

# Medical Affairs and Scientific Communications Forum

Virtual Primer: March 10-11 | Virtual Short Courses: March 16-18  
In-Person and Virtual Forum: March 21-23



## PROGRAM CO-CHAIRS

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Indegene

## Overview

DIA's *Medical Affairs and Scientific Communications Forum* is designed for medical affairs professionals, by medical affairs professionals. This forum provides a comprehensive understanding of the regulatory and compliance environment directly affecting the daily activities of medical affairs and scientific communication professionals. Made up of multiple general and breakout sessions within three tracks covering medical communications, medical writing, and medical science liaisons, you can pick and choose which sessions to attend and create your own unique forum.

## Highlights

- **Three Tracks:** Medical Communications, Medical Writing, and Medical Science Liaisons
- **Virtual Medical Communications Primer:** The Fundamentals of Medical Communications *\*Additional fee required*
- **Three Virtual Half-Day Short Courses** *\*Additional fee required*
- **Cross-functional General Sessions**
- **Poster Presentations highlighting original research from residents and fellows in training, and professionals**
- **Podium Pearl Poster Presentations**
- **Paint and Sip Community Service Event**

## Who Should Attend

Professionals involved in:

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

## PRIMER | THURSDAY, MARCH 10 Sessions are held in ET

**10:00AM-2:30PM ET**      **Virtual Medical Communications Primer: The Fundamentals of Medical Communications – PART 1**  
*\*The Primer requires an additional registration fee. You do not need to be registered for the Forum to attend\**

## PRIMER | FRIDAY, MARCH 11

**10:00AM-2:30PM ET**      **Virtual Medical Communications Primer: The Fundamentals of Medical Communications – PART 2**  
*\*The Primer requires an additional registration fee. You do not need to be registered for the Forum to attend\**

## SHORT COURSE | WEDNESDAY, MARCH 16

**10:00AM-1:00PM ET**      **Virtual Short Course #1:** Medical Communications: Compliance in 2022  
*\*Short Course requires an additional registration fee. You do not need to be registered for the Forum to attend\**

## SHORT COURSE | THURSDAY, MARCH 17

**10:00AM-1:30PM ET**      **Virtual Short Course #2:** Advertising and Promotional Content Review: The Role of Medical Information  
*\*Short Course requires an additional registration fee. You do not need to be registered for the Forum to attend\**

## SHORT COURSE | FRIDAY, MARCH 18

**10:00AM-1:30PM ET**      **Virtual Short Course #3:** Statistics for Non-Statisticians  
*\*Short Course requires an additional registration fee. You do not need to be registered for the Forum to attend\**

## DAY ONE | MONDAY, MARCH 21 ROOMS

<b>11:00AM-5:00PM</b>	Forum Registration	Oceana Grand Ballroom Foyer
<b>1:00-1:30PM</b>	Welcoming Remarks and Presentation of Excellence in Service Award	Oceana Grand Ballroom 6
<b>1:30-2:15PM</b>	<b>Session 1:</b> Opening Keynote – The Power of Communication	Oceana Grand Ballroom 6
<b>2:15-3:00PM</b>	Refreshment and Networking Break in the Exhibit Hall	Oceana Grand Ballroom 7-12
<b>3:00-4:00PM</b>	<b>Session 2:</b> CONCURRENT SESSIONS <b>Track 1:</b> Team Engagement <b>Track 2:</b> Recruiting and Retaining Medical Writing Talent in Pharma <b>Track 3:</b> Great Stories Don't Just Happen – Becoming a Storytelling Virtuoso	Oceana Grand Ballroom 6 Timor Sea Banda Sea
<b>4:10-5:10PM</b>	<b>Session 3:</b> CONCURRENT SESSIONS <b>Track 1:</b> Medical Information Insight <b>Track 2:</b> DSUR Best Practices: Empowering Medical Writers to create ICH-compliant Development Safety Update Reports <b>Track 3:</b> The Business of Science: A Strategic Approach to MSL Territory Planning, A Sobi Perspective	Oceana Grand Ballroom 6 Timor Sea Banda Sea
<b>5:10-6:30PM</b>	Networking Reception and Community Service Event	Wintilan Outdoor Pavilion

## DAY TWO | TUESDAY, MARCH 22

<b>7:00AM-4:45PM</b>	Registration	Oceana Grand Ballroom Foyer
<b>7:00-8:00AM</b>	Networking Breakfast in the Exhibit Hall	Oceana Grand Ballroom 7-12

8:00-9:00AM	<b>Session 4:</b> General Session: Emergency Use Authorizations (EUA) Panel Discussion	Oceana Grand Ballroom 6
9:10-10:25AM	<b>Session 5:</b> CONCURRENT SESSIONS <b>Track 1:</b> Customer Engagement: Ensuring an Optimal Customer Experience Through Contact Center Support Models and Omnichannel Platform <b>Track 2:</b> Lean Authoring and Global CTD Submission <b>Track 3:</b> Novel and Emerging Technologies	Oceana Grand Ballroom 6 Timor Sea Banda Sea
10:35-11:05AM	<b>Non-CE/Sponsored Session:</b> Enabling Real-Time Responses & Engagement: Medical, MI, Commercial & HCPs - <i>In Person Exclusive</i>	Ocean Grand Ballroom 4-5
10:25-11:10AM	Refreshment and Networking Break in the Exhibit Hall	
11:10AM-12:25PM	<b>Session 6:</b> CONCURRENT SESSIONS <b>Track 1:</b> Digital Innovation in the Communication of Scientific Information: An Ongoing Conversation <b>Track 2:</b> Publications Trends and Best Practices <b>Track 3:</b> The Art of Medical Science Liaising – How is the Canvas Changing	Oceana Grand Ballroom 6 Timor Sea Banda Sea
12:25-1:45PM	Networking Luncheon in the Exhibit Hall	Oceana Ballroom 7-12
12:25-1:45PM	<b>Resident and Fellow Professional Development Luncheon:</b> Stop, Look and Listen: Negotiation Skills	Oceana Grand Ballroom 4-5
1:45-3:00PM	<b>Session 7:</b> CONCURRENT SESSIONS <b>Track 1:</b> Patient Engagement <b>Track 2:</b> The Power of Language in Communicating Science <b>Track 3:</b> Taking a Peek at the Next MSL Generation	Oceana Grand Ballroom 6 Timor Sea Banda Sea
3:00-3:45PM	Refreshment and Networking Break in the Exhibit Hall	Oceana Grand Ballroom 7-12
3:45-4:45PM	<b>Session 8:</b> BREAKOUT SESSIONS <b>Track 1:</b> Hot Topics <b>Track 2:</b> Transparency and Public Disclosure Requirements for Medical Writing Submission Documents <b>Track 3:</b> Unlocking the Mysteries of HEOR	Oceana Grand Ballroom 6 Timor Sea Banda Sea
4:45-6:00PM	Resident and Fellow Poster Reception and Networking	Oceana Grand Ballroom 7-12

## DAY THREE | WEDNESDAY, MARCH 23

7:00AM-12:00PM	Registration	Oceana Grand Ballroom Foyer
7:00-8:00AM	Networking Breakfast in the Exhibit Hall	Oceana Grand Ballroom 7-12
8:00-9:30AM	<b>Session 9:</b> BREAKOUT SESSIONS <b>Track 1:</b> Podium Pearls <b>Track 2:</b> Round Table Discussions ( <i>In-Person Exclusive</i> ) <b>Track 3:</b> Round Robin and Lessons Learned ( <i>In-Person Exclusive</i> )	Oceana Grand Ballroom 6 Timor Sea Banda Sea
9:30-10:30AM	Refreshment and Networking Break in the Exhibit Hall - View Professional Posters	Oceana Grand Ballroom 7-12
10:30-11:30AM	<b>Session 10:</b> Closing Keynote Address: Completing the Picture: Identifying the Missing Pieces Necessary for Patient Centered Care	Oceana Grand Ballroom 6
11:30-11:45AM	<b>Session 11:</b> DIA Communities Update	Oceana Grand Ballroom 6
11:45AM-12:00PM	Closing Remarks	Oceana Grand Ballroom 6
12:00-1:00PM	Networking Luncheon and Exhibits - View Professional Posters	Oceana Grand Ballroom 7-12
1:00PM	Forum Adjourns	

# Track Descriptions

## Track 1: Medical Communications Track

Medical Information/Communications departments need to be agile to meet changing customers' needs. The rapid shift to a more virtual environment in the face of an ongoing global pandemic is challenging these groups to deliver and engage in different ways. Hear how your colleagues have navigated rapid shifts in the external environment. Gain tangible insights on navigating the digital space and keeping pace with changing customer expectations. Learn how organizations are transforming customer interactions into actionable insights through technology and digital transformation. Apply these learnings to refine content creation and dissemination to meet evolving customer needs.

## Track 2: Medical Writing Track

Network and learn from your Medical Writing and Communications colleagues. Independent industry experts will share the latest approaches in medical regulatory and publication writing. Sessions include challenges and opportunities in medical writing as result of the COVID-19 pandemic, streamlined processes in medical writing and eCTD submissions, recruiting and retaining needed medical writing talent, DSUR best practices, processes and best practices in publication writing, topics in transparency and disclosure, and much more. Attend the Medical Writing track for an exciting and informational look into the challenges and emerging opportunities in Medical Writing.

## Track 3: Medical Science Liaisons

As the frontline scientific storyteller in the pharmaceutical industry, the Medical Science Liaison role continues to be dynamic and growth oriented. This track is appropriate for current or prospective Medical Affairs Professionals, including Medical Science Liaisons (MSLs), MSL Directors, MSL Operations, HEOR Liaisons, Clinical Liaisons, other field medical staff, and anyone with interest in learning more about the issues impacting this critical field medical role. You will find a comprehensive and cohesive agenda that has been curated and peer-reviewed by recognized thought leaders from the MSL and Medical Affairs community. The content is high-quality and non-biased, developed BY field medical professionals FOR field medical professionals in the setting of DIA's neutral, global forum. This is your opportunity to network with the field based medical community.

## 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 **28.75** contact hours or **2.875** continuing education units (CEU's).



**ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, MAY 6, 2022**

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, 2022**, 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](http://www.cpemonitor.net). 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.



Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU.

As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to 1.7\* CEUs for this program.

Participants must attend the entire virtual Primer and/or Short Courses in order to be able to receive an IACET statement of credit. No partial credit will be awarded. **\*IACET CEUs are only available for Primer and Short Courses.**

## Statement of Credit

If you would like to receive a statement of credit for the days you attend the live **virtual primer and/or short course(s)**, you must virtually attend the primer and/or short course(s), in their entirety, achieve a passing score of 80% or better on the post-assessment, and complete the program evaluation and request CE credit online through My Transcript (see instructions below).

If you would like to receive a statement of credit for the days you attend the **in-person or live virtual forum**, you must attend each day the forum in their entirety, complete and return a CE Verification of Attendance Form (see instructions below), complete the post program evaluation, and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, April 6, 2022**.

**If you are claiming ACPE credit for this in-person or live virtual forum you must:**

1. Complete a CE Verification of Attendance Form
2. Return it to [CE@DIAglobal.org](mailto:CE@DIAglobal.org) by **March 30, 2022**
3. Access your DIA account and select My Transcript to claim your ACPE credit, available on **Wednesday, April 6, 2022**

### Nursing

As an Accredited Provider by the Accreditation Council for Pharmacy Education (ACPE) the American Nurses Credentialing Center (ANCC) recognizes ACPE Credit(s)<sup>™</sup> issued by DIA as acceptable toward license Nurses Credentialing Center (ANCC) recognizes ACPE Credit(s)<sup>™</sup> issued by DIA as acceptable toward license CE **requirements** for nursing. Please refer to page five in the requirements for additional information.

## TO ACCESS MY TRANSCRIPT

- Visit [DIAglobal.org](http://DIAglobal.org)
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Select **My Transcripts** then **Manage My Transcripts**

## ACCESS PRESENTATIONS

- Visit [DIAglobal.org](http://DIAglobal.org)
- **Sign In** with your DIA User ID and Password
- Select the Welcome Menu in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Choose **My Presentation**

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

## Virtual Meeting Pharmacy Credit Breakdown

**Virtual Medical Communication Primer: The Fundamentals of Medical Communication** Pharmacy 8 contact hours or .8 CEUs, Activity Type: Application 0286-0000-22-010-L04-P; IACET .8 CEUs

### Short Courses

**Virtual Short Course 1: Medical Communications: Compliance in 2022** Pharmacy 3.25 contact hours or .325 CEUs, Activity Type: Application 0286-0000-22-011-L04-P; IACET .3 CEUs

**Virtual Short Course 2: Advertising and Promotional Content Review: The Role of Medical Information** Pharmacy 3.25 contact hours or .325 CEUs, Activity Type: Knowledge 0286-0000-22-012-L04-P; IACET .3 CEUs

**Virtual Short Course 3: Statistics for Non-Statisticians** Pharmacy 3.25 contact hours or .325 CEUs, Activity Type: Knowledge 0286-0000-22-013-L04-P; IACET .3 CEUs

**Welcoming Remarks and Presentation of Excellence in Service Award: NO CE**

**Session 1: Opening Keynote – The Power of Communication:** Pharmacy .75 contact hours or .075 CEUs  
UAN: 0286-0000-22-014-L04-P; Knowledge

**Session 2 Track 1: Team Engagement:** Pharmacy 1 contact hours or .1 CEUs  
UAN: 0286-0000-22-015-L04-P; Knowledge

**Session 2 Track 2: Recruiting and Retaining Medical Writing Talent in Pharma: NO CE**

**Session 2 Track 3: Great Stories Don't Just Happen – Becoming a Storytelling Virtuoso: NO CE**

**Session 3 Track 1: Medical Information Insights:** Pharmacy 1 contact hours or .1 CEUs  
UAN: 0286-0000-22-016-L04-P; Knowledge

**Session 3 Track 2: DSUR Best Practices: Empowering Medical Writers to Create ICH Compliant Development Safety Update Reports:** Pharmacy 1 contact hours or .1 CEUs  
UAN: 0286-0000-22-017-L04-P; Knowledge

**Session 3 Track 3: The Business of Science: A Strategic Approach to MSL Territory Planning** Pharmacy 1 contact hours or .1 CEUs  
UAN: 0286-0000-22-018-L04-P; Knowledge

**Session 4: General Session Emergency Use Authorizations (EUA) Panel Discussion:** Pharmacy 1 contact hours or .1 CEUs  
UAN: 0286-0000-22-019-L04-P; Knowledge

**Session 5 Track 1: Customer Engagement: Ensuring an Optimal Customer Experience Through Contact Center Support Models and Omnichannel Platform:** Pharmacy 1.25 contact hours or .125 CEU  
UAN: 0286-0000-22-020-L04-P; Knowledge

**Session 5 Track 2: Lean Authoring and Global CTD Submission:** Pharmacy 1.25 contact hours or .125 CEUs  
UAN: 0286-0000-22-021-L04-P; Knowledge

**Session 5 Track 3: Novel and Emerging Technologies:** Pharmacy 1.25 contact hours or .125 CEUs  
UAN: 0286-0000-22-022-L04-P; Knowledge

**Session 6 Track 1: Digital Innovation in the Communication of Scientific Information: An Ongoing Conversation:** Pharmacy 1.25 contact hours or .125 CEUs  
UAN: 0286-0000-22-023-L04-P; Knowledge

**Session 6 Track 2: Publications Trends and Best Practices:** Pharmacy 1.25 contact hours or .125 CEUs  
UAN: 0286-0000-22-024-L04-P; Knowledge

**Session 6 Track 3: The Art of Medical Science Liaising – How is the Canvas Changing:** Pharmacy 1.25 contact hours or .125 CEUs  
UAN: 0286-0000-22-025-L04-P; Knowledge

**Session 7, Track 1 Patient Engagement:** Pharmacy 1.25 contact hours; or .125 CEUs  
UAN: 0286-0000-22-026-L04-P; Knowledge

**Session 7 Track 2: The Power of Language in Communicating Science:** Pharmacy 1.25 contact hours; or .125 CEUs  
UAN: 0286-0000-22-027-L04-P; Knowledge

**Session 7 Track 3: Taking a Peek at the Next MSL Generation:** Pharmacy 1.25 contact hours or .125 CEUs  
UAN: 0286-0000-22-028-L04-P; Knowledge

**Session 8 Track 1: Hot Topics:** Pharmacy 1 contact hours or .1 CEUs  
UAN: 0286-0000-22-029-L04-P; Knowledge

**Session 8 Track 2: Transparency and Public Disclosure Requirements for Medical Writing Submission Documents:** Pharmacy 1 contact hours or .1 CEUs  
UAN: 0286-0000-22-030-L04-P; Knowledge

**Session 8 Track 3: Unlocking the Mysteries of HEOR:** Pharmacy 1 contact hours or .1 CEUs  
UAN: 0286-0000-22-031-L04-P; Knowledge

**Session 9 Track 1: Podium Pearls:** Pharmacy 1.5 contact hours or .15 CEUs  
UAN: 0286-0000-22-032-L04-P; Knowledge

Session 9 Track 2: Round Table Discussions: **NO CE**

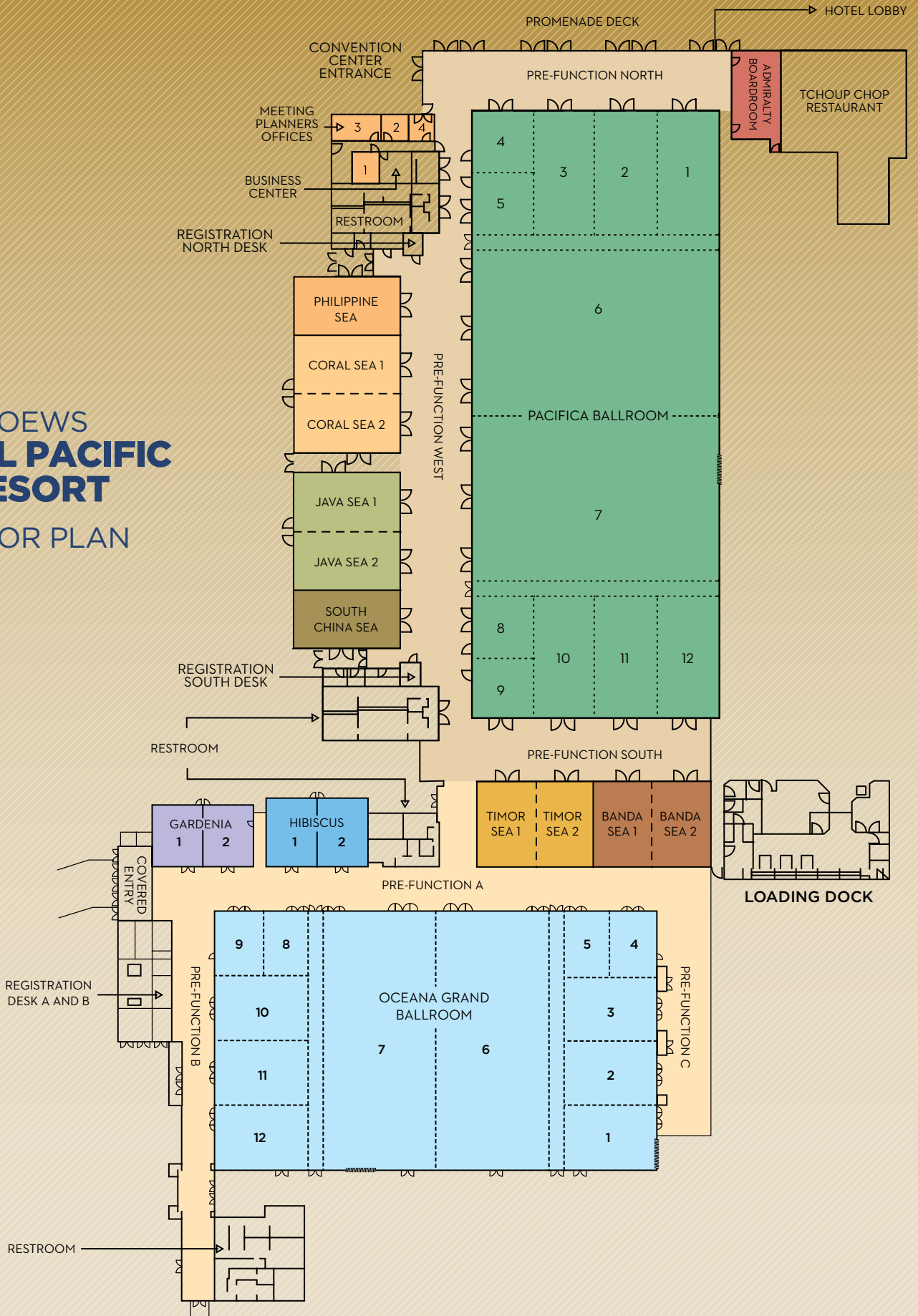
**Session 9 Track 3: Round Robin and Lessons Learned (In-Person Exclusive): NO CE**

**Session 10: Closing Keynote:** Pharmacy 1 contact hours or .1 CEUs  
UAN: 0286-0000-22-033-L04-P; Knowledge

Session 11: DIA Communities Update: **NO CE**

# LOEWS ROYAL PACIFIC RESORT

## FLOOR PLAN



**10:00AM-2:30PM ET Virtual Medical Communications Primer:** The Fundamentals of Medical Communications – PART 1\*

**Session Chair**

**Payal Desai**, Associate Director, Medical Information and Knowledge Integration, Janssen Scientific Affairs, LLC

**Co-Instructors**

**Komal Bawa, PharmD**, Evidence Synthesis Scientist, US Medical Affairs, Genentech

**Deirdre Healy, RPh, MBA**, Vice President, Medical and Scientific Affairs, Eversana, Complete Commercialization Division

**Vineeth Nair, PharmD, MPH**, Global Medical Information Content Manager, Sanofi

**Ellen Whipple, PharmD**, Owner and Principal Writer, EW Associates, LLC

*\*This Primer requires an additional registration fee. You do not need to be registered for the Forum to attend\**

*This will be a full day of content broken out into two half days*

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 a very regulated industry, 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 primer 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 companies' 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. 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 balanced communications and proper documentation. Topics will also include important elements of writing a standard response letter (including 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 their job function and a broader awareness of the regulatory environment. You'll also learn how to work better as part of interdisciplinary teams, and practice evidence-based medicine evaluation.

**At the conclusion of the primer, 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 provide on promotional review committees

## PRIMER | FRIDAY, MARCH 11

**10:00AM-2:30PM ET Virtual Medical Communications Primer:** The Fundamentals of Medical Communications – PART 2\*

## SHORT COURSE | WEDNESDAY, MARCH 16

**10:00AM-1:00PM ET Virtual Short Course #1:** Medical Communications: Compliance in 2022

*\*This Short Course requires an additional registration fee. You do not need to be registered for the Forum to attend\**

### Instructors

**Monica Kwarcinski, PharmD**, Vice President, Medical Affairs, Purdue Pharma L.P.

**Gary Messplay, JD**, Partner, King & Spalding, LLP

**Raegan McClain**, Chief Compliance Officer, Oyster Point Pharma, Inc.

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 this 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
- Discuss FDA guidances relevant to medical communications
- 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

## SHORT COURSE | THURSDAY, MARCH 17

**10:00AM-1:30PM ET Virtual Short Course #2:** Advertising and Promotional Content Review: The Role of Medical Information

*\*This Short Course requires an additional registration fee. You do not need to be registered for the Forum to attend\**

### Instructors

**Kajal Patel, PharmD**, Senior Medical Information & Review Manager, Takeda Pharmaceuticals

**VeeJaye Sinha**, Medical Review Associate Director, Takeda Pharmaceuticals

This short course is intended to provide a greater understanding of the role and value of medical information in the advertising and promotional content review process. During this course we will describe the synergies of the medical information and review roles and explore the data requirements for product claims. You will gain an appreciation of the importance of good communication and relationship building in the review process. Finally, you will have an opportunity to apply these learning to real case examples.



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

- Identify the role of medical information in the review process
- Describe the synergies of the medical information and review role
- Apply the data requirements for product claims in the review process

## SHORT COURSE | FRIDAY, MARCH 18

### 10:00AM-1:30PM ET **Virtual Short Course #3: Statistics for Non-Statisticians**

*\*This Short Course requires an additional registration fee. You do not need to be registered for the Forum to attend\**

**Instructor**

**Barry Drees, PhD**, Senior Partner, Trilogy Writing & Consulting, Germany

This course teaches the correct presentation and communication of the results from statistical analyses of clinical trials. The following statistical concepts are covered in depth: study populations, the meaning and uses of sensitivity analyses, descriptive statistics, odds and hazard ratios, estimates and confidence intervals, and sample size calculations. Emphasis is placed on understanding statistical presentations and reporting statistical information, not on calculations or mathematical explanations.

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

- Determine whether data are normally distributed and what this tell us
- Examine sensitivity analyses and why they are so important
- Discuss how point estimates and 95% Confidence Intervals to predict the future

## DAY ONE | MONDAY, MARCH 21

**11:00AM-5:00PM** **Forum Registration** Oceana Grand Ballroom Foyer

**1:00-1:30PM** **Welcoming Remarks and Presentation of Excellence in Service Award** Oceana Grand Ballroom 6

**Amy Van Sant, PharmD, MBA**, President, Medical Affairs, Ashfield Engage

**David Meats**, Associate Director, Regulatory Services Management, Synchrogenix, a Certara Company

**J. Lynn Bass, PharmD, RPh**, Senior Director, Medical Sciences, Medexus Pharma

**Congratulations to our 2022 Excellence in Service Awardees**

**Kevin Appareti, MD**, Senior Director, Global Medical Science Liaison, Royal Philips

**Maureen Feeny, PharmD, RPh, MBA**, Vice President Scientific and Medical Communications, Takeda

**Eileen Girtten, MS**, Director, Medical Writing, Pfizer, Inc.

**1:30-2:15PM** **Session 1: Opening Keynote – The Power of Communication** Oceana Grand Ballroom 6

This will discuss the Pennycook lab's research agenda on COVID-19 misinformation (for papers, see <https://bit.ly/3EAmr6K>). Dr. Pennycook will describe the results of a large-scale study conducted in 16 countries and examine factors that predict susceptibility to belief in COVID-19 misinformation, as well as interventions to identify misinformation at scale and to reduce the sharing of COVID-19 misinformation on social media. Dr. Pennycook will also describe research showing the power of communications from cultural elites for shaping laypeople's attitudes towards COVID-19 vaccination.

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

- Determine factors which predict susceptibility to believe misinformation
- Identify potential interventions to reduce the sharing of misinformation
- Recognize the cultural influences that shape people's attitudes

**Gordon Pennycook, PhD, MA**, Assistant Professor, Behavioral Sciences, Hill/Levene Schools of Business, University of Regina, Canada

**Track 1:** Team Engagement

Oceana Grand Ballroom 6

**Session Chair****Hanady Elhadidy, PharmD**, Director, US MI and Global Escalations, Bristol-Myers Squibb

This panel discussion will be focused on team engagement in a hybrid/virtual environment. The panelists will share their thoughts and experiences on creating high performance teams and driving effectiveness and connectivity in different workplace settings.

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

- Discuss challenges as we return to a hybrid work environment
- Formulate strategies for leading high-performance teams who can work effectively across diverse flexible working arrangements and accelerated timelines
- Discuss tools for driving emotional intelligence competency among teams

**Speakers****Mary Coffey, PharmD, RPh**, Senior Director, WW Scientific Content and US Market Capabilities, Bristol Myers Squibb**Roseanne Degnan, PharmD**, Associate Director, Medical Information and Knowledge Integration, Janssen Scientific Affairs**Sara Parambil, PharmD**, Associate Director, MI Engagement and Established Brand Lead, AstraZeneca**Track 2:** Recruiting and Retaining Medical Writing Talent in Pharma

Timor Sea

**Session Co-Chairs****Diane Cleverley, PhD**, Senior Regulatory Writer, Synchrogenix, a Certara Company**Meera Kodukulla, PhD**, Senior Director, Scientific Publications, AstraZeneca

Medical writing is an established core competency in the pharmaceutical industry providing a compelling value proposition with deep knowledge, skills, and experience. The demand for skilled medical writing professionals in Pharma and Healthcare continues to rise with the accelerated pace of drug development, enhanced regulatory and data transparency requirements, and innovation in digital communications. A career in medical writing presents diverse opportunities for scientific professionals to apply their scientific knowledge and writing expertise to translate clinical evidence into impactful and timely regulatory documents and peer-reviewed publications. We present an argument for why medical writing should be not just an alternative career, but a career of choice. The focus of this chat will be on 3 main areas of current interest for both Sponsors and Agencies: hiring in talented writers, training new and current writers and retaining top talent.

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

- Employ practical tips on identifying talented medical writers
- Define Best Practices for training new and current writers
- Develop a plan to retain valuable talent for their company

**Speakers****Demetrius Carter, MBA**, Senior Vice President, Regulatory Services, Synchrogenix, A Certara Company**Track 3:** Great Stories Don't Just Happen – Becoming a Storytelling Virtuoso

Banda Sea

**Session Chair****Kay Uttech, PharmD, RPh, MA**, Vice President, Strategic Initiatives, Indegene

Scientific storytelling is vital for MSLs and necessitates on-going work to fine hone the skills as scientific engagement evolves and expands to include more diverse tools and groups of healthcare professionals (HCPs). Central to skills development is effective coaching by managers and peers that recognizes individual

authenticity. This session will provide practical tips for MSLs and management on how to continue to advance the HCP engagement journey through scientific storytelling while capturing valuable clinical and business insights.

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

- Summarize how to build more a storied presentation that connects HCPs to complex information and data
- Explain how well told stories impact both engagement with key topics and retention of information
- Apply strategies to deliver effective feedback on MSL scientific storytelling as a manager or peer

**Data Storytelling**

**Carol Heggie, RN**, Vice President, Field Medical, Takeda Pharmaceuticals USA Inc

**Sharing Sentiments on Scientific Storytelling: How to Give Feedback**

**Jennifer Davis, PharmD, MS**, Associate Director, Medical Training - Vaccines, Sanofi Pasteur

4:10-5:10PM

**Session 3: CONCURRENT SESSIONS**

**Track 1:** Medical Information Insights

Oceana Grand Ballroom 6

**Session Chair**

**Sonia Sandhu, PharmD**, Director, Medical Information, Gilead Sciences, Inc.

Med info insights are unique and are based upon the direct knowledge of product related scientific needs of external HCPs and consumers who have contacted MI. Our insights require critical analysis and strategic thinking, and they provide a unique perspective into external customers. The actionable insights help inform, data gaps, clarify messages, support safe and effective use of company products, inform future data generation priorities, internal medical trainings, content development label updates and much more.

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

- Utilization of MI data to uncover actionable insights and impact on the organization
- Identify the impact of MI insights on data generation priorities
- Develop strategies to build a robust voice of the customer through insights

**Speakers**

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

**Seth Tyree, MS**, Senior Vice President, Solutions Strategy, Stratifyd

**Sophie Forge, MS**, Global Head of Medical Data to Insights, GlaxoSmithKline

**Track 2:** DSUR Best Practices: Empowering Medical Writers to Create ICH-compliant Development Safety Update Reports

Timor Sea

**Session Chair**

**Andrea Meyers**, Senior Vice President, Medical Writing, Syneos Health

The Development Safety Update Report (DSUR) is a document written by medical writers; however, there are two distinct pathways required to develop an ICH-compliant DSUR – the process of gathering the information required and the task of compiling the information into the DSUR template. This session will address DSUR best practices for the medical writer to ensure a process is in place to drive the production of the deliverable. Common pitfalls, misconceptions and “tips and tricks” for writing the DSUR will be shared, with audience participation encouraged.

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

- Identify key stakeholders required for a successful DSUR
- Develop timelines to manage the acquisition of data for the DSUR
- Create an ICH-compliant DSUR within the 60-day regulatory requirement

**Why the DSUR is Not a Medical Writing Deliverable**

**Andrea Meyers**, Senior Vice President, Medical Writing, Syneos Health

**A Practical Approach to Compiling the DSUR**

**Mari Welke, MA**, Director, Safety and Innovation, Synchrogenix, a Certara Company

**Track 3:** The Business of Science: A Strategic Approach to MSL Territory Planning, A Sobi Perspective

Banda Sea

**Session Chair**

**Danielle Day, PhD**, Senior Medical Director, Immunology, Rare Disease, Sobi

The MSL territory plan can either be a strategic roadmap guiding the way to meaningful outcomes, or a check-the-box exercise that gets completed and never looked at again. Incorporating an entrepreneurial mindset when designing a territory plan can give the MSL an opportunity to run their geography as a small business, identifying unique opportunities for impact to patients, providers and payers that correspond to overall medical and company goals. This session will highlight what we can learn from medical and cross-functional partners who have been able to create effective territory plans that make it easy to demonstrate MSL impact and outcomes within their key external and internal stakeholders.

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

- Discuss the purpose and potential impact of a strategic territory plan
- Create a territory plan that ties into overall company and Medical Affairs strategies
- Identify best practices to identify the unique opportunities within distinct territories

**Speakers**

**Christina Wright, PharmD**, MSL Lead, Southeast MSLs - Immunology, TG Therapeutics

**Elaine Nadeau, PharmD**, Senior Director, Head of US Field Medical Affairs & Medical Excellence, Sobi

**Carol Vu**, Thought Leader Liaison Director, Sobi

**5:10-6:30PM**

**Networking Reception and Community Service Event**

Wintilan Outdoor Pavilion

Join DIA as we partner with the Foundation for Hospital Art, a non-profit organization that uses art to bring comfort to people in healthcare facilities around the world. The traditional hospital setting is exemplified by white, sterile walls and ceilings. Examine rooms, waiting rooms, corridors - areas where health professionals and other caregivers work, where families and patients wait - are too often colorless, lifeless, and certainly not inviting. The Foundation for Hospital Art was officially established in 1984 and is dedicated to involving patients and volunteers worldwide to create colorful, soothing artwork donated to hospitals to help soften the often-stressful hospital experience. Over 1,000,000 volunteers and patients have unified in an effort to create over 48,000 paintings for over 6,000 hospitals in 195 countries!

Join us as we complete a paint-by-numbers mural to be donated at the completion of the forum. No artistic experience necessary as the template is easy to follow. So, grab a brush and help us add some color to brighten someone's day!

**DAY TWO | TUESDAY, MARCH 22**

**7:00AM-4:45PM**

**Registration**

Oceana Grand Ballroom Foyer

**7:00-8:00AM**

**Networking Breakfast in the Exhibit Hall**

Oceana Grand Ballroom 7-12

**8:00-9:00AM**

**Session 4:** General Session: Emergency Use Authorizations (EUA) Panel Discussion

Oceana Grand Ballroom 6

The panel will take questions about the EUA submission process and share lessons learned and recommendations for agile submission practices with the audience. There will be emphasis on impact on Medical Writing function.

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

- Discuss tips for optimizing the submission timeline and determine when to escalate.
- Identify one or more tips for clear effective communication to facilitate the progress the submission timeline.
- Define roles and responsibilities of the submission team (i.e. RACI use)

**Lakshmi Ramkumar, PhD**, Senior Director, Head of Medical Writing, Moderna

**Karen Hager, MS**, Senior Director, Clinical Research, Medicago

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**9:10-10:25AM**

**Session 5: CONCURRENT SESSIONS**

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**Track 1:** Customer Engagement: Ensuring an Optimal Customer Experience Through Contact Center Support Models and Omnichannel Platform Oceana Grand Ballroom 6

**Session Chair**

**Robert Tamburri, PharmD, MBA**, Director, Medical Information Communication Channel, Janssen Scientific Affairs, LLC

How we engage with our customers continues to evolve with expanding markets and changing customer preferences. It becomes increasingly important to ensure that the optimal contact center support model is implemented and that the appropriate customer interaction platforms are utilized. In this session, we will review various contact center support models that are used in providing Medical Information support. We will explore omnichannel platforms that allow customers to engage with Medical Information teams in a manner that is aligned with their preferences. There will also be discussion on how the evolving landscape plays a critical role in identifying customer preferences related to how they want to engage with Medical Information contact centers.

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

- Identify factors that contribute to an optimal customer experience
- Appraise various contact center support models
- Evaluate Omnichannel platforms for enhanced customer engagement

**Customer Engagement – Contact Center Support Models**

**Charlie Guerini**, Senior Director, Global Operations and Head of Innovation, Alphanumeric

**Customer Engagement Through Omnichannel Platforms**

**Samit Shah, PharmD**, Associate Director, MICC Omni Channel, Janssen Scientific Affairs, LLC

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**Track 2:** Lean Authoring and Global CTD Submission

Timor Sea

**Session Chair**

**David Meats**, Associate Director, Regulatory Services Management, Synchrogenix, a Certara Company

In this session, participants will learn the key tenets of the lean authoring methodology and process. In addition, attendees will learn how to apply these techniques to simplify and shorten the length of certain components of an eCTD submission. These taken in tandem can reduce the complexity, length, and potential for error.

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

- Identify the key tenets of the lean authoring methodology and process
- Apply these tenets to an eCTD submission
- Identify the positives and challenges to this type of regulatory writing style

**Speakers**

**Katie Bates**, Medical Writer and Consultant, Whitsell Innovations, Inc.

**Elizabeth Brown, MS, PMP**, Director, Oncology Medical Writing, Merck & Co., Inc.

**Session Co-Chairs****Paul Minne, PharmD, RPh**, Director, MSL Team, Neurocrine Biosciences**Kay Uttech, PharmD, RPh, MA**, Vice President, Strategic Initiatives, Indegene

This session will incorporate real life cases and panel discussions showing how technology can turn a problem into a solution. We will highlight uses of new technologies and discuss ways to potentially incorporate them into producing results for Medical Affairs teams. Emerging technology applications into medical affairs best practices and implications for organizations change will be the center of the dialogue.

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

- Interpret digital literacy to compare and contrast the impact that technology has on Medical Affairs
- Apply technology solutions to common issues and landscape changes occurring in industry
- Assess the potential future benefits of virtual reality, artificial intelligence, and machine learning and their implications for Medical Affairs

**What Problem are we Solving?****Chris Wasden, EdD**, Head of Pharma Specialty Solutions and Corporate Strategy, Happify Health**Tools to Change Medical Affairs****Colin Baughman, MBA**, Managing Partner and Founder, True North Solutions Inc.**Field Medical Perspectives****Christy Cheung, PharmD, RPh**, Medical Science Liaison, Sanofi Genzyme, Canada**10:25-11:10AM****Refreshment and Networking Break in the Exhibit Hall**

Oceana Grand Ballroom 7-12

**10:35-11:05AM****Non-CE/Sponsored Session:** Enabling Real-Time Responses & Engagement: Medical, MI, Commercial & HCPs - *In Person Exclusive*

Oceana Grand Ballroom 4-5

**11:10AM-12:25PM****Session 6: CONCURRENT SESSIONS****Track 1:** Digital Innovation in the Communication of Scientific Information: An Ongoing Conversation

Oceana Grand Ballroom 6

**Session Chair****Marie-Ange Noue, PhD**, Senior Director, Head of Scientific Communications, EMD Serono, Canada

This is an ongoing conversation about digital innovation in the provision of medical information. During this session, panelists will discuss current trends, insights, experiences, and challenges related to the adoption of innovative technologies to disseminate scientific content in a novel, inclusive, and compliant manner.

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

- Explain the importance of removing barriers and embedding sustainable and inclusive practices to improve accessibility to digital medical information
- Discuss innovations and trends in communicating scientific data
- Describe what is new in AI and automation
- Identify opportunities that regulatory considerations create in the use of digital innovation AI

**Writing for Accessibility - Medical Information in the Digital Age****Joanna Rizos, MBA, RPh**, Medical Affairs Manager, Eli Lilly, Canada**Innovative Ways to Communicate Data to External Stakeholders (outside of the traditional SRDs) and Data Visualization as a Way to Drive Engagement During Customer Interaction****John Jones, MBA**, Information Technology SME, PhactMI

## Trends, Insights, and Challenges in the Provision of Digital Medical Information: Spotlight on Artificial Intelligence and Automation

**Sandeep Gantotti**, Associate Vice President, Indegene Enterprise Medical, Indegene Pvt Ltd, India

## Legal/Regulatory Considerations When Adopting Innovative Digital Tools

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

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**Track 2:** Publications Trends and Best Practices

Timor Sea

### Session Chair

**Jennie Jacobson, PhD**, Associate Director, Publications and Scientific Communications, Incyte

The scientific publications field is always advancing. This session will describe new trends from ongoing ISMPP Good Publication Practice and authorship selection and provide tips for use of expanded digital content to enhance publications. Best practices for addressing challenges in publications will be discussed.

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

- Discuss new publication trends from ongoing ISMPP initiatives
- Identify key concepts of substantial contribution and authorship
- Design effective digital content and social media posts to enhance publications

### Thinking About Good Publication Practice

**Lisa DeTora, PhD**, Associate Professor, Director of STEM Writing, Hofstra University

### Best Practices to Aid Author Selection in Biomedical Publications

**Meera Kodukulla, PhD**, Senior Director, Scientific Publications, AstraZeneca

### Enhancing Publications Through Expanded Digital Content and Social Media

**Jennie Jacobson, PhD**, Associate Director, Publications and Scientific Communications, Incyte

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**Track 3:** The Art of Medical Science Liaising – How is the Canvas Changing

Banda Sea

### Session Co-Chairs

**J. Lynn Bass, PharmD, RPh**, Senior Director, Medical Sciences, Medexus Pharma

**Donna Booth, PharmD**, Director, Field Medical HTA and Policy, US Medical Affairs, GlaxoSmithKline

The field based medical affairs teams serve as conduits of medical and scientific information and are positioned at the heart of pharma's network of thought leaders and other experts. However, it has been difficult to realize the true impact of their field activities. In this session, we will evaluate the impact of two specific areas of interest - through expanding career opportunities for individuals along with expanding the base of customer segments. Each of these will provide insight into future methods to assess impact of these important roles.

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

- Describe new and expanded customer segments for field medical affairs
- Examine the impact and value to the company resulting from interactions with these new customer segments
- Review potential career paths for field medical affairs and how this career path adds value to both the individual and the company

**Jeff Vaughan, PharmD, MS**, National Director, Field Medical Science, Ashfield Engage

**Rachel Couchenour, PharmD, MA**, Vice President, Head of Medical Affairs, Traverre Therapeutics

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12:25-1:45PM

## Networking Luncheon in the Exhibit Hall

Oceana Ballroom 7-12

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12:25-1:45PM

## Resident and Fellow Professional Development Luncheon:

Oceana Grand Ballroom 4-5

Stop, Look and Listen: Negotiation Skills

### Session Chair

**Stacy Follman, PharmD, RPh**, Director, Student Affairs, Pfizer, Inc.

**Track 1:** Patient Engagement in Scientific Publications

Oceana Grand Ballroom 6

**Session Chair****Tamei Elliott**, Senior Manager, Scientific Programs, DIA

Scientific terminology and jargon prevent lay audiences from clearly understanding the important findings and implications of research articles. This is where plain language summaries (PLS) come into play—they succinctly translate the key messages from these articles into everyday language that a large audience—patients, patient caregivers, healthcare practitioners, and others—can easily understand. Recently, the medical publishing community has made great strides in reaching consensus on the development and publication of PLSs, with new guidance and recommendations coming from several organizations and publishers. The ongoing conversations around PLS, though, have identified several challenges that need to be resolved before PLS can truly meet their objective of making peer-reviewed research accessible to all.

Pharma is now partnering with diverse patient advocates to develop guidance on how to co-author scientific publications that are relevant to patients and written in language they can understand. Learn how Pharma has worked with patient advocates to co-develop this internal process and what the impact has been so far in involving patients in this new way.

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

- Explain how Pharma is partnering with patients/advocate(s) to develop an internal guidance around co-authoring scientific publications
- Identify of how plain language summaries support peer reviewed literature and how they assist to understand the medical literature using lay language
- Assess the challenges associated with plain language summaries

**Pharma - Patient Collaboration: Developing a Company-wide Patient Authorship Process****Angela Sykes, MS**, Senior Director, Team Leader, Publications Standard and Best Practices Lead, Pfizer, Inc.**Trishna Bharadia**, Patient Advocate, International Speaker, Writer, Advisor and Content Reviewer**Making Research Accessible to All: Plain Language Summary Consensus and Challenges****Felicity Poole**, Commissioning Editor - Infectious Diseases Portfolio, Taylor & Francis Group, United Kingdom**Track 2:** The Power of Language in Communicating Science

Timor Sea

**Session Chair****Meera Kodukulla, PhD**, Senior Director, Scientific Publications, AstraZeneca

Audience expectations and understanding of common terms, like “narrative” or “story,” vary across different groups, complicating the role of the medical communicator. This session will review how an awareness of rhetorical strategies and the function of stories can improve the quality of medical communications and earn the reader’s trust. The speaker will illustrate how specific concepts like “practical wisdom” (phronesis) and “applied knowledge” (techne), which were first described by Aristotle, can carry over into today’s medical communication practice, from medical writing through to scientific communications. Using specific examples from regulatory documentation and biomedical publishing, the speaker will discuss how guidance documents that set the tone for “practical wisdom” and an awareness of the narratives different groups bring to medicine can promote the best application of knowledge to reach different audiences, such as regulators, health care providers, and the public.

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

- Develop specific strategies for applying knowledge about rhetorical strategy and story to medical writing and communication
- Design written and other communications to more effectively address the needs of specific audiences
- Integrate information about rhetorical strategy and story in influencing cross-functional groups of collaborators

**Speaker****Lisa DeTora, PhD**, Associate Professor, Director of STEM Writing, Hofstra University



**Session Chair****J. Lynn Bass, PharmD, RPh**, Senior Director, Medical Sciences, Medexus Pharma

Medical Science Liaisons reside at the heart of the pharmaceutical industry's relationships with external thought leaders and experts, and serve as the conduit for the exchange of medical and scientific data through a variety of methods. New technologies and digitalization methods have arisen to improve communication streams, but how effective are these methods as the audience for MSLs changes and evolves? It's important to assess how these field medical roles are anticipated to mature over the next 3-5 years. This session will seek to interface with Medical Affairs thought leaders who survey MSL trends for the future to assess their impressions of what success may look like for these teams of the future.

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

- Debate with Medical Affairs thought leaders on the current value of field MSL teams
- Discuss what new methods and technology may be anticipated for thought leader interactions in the future
- Evaluate what new evolutionary trends to expect for the role of the MSL in the future

**Speaker****Sean Ryan**, Consultant, McKinsey & Company**Maureen Feeney, PharmD, RPh, MBA**, Vice President Scientific and Medical Communications, Takeda**3:00-3:45PM****Refreshment and Networking Break in the Exhibit Hall**

Oceana Grand Ballroom 7-12

**3:45-4:45PM****Session 8: BREAKOUT SESSIONS****Track 1: Hot Topics**

Oceana Grand Ballroom 6

**Session Chair****Amy Van Sant, PharmD, MBA**, President, Medical Affairs, Ashfield Engage

Our environment is constantly changing, and companies face increasing challenges to deliver high-quality and impactful medical communications. This session will touch on three 'hot topics' trending in the industry that may shape how we work in the future. Guest speakers will review some of the cutting edge work they are doing around these hot topics. The format of this session will be informal and audience questions are encouraged.

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

- Discuss the complexities, challenges and successes in medical communications in light of FDA Guidance impacting medical communications
- Examine on a global level about the impact of health equity
- Describe the impact of medical communications under an Emergency Use Authorizations (EUA)
- Identify emerging trends and their impact on Medical Communications

**FDA Guidance****Hira Shah, PharmD**, Director, Regulatory Affairs Advertising & Promotion, Regeneron**Health Equity****Stephanie Young Moss, PharmD, MS**, Pharmacist, Owner, Integrative Pharmacy Outcomes and Consulting**Virtual Congresses****Constance Stangarone**, Convention Services, Principal Manager, Genentech

**Session Chair**

**Ruggero Galici, PhD**, Director, Nonclinical and Clinical Pharmacology Writing, Alexion Pharmaceuticals, AstraZeneca Rare Disease

The EU is launching two electronic systems that will facilitate clinical data transparency and public disclosure. The Clinical Trial Information System (CTIS) and the European Database for Medical Devices (Eudamed) are expected to be functional in 2022. This presentation will discuss the changes in transparency and disclosure requirements in the EU, and the global impact of these new requirements on global submission documents. Early experiences with these systems will be shared, including the documents impacted, how they are impacted, and the timelines involved.

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

- Describe the new requirements in transparency and public disclosure in the EU in connection with the new systems CTIS and Eudamed
- Identify the medical writing documents impacted and how they are impacted
- Describe the role that medical writers in complying with the requirements of CTIS and Eudamed

**Speaker**

**Raquel Billiones, DrSc, PhD**, Associate Director, Medical Writing, Alexion Pharmaceuticals, AstraZeneca Rare Disease, Switzerland

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**Track 3:** Unlocking the Mysteries of HEOR

**Session Chair**

**Sonja Hokett, PharmD, MS**, Executive Director, Head of Medical Managed Care, BioXcel Therapeutics

This session will address two topics related to creation of a value story through creative analysis and implementation of a wide range of data as well as understanding the career path from MSL to a field HEOR role considering a broad range of perspectives.

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

- Outline the strengths and limitations of data gained from various research designs
- Discuss creative ways to collect real world data to incorporate into a comprehensive value story
- Detail the field HEOR roles and responsibilities
- Describe 'hidden' collaboration, communication, and other aspects of the role to consider

**Let's Get Real – Creative Ways to Incorporate Real World Evidence into Your Value Story**

**Morgan Bron, PharmD, MS**, Ingrezza Franchise HEOR Lead, Health Economics and Outcomes Research, Neurocrine Biosciences

**Breaking into the HEOR Field Role – Things to Consider**

**Mae Kwong, PharmD**, Senior Director, Medical Managed Care, BioXcel Therapeutics

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4:45-6:00PM

**Resident and Fellow Poster Reception and Networking**

Oceana Grand Ballroom 7-12

**DAY THREE | WEDNESDAY, MARCH 23**

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7:00AM-12:00PM

**Registration**

Oceana Grand Ballroom Foyer

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7:00-8:00AM

**Networking Breakfast in the Exhibit Hall**

Oceana Grand Ballroom 7-12

**Track 1:** Podium Pearls

Oceana Grand Ballroom 6

**Session Chair****Dannis Chang, PharmD**, Executive Director, Head of Medical Capabilities, Mirati Therapeutics

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 optimizing medical review, medical information contact centers, delivering content to HCPs, and patient insights.

**Optimizing Medical Review Through Process, Human Resources, and Technology****Diane Litwinko, PharmD**, Director, Global Medical Information, Organon**Understanding Current Trends and Needs: Medical Information Contact Center Services****Michael DeLuca, PharmD, MBA, MS, RPh**, Senior Vice President of Medical Affairs, Eversana**Partner4Better: Value of Delivering Educational Content to HCPs Around the Globe****Alicia Cadogan, PharmD, RPh**, Director, Oncology Medical Information, Pfizer, Inc.**Bringing Forward the Patient Voice Leveraging Global Medical Information Patient Insights****Truc Dinh, PharmD**, Senior Manager, Medical Information, Gilead Sciences, Inc.**Track 2:** Round Table Discussions (*In-Person Exclusive*)

Timor Sea

A round table discussion session where members use moderator-driven discussion topics to springboard fruitful conversations amongst themselves for a prescribed period of time.

**Topics include**

- Recognize best practices for presenting patient information in medical writing
- Appraise the value of involving the medical writer in TFL generation
- Contrast the advantages of using a shell or template to waiting to have all data available to start a document
- Compare the many roles of the medical writer at each participant's company
- Describe the training program for each participant's company

**Track 3:** Round Robin and Lessons Learned (*In-Person Exclusive*)

Banda Sea

**Session Chair****J. Lynn Bass, PharmD, RPh**, Senior Director, Medical Sciences, Medexus Pharma, United States

One meeting is clearly not enough time to touch on the numerous activities MSLs engage in on a day to day and month to month basis. This session seeks to review a broad list of topics relevant to the MSL role during mini/roundtable sessions. Topics to be reviewed include: 1) Hiring & Interviewing in a Virtual World 2) Continued post-pandemic challenges for MSLs 3) Benefits of joining a Medical Affairs/ MSL Professional Society 4) How to "Nuance the No" 5) Rightsizing teams: Building MSL teams

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

- Examine a variety of topics relevant to the current and future of the MSL role
- Discuss best practices with MSL industry leaders
- Participate in a question-and-answer session to evaluate challenges from current MSLs

10:30-11:30AM

**Session 10:** Closing Keynote Address: Completing the Picture:  
Identifying the Missing Pieces Necessary for Patient Centered Care

Oceana Grand Ballroom 6

This session will summarize some of the recent changes in the representation of specific patient variables (e.g., age, sex, gender, race and ethnicity) in clinical literature, citing where there have been improvements in representation and where there are still gaps. In addition, this presentation will highlight the importance of differentiating the representation of these variables in subject populations from the practice of disaggregating and reporting sub-group data.

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

- List and cite recent improvements in representation of specific populations in clinical literature
- Determine remaining gaps in the data evaluating specific populations in clinical literature
- Define strategies for interpreting clinical literature to inform patient care decisions

**Rebecca Sleeper, PharmD, FCCP, FASCP**, Senior Associate Dean and Professor, TTUHSC Jerry H. Hodge School of Pharmacy and Co-Chair Sex and Gender Summit

11:30AM-11:45PM

**Session 11:** DIA Communities Update

Oceana Grand Ballroom 6

**Monica Kwarcinski, PharmD**, Vice President, Medical Affairs, Purdue Pharma L.P.

**Nimita Limaye, PhD**, Research Vice President, Life Sciences R&D Strategy and Technology, IDC

**J. Lynn Bass, PharmD, RPh**, Senior Director, Medical Sciences, Medexus Pharma

11:45-12:00PM

**Closing Remarks**

Oceana Grand Ballroom 6

**J. Lynn Bass, PharmD, RPh**, Senior Director, Medical Sciences, Medexus Pharma

**Andrea Meyers**, Senior Vice President, Medical Writing, Syneos Health

**Dannis Chang, PharmD**, Executive Director, Head of Medical Capabilities, Mirati Therapeutics

12:00-1:00PM

**Networking Luncheon and Exhibits - View Professional Posters**

Thank you for joining us at MASC! We will be raffling off a complimentary registration to the 2023 Forum during this in-person luncheon. Must be present to win!

1:00PM

**Forum Adjourns**



# Medical Affairs and Scientific Communication Sponsored Event

Separate RSVP is required for each event. These sponsored sessions are open to all, including those not registered for the full conference. These sponsored sessions are separate to the conference content included in registration. Upon completion of your RSVP a login link will be sent to you for the session. By registering for this sponsored session, you are agreeing to share full contact information with the Solution Provider. You also understand that the Solution Provider, and DIA, may contact you with messages regarding products and/or services.

**TUESDAY, MARCH 22**

**ROOM**

**10:35-11:05AM ET**

**Non-CE/Sponsored Event:** Case Study hosted by Soterius, Inc.  
*In Person Exclusive*

Ocean Grand Ballroom 4-5

## **Enabling Real-Time Responses & Engagement: Medical, MI, Commercial & HCPs**

Current practices followed by most organizations in responding to unsolicited queries from Health Care Professionals often take between 24 hours to 2 days. Medical team often has time available on their schedule, but they are not immediately present (or reachable) to engage in a scientific exchange. Soterius implemented its integrated platform at sponsors to accelerate these interactions, integrating availability and expertise check and several communication methods, improving engagement speed and quality.

### **Featured Topics**

- HCPs truly value scientific/medical discussions and engagement, but have busy schedules
- Need for faster response and better engagement tools
- Ability to connect on-line and off-line, self-serve scheduling and requesting information
- Processes and Technology that support in-person and virtual meetings
- Video, Chat, Phone, Meeting Platforms – So many methods, need for a single, integrated platform
- Availability Check, Product or Disease Area Expertise, Territory and other factors determine who might be best suited to answer a question
- Compliant Process, HCP Confirmation, Meeting Controls
- Sharing Content, Capturing Meeting Details, Compliance Records
- Outcome and Results, Future Vision

### **Speaker**

**Suneet Walia, ACA**, CEO, Soterius, Inc.

**[Click here to RSVP](#)**