycles

Kelly Pincus, PharmD
Director, Medical Information
Cardiovascular, Metabolic, Immunology, Critical Care Handling
Safety Inquires
GlaxoSmithKline

Tackling Tough Questions – Answering Adverse Event Questions

Hiren Patel, PharmD
Director, Medical Information
Sunovion Pharmaceuticals, Inc.

Road Trip! Planning for a Successful Congress

Tanya Basu
Director, Medical Communications
Shire Pharmaceuticals

TRACK 2A
Scientific Communication Strategy

Session Chair
David Clemow, PhD
Advisor, Scientific Communications Information Strategy
Eli Lilly and Company

This session will provide insights and best practices for creating and organizing consistent messaging across regulatory submission and publication documents, with a focus on mapping clinical trial data outputs to key messages and downstream disclosure documents. The role of scientific communications (medical writing) in medical key message development, knowledge management, and dissemination will be discussed, with suggestions for process integration with other medical functions to aid with synergy.

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

- Apply and map clinical trial data outputs and related key messages from target profile through regulatory submission documents and publication disclosures
- Define the role of scientific communications in medical key message development, knowledge management, and dissemination related to cross-functional partners
- Explain the involvement of the medical writer role in scientific communications strategy

Submission Communication Strategy Document to Drive Consistent Messaging in CTD Dossiers

David Brown, MA
Therapy Area Leader, Medical Communications Science
AstraZeneca

Medical and Scientific Key Message Development, Knowledge Management, and Dissemination

David Clemow, PhD
Advisor, Scientific Communications Information Strategy
Eli Lilly and Company

Medical Writing Leadership in Scientific Communications Strategy

Michael Bourque, MS
Associate Director, Principal Regulatory Writer
Synchrogenix, a Certara Company

TRACK 2B
Secrets of the Editorial Office

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

Why do editorial offices insist on things being *that* way and why do different journals ask for things in quite different styles? How can you make your manuscript better? How can you ensure your article will be reviewed? The editorial office is actually there to help authors (though it might not always seem like it!). Join us and find out what happens after your manuscript is submitted to a research journal.

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

- Describe the process for review of a manuscript
- Evaluate the editor's role in the review process
- Assess the need to adhere to submission requirements

Jan Higgins, PhD
Managing Editor, Genetics in Medicine
American College of Medical Genetics and Genomics

Elizabeth Blalock, MA
Managing Editor, Journal of Investigative Dermatology
Society for Investigative Dermatology

TRACK 3
Are You Prepared to Ride the Tsunami of Change in Medicine or Will You Drown?

Session Chair
Robin Winter-Sperry, MD
Head, Global Field Based Medical Excellence & Insights
Sanofi Genzyme

Be disruptive, be provocative but be educated. This session will focus on the changes occurring in medicine from multiple perspectives. Leaders from medical media and digital medicine will provide a highly interactive and engaging session on ways to adapt field based medical teams to meet changing KOL needs.

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

- Recognize areas that are emerging in the field of digital medicine and trends in the industry
- Identify methods by which MSLs and their Medical Affairs colleagues are evolving and adapting to the changing medical environment both locally and globally

Kirk Shepard, MD
Senior Vice President, Head of Global Medical Affairs Oncology
Eisai, Inc.

Taren Grom
Editor
PharmaVoice

Jonathan Weiner, PharmD, MBA
Director of Innovation in Scientific Exchange
Sanofi

5:30-6:30PM

Resident and Fellow Poster Reception and Networking

7:00-9:00PM

Dinner on the Town

Traveling on your own or looking to connect with fellow attendees? Visit the DIA Registration Desk to link up for dinner! Sign-up sheets will be provided for various local restaurants. Cost of dinner is the responsibility of the individual attendee.

DAY THREE | WEDNESDAY, MARCH 21

6:00-7:00AM

DIAfit: PIYO Mix (Pilates/Yoga)

Instructor
Tracy Meats
Certified Personal Trainer

Enjoy a class that will awaken your core muscles and elongate your posture with fundamental Pilates exercise and basic yoga poses.

7:00AM-2:45PM

Registration

7:00-8:00AM

Networking Breakfast in the Exhibit Hall

8:00-9:30AM

Session 10
Breakout Sessions

TRACK 1
Podium Pearls

Session Chair
Poonam Bordoloi, PharmD
I&I Lead, Research and Early Pipeline Medical Communications
Celgene Corporation

Medical communications professionals will be presenting their successes, challenges, and "pearls of wisdom" on various topics through podium presentations.

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 and new tools for engagement, collaborating across medical affairs, contact center and actionable insights, EU collaborative pharma portal(s), proactive HCP Whatsapp Broadcast initiative launched outside the US, and the use of readability formulas within medical writing for clinical trial summaries

Medical Information (MI) Social Media Activities in Canada: Impact of Post Type on Engagement Rate

Rania Gaspo, PhD
Director, Global Therapy Area Lead, External Medical Communications
Pfizer, Inc., Canada

How Successful Medical Affairs Teams Make the Most of Their Real-World Data to Benefit Patients

Isabelle Widmer, MD
Medical Affairs Consultant
Elytra GmbH

Analysis of Medical Information Contact Center Data: Business Insights and Opportunities

Nicholas Liu, PharmD
Medical Information Associate
Lundbeck

A MILEstone - Creating the European Industry Association for Medical Information

Aurelio Benassini, MD
Executive Director Global Medical Information
Merck & Co.

MI-ND Medical Information-News Delivery: Providing Customers with Medical Information "Proactively" by Using WhatsBroadcast

Marie-Luise Helmich, PhD
Head of Europe Medical Information
Sanofi, Germany

Clinical Trial Summaries: Readability to Effectively Inform Patients

Autumn Watson
Biomedical Writing Student
University of The Sciences In Philadelphia

TRACK 2
Managing Up, Down, and Across: Effective Medical Writing Management Strategies and Business Practices

Session Co-Chairs
Michael Church, MA
Senior Director, Medical Writing
Syneos Health

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

All medical writing managers face a common set of problems. Forecasting work for staff accurately can be challenging as timelines shift and clinical plans change; teammates may struggle to work well together; experience levels across both internal staff and external contractors may vary greatly; and developing junior-level staff may become an afterthought in the midst of the chaos of just getting work done. This session will tackle the issues of running an effective medical writing business through a panel discussion with leaders and managers from a variety of backgrounds and companies and will provide a forum for associates and managers in medical writing to ask questions and exchange information to improve business practices.

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

- Develop effective resourcing strategies for medical writing projects
- Discuss the complications of forecasting medical writing
- Operate more effectively with direct reports, peers, contract staff, and management
- Implement peer-mentoring strategies to develop staff
- Recognize risks within a medical writing business and develop mitigation strategies

Cynthia Hooper, MA
Advisor, Biometrics Business Management and Advanced Analytics
Eli Lilly and Company

Carri Taylor, MBA
Associate Director, Medical Writing
inVentive Health

Holly Zoog, PhD, ELS
Executive Director, Medical Writing
Ultragenyx Pharmaceuticals, Inc.

Matthew Robillard, MBA
Senior Director, Regulatory Strategic Writing
AbbVie, Inc.

TRACK 3
The Strategic MSL – Applying Business Acumen

Session Co-Chairs
Kathleen Guindon, MS, PhD, RN
Director, Clinical Science Liaison
Puma Biotechnology

Rebecca Vermeulen, RPh
Head, Customer Strategy Global Medical Affairs
Hoffmann-La Roche, Ltd.

The ability to execute in customer-facing roles is changing. Business acumen is evolving into a core competency. Business acumen involves a keenness and quickness in understanding and dealing with a business situation. As a strategic skill, business acumen helps MSLs to manage their customers' needs in alignment with organization goals. Success requires relationship development with key people in other organizational departments, and understanding their challenges. This leads to understanding their product and disease space more comprehensively. The end result is sound, strategic decision-making with all stakeholders in mind.

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

- Define business acumen and describe the importance of applying it in practice
- Utilize strategies to develop business acumen and support medical strategy
- Recognize what good business acumen looks like when applied in the field, and learn strategies for measuring success

Kathleen Guindon, MS, PhD, RN
Director, Clinical Science Liaison
Puma Biotechnology

Rebecca Vermeulen, RPh
Head, Customer Strategy Global Medical Affairs
Hoffmann-La Roche, Ltd.

9:30-10:30AM

Refreshments and Networking Break in the Exhibit Hall - View Professional Posters

DAY THREE | WEDNESDAY, MARCH 21

10:30AM-12:00PM

Session 11
Breakout Sessions

TRACK 1
Global Warming: Conserve Energy and Unify Partners

Session Chair
Anne Arvizu, PharmD, FASCP, PCC
CEO and Medical Affairs Advisor
RxER Communications

A fresh, tactical, and strategic approach to globalizing your MI Team. From the start up biotech prior to launch, to the global giant going through another re-org and acquiring new therapy areas, or companies. Change is always a factor to juggle in the global world. In the past, globalization sessions have focused on large pharma breakthroughs leaving many companies saying, "well, I'd like to do that in five years" or "that's the goal" if I could get the budget. With the influx of small biotech companies and mid-sized pharma companies, together making up the majority of the industry and the new face of medical information, this year's session focuses on practical takeaways for making a shift and gaining the right partnership and advocacy, no matter the size of the organization.

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

- Identify practical approaches to enable globalization process within an MI team
- Work with partners and stakeholders to rally and ratify your cause
- Select regulatory and compliance tactics to apply to globalizing an MI team

Success at the Core: A Team Approach for Launching Global Medical Information

Heather Sun, PharmD
Director, Global Medical Information
Alnylam Pharmaceuticals, Inc.

Don't Globe it Alone: Expanding Awareness, and Country Capabilities in MI

Tim Fish, DNP, MBA, RN, CENP
Director, Global Medical Information
Sarepta Therapeutics, Inc.

Making Contact: An Instant Globalization Footprint

Michele Simon
Director of Operations
PPD

TRACK 2A
Understanding Patient-Reported Outcomes (PROs) in Clinical Trials: The Value of Patient Experience

Session Chair
Darryl L'Heureux, MsC, PhD, Mpharm
Medical Writing Manager
Bristol-Myers Squibb

This session will provide an introduction to PRO assessment, its role in the context of clinical trials, and emerging issues given evolving regulatory and payer landscapes.

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

- Differentiate PROs from other clinical outcomes and discuss the importance of their assessment
- Identify relevant considerations for collecting and evaluating PRO data
- Understand current issues regarding uses of PRO data for regulatory and payer applications

An Introduction to PRO Assessment

Gregory Maglinte, PhD, PharmD, MPH
WWHEOR Immuno-Oncology Lead
Bristol-Myers Squibb

Current Issues in the Application and Interpretation of PRO Data

Ari Gnanasakthy, MBA, MSc
Principal Scientist, Patient-Centered Outcomes Assessment
RTI Health Solutions

TRACK 2B
Personalized Medicine: Gene Therapy

Session Chair
Eileen Girten, MS
Principal Medical Writer
PRA Health Sciences

You will leave this session with a basic understanding of what gene therapy is, how gene therapy works, and the challenges associated with education and awareness in the gene therapy space.

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

- Differentiate between basic types of gene therapy
- Explain how gene therapy works using simple terms
- Describe the key challenges associated with educating audiences about gene therapy
- Identify key insights regarding the straightforward communication of complex science

AAV Gene Therapies for Rare Disease

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

TRACK 3
MSL Training – All Things Considered

Session Chair
Craig Klinger, RPh
Consultant Field Medical Shared Services – Trainer
Eli Lilly and Company

Rebecca Vermeulen, RPh
Head, Customer Strategy Global Medical Affairs
Hoffmann-La Roche, Ltd.

During this session we will discuss the challenges of centralized versus decentralized training in a global environment and how you manage content across regions. We will address technology and methods of sharing training to meet educational needs of MSLs across the globe. The session is being developed to consist of short introductory presentations to concepts and then a panel discussion with your participation.

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

- Define the needs to appropriately train an adult-based learner to prepare for a MSL role
- Describe centralized verus decentralized MSL on-boarding and training
- Identify technology which can facilitate training in a virtual setting
- Assemble a learning plan to facilitate on-boarding and continue the education of MSLs

Craig Klinger, RPh
Consultant Field Medical Shared Services – Trainer
Eli Lilly and Company

Harry Varav, PharmD
Director Global Learning and Performance R&D
Amgen, Inc.

Randy Miller, PharmD, RPh
National Director, Medical Science Liaisons
Alnylam Pharmaceuticals

12:00-1:30PM

Networking Luncheon and Exhibits - View Professional Posters

1:30-2:45PM

To Thine Own Self be True: How Understanding Who You Are and What You Want Will Help You Build and Market Your Brand

We will show you how understanding your personality will help you make the most of your unique combination of talents to help you achieve career happiness. In our fun, dynamic, and interactive session, short presentations on personality types, presenting yourself, and networking activities, will be interspersed with breakout activities so you can practice and network with other conference goers. You will learn how to effectively communicate your professional background, understand the benefits of building a consistent brand, and discuss strategies for effective networking and the do's and don't of using social media.

Arlene Kray, PhD, PharmD
Associate Director, Medical Writing
PRA Health Sciences

Isabelle Widmer, MD
Medical Affairs Consultant
elytra GmbH, Switzerland

Robin Whitsell
President
Whitsell Innovations, Inc.

At the conclusion of the short course, participants should be able to:

- Implement best practices for networking without fear/apprehension
- Understand the value of a consistent personal brand and how to develop one
- Utilize social media to effectively communicate ones' personal brand

1:30-3:30PM

Career Fair!

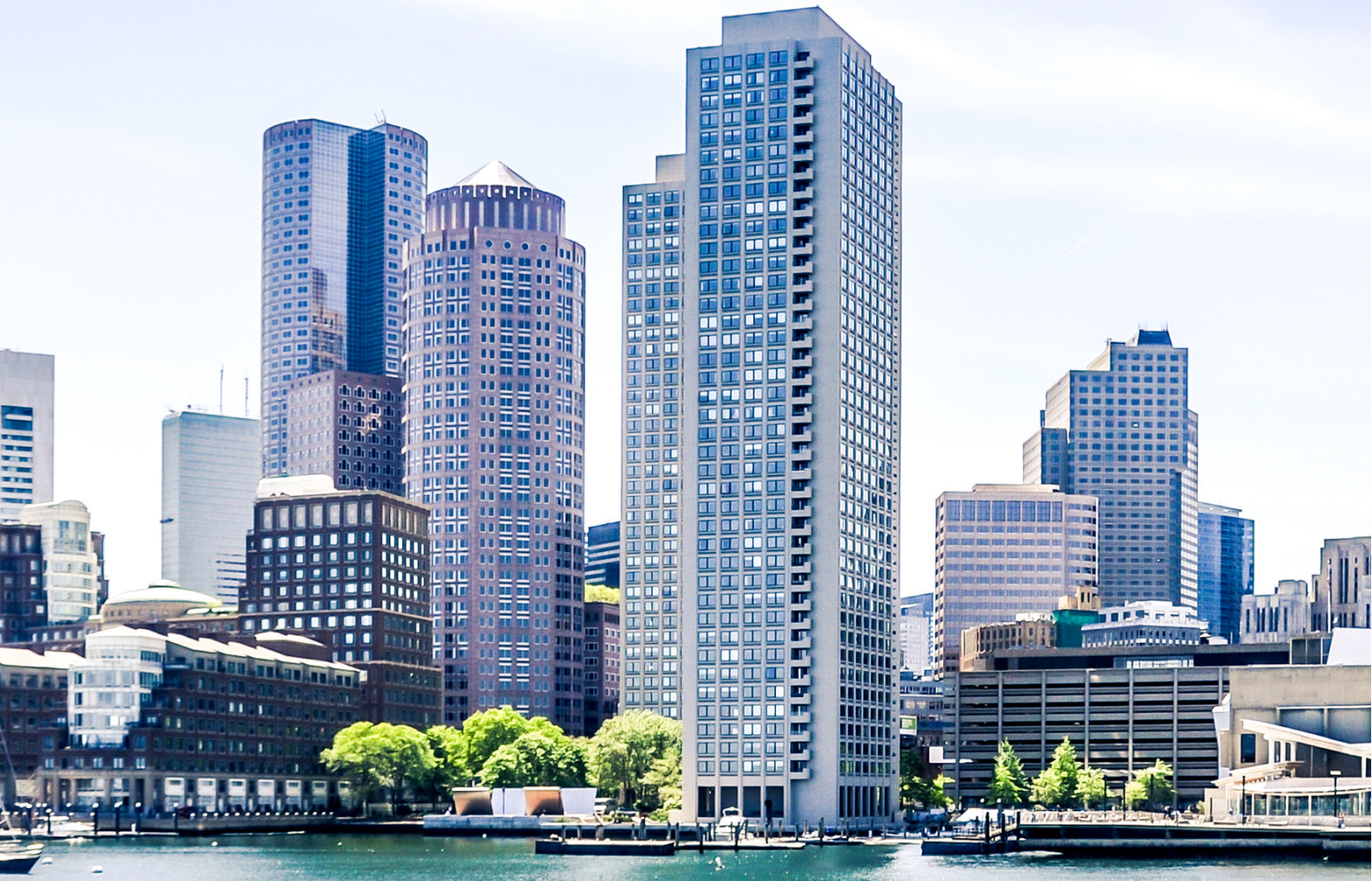
3:30PM

Conference Adjourns

DIA 2018

GLOBAL ANNUAL MEETING

BOSTON | JUNE 24-28



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