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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
- Four Half-Day Short Courses *Additional fee required
- Cross-functional General Sessions dedicated to the future of medical affairs
- Poster Presentations highlighting original research from residents and fellows in training, and professionals
- Podium Pearl Poster Presentations

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

SAVE THE DATE!

Medical Affairs and Scientific Communications Forum

March 22-24, 2022
Loews Royal Pacific Resort, Orlando, FL



Schedule At-A-Glance

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

*See track descriptions on page 5.

PRIMER | WEDNESDAY, MARCH 17

10:00AM-2:30PM **Medical Communications Primer:** The Fundamentals of Medical Communications – PART 1
*Additional Fee Required

PRIMER | THURSDAY, MARCH 18

10:00AM-2:30PM **Medical Communications Primer:** The Fundamentals of Medical Communications – PART 2
*Additional Fee Required

SHORT COURSES | FRIDAY, MARCH 19

9:30AM-1:00PM **Short Course #1:** Medical Communications: Compliance in 2021

Short Course #2: Statistics for Non-Statisticians

1:30-5:00PM **Short Course #3:** Advertising and Promotional Content Review: The Role of Medical Information

Short Course #4: Lean Authoring

DAY ONE | MONDAY, MARCH 22

9:50-10:15AM Welcome, Opening Remarks, and Presentation of Excellence in Service Award

10:15-11:00AM **Session 1:** Keynote Address: Developing a Positive Mindset in Challenging Times

11:00-11:30AM BREAK / Visit the Virtual Exhibit Hall

11:30AM-12:30PM **Session 2:** BREAKOUT SESSIONS

Track 1: When Virtual Becomes Reality – Maximizing Internal Engagement

11:30AM-12:45PM **Track 2:** The Impact of the COVID-19 Pandemic on Medical Writing: What 2020 Taught us About the way

Track 3: Life Going Virtual

Or view from the On Demand Library

12:45-1:45PM BREAK / Visit the Virtual Exhibit Hall

1:45-3:00PM ET

Session 3: BREAKOUT SESSIONS

Track 1: Medical Information Support in a Virtual World - Adapting to Ensure an Exceptional Customer Experience and Support During a Crisis Situation

Track 2: Guiding Journal Targeting: Shooting for the Moon may Leave you Lost in Space

Track 3: COVID-19 Experience from the Field – An HCP Panel

Or view from the On Demand Library

DAY TWO | TUESDAY, MARCH 23

10:00-11:15AM ET

Session 4: BREAKOUT SESSIONS

Track 1: Leveraging Technology to Satisfy Shifting Customer Expectations in the Digital Era: Best Practice Examples and Compliance Considerations

Track 2: End-to-End Messaging in Medical Writers

Track 3: Augmented Efficiency - Showcasing Field Medical Value through Artificial Intelligence and Natural Language Processing

Or view from the On Demand Library

11:15AM-12:15PM

BREAK / Visit the Virtual Exhibit Hall

12:15-1:30PM

Session 5: BREAKOUT SESSIONS

Track 1 and **3:** So You've Got Insights, Now What?

Track 2: Labeling Across Borders, Audiences, and Technologies

Or view from the On Demand Library

1:30-2:00PM

BREAK / Visit the Virtual Exhibit Hall

1:40-2:00PM ET

Q&A Session: Using Type 9 NDA Classification to Accelerate Multiple Approvals for Your Drug Product

2:00-3:15PM ET

Session 6: BREAKOUT SESSIONS

Track 1: 360 View: Virtual Congresses

Track 2: Plain Language and Patient Advocacy

Track 3: Mission Launching: Navigating the Challenges to Drive Success

Or view from the On Demand Library

3:30-4:30PM

Resident and Fellow Professional Development Session: On Your Mark, Get Set, Innovate!

DAY THREE | WEDNESDAY, MARCH 24

10:00-11:15AM

Session 7: BREAKOUT SESSIONS

Track 1: Podium Pearls

Track 2: Empowerment: Developing and Retaining Writers Globally

Track 3: The New Ecosystem of KOL Engagement

Or view from the On Demand Library

11:15AM-12:15PM

BREAK / Visit the Virtual Exhibit Hall – View Professional Posters!

11:20-11:40AM

Q&A Session: Writing CSRs and Protocols for Potential Public Release

12:15-1:15PM	Session 8: BREAKOUT SESSIONS
	Track 1: AMCP Format
12:15-1:30PM	Track 2: Applying Learning from Rare Disease to Support Diversity in Clinical Trials Track 3: Clinical Trials <i>Or view from the On Demand Library</i>
1:30-2:00PM	BREAK / Visit the Virtual Exhibit Hall
2:00-2:30PM	Community Update and Closing Remarks
2:30PM	Forum Adjourns

ON DEMAND

Track 2: The RACE Act: Implications for Pediatric Clinical Development

Track 2: Writing CSRs and Protocols for Potential Public Release

Track 2: Using Type 9 NDA Classification to Accelerate Multiple Approvals for Your Drug Product

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 a pandemic is challenging these groups to deliver in different ways. Hear how some of these functions have navigated rapid shifts in the external environment. Gain tangible insights on navigating the digital space and keep pace with changing customer expectations. Learn how organizations are transforming customer interactions into actionable insights through technology. Apply these learnings to refine content creation and dissemination to meet evolving digital 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, handling submissions from beginning to end, Labeling Across Borders, Plain Language and Patient Advocacy, Empowerment of Medical Writers and Developing Junior Writers and Overseas Writers, and Writing Protocols to Support Diversity in Clinical Trials. 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

This track is appropriate for current or prospective Field Medical Professionals, including: Medical Science Liaisons (MSLs), MSL Directors, MSL Operations, HEOR Liaisons, Clinical Liaisons, other field medical staff, and anyone else with interest in learning more about the issues impacting the Field Medical role. You will find a comprehensive and cohesive agenda that has been curated and peer-reviewed by recognized thought leaders from the global MSL and Field Medical 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 and be a Medical thought leader!

Virtual Meeting March 22-24 - 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 23 contact hours or 2.3 continuing education units (CEU's).



ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, MAY 7, 2021

If you are claiming ACPE credit for this virtual meeting you must:

1. Complete a CE Verification of Attendance Form
2. Return it to CE@DIAglobal.org by **March 31, 2021**
3. Access your DIA account and select My Transcript to claim your ACPE credit, available on **Wednesday, April 7, 2021**

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 7, 2021**, 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. 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 1.3* 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 conference, you must virtually attend the short course and/or individual days of the conference, 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 7, 2021**.

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Thank you to our media partners:



IMPORTANT NOTICE:

CE is available for Primer, Short Courses, and various Forum Sessions. No CE is available for On-Demand session recordings.

Virtual Meeting Pharmacy Credit Breakdown

Medical Communication Primer: The Fundamentals of Medical Communication Pharmacy 7 contact hours or .7 CEUs, Activity Type: Application UAN: 0286-0000-21-010-L04-P; IACET .7 CEUs

Short Courses

Short Course 1: Medical Communications: Compliance in 2021 Pharmacy 3.25 contact hours or .325 CEUs, Activity Type: Application UAN: 0286-0000-21-011-L04-P; IACET .3 CEUs

Short Course 2: Statistics for Non-Statisticians Pharmacy 3.25 contact hours or .325 CEUs, Activity Type: Application UAN: 0286-0000-21-012-L04-P; IACET .3 CEUs

Short Course 3: Advertising and Promotional Content Review: The Role of Medical Information Instructors Pharmacy 3.25 contact hours or .325 CEUs, Activity Type: Application UAN: 0286-0000-21-013-L04-P; IACET .3 CEUs

Short Course 4: Lean Authoring Pharmacy 3.25 contact hours or .325 CEUs, Activity Type: Application UAN: 0286-0000-21-014-L04-P; IACET .3 CEUs

Session 1: Keynote Address: Developing a Positive Mindset in Challenging Times: Pharmacy .75 contact hours or .075 CEUs UAN: 0286-0000-21-015-L04-P; Knowledge

Session 2 Track 1: When Virtual Becomes Reality – Maximizing Internal Engagement: Pharmacy 1 contact hours or .1 CEUs UAN: 0286-0000-21-016-L04-P; Knowledge

Session 2 Track 2: The Impact of the COVID-19 Pandemic on Medical Writing: What 2020 Taught us About the way we Plan, Author, and Deliver Scientific Communications and Regulatory Submissions: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-017-L04-P; Knowledge

Session 2 Track 3: Life Going Virtual: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-018-L04-P; Knowledge

Session 3 Track 1: Medical Information Support in a Virtual World - Adapting to ensure an exceptional customer experience and support during a crisis situation: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-019-L04-P; Knowledge

Session 3 Track 2: Guiding Journal Targeting: Shooting for the Moon may Leave you Lost in Space NO CE

Session 3 Track 3: COVID-19 Experience from the Field – An HCP Panel Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-020-L04-P; Knowledge

Session 4 Track 1: Leveraging Technology to Satisfy Shifting Customer Expectations in the Digital Era: Best Practice Examples and Compliance Considerations: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-021-L04-P; Knowledge

Session 4 Track 2: End-to-End Messaging in Medical Writers: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-022-L04-P; Knowledge

Session 4 Track 3: Augmented Efficiency - Showcasing Field Medical Value through Artificial Intelligence and Natural Language Processing: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-023-L04-P; Application

Session 5 Track 1 and 3: So You've Got Insights, Now What?: Pharmacy 1.25 contact hours or .125 CEU UAN: 0286-0000-21-024-L04-P; Knowledge

Session 5 Track 2: Labeling Across Borders, Audiences, and Technologies: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-025-L04-P; Knowledge

Session 6 Track 1: 360 View: Virtual Congresses NO CE

Session 6 Track 2: Plain Language and Patient Advocacy: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-026-L04-P; Knowledge

Session 6 Track 3: Mission Launching: Navigating the Challenges to Drive Success: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-027-L04-P; Application

Session 7, Track 1 Podium Pearls; Pharmacy 1.25 contact hours; or .125 CEUs UAN: 0286-0000-21-033-L04-P; Knowledge

Session 7 Track 2: Empowerment: Developing and Retaining Writers Globally NO CE

Session 7 Track 3: The New Ecosystem of KOL Engagement: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-028-L04-P; Knowledge

Session 8 Track 1: AMCP Format: Pharmacy 1 contact hours or .1 CEUs UAN: 0286-0000-21-029-L04-P; Knowledge

Session 8 Track 2: Applying Learning from Rare Disease to Support Diversity in Clinical Trials: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-030-L04-P; Knowledge

Session 8 Track 3: Why Science Needs More Diversity in Clinical Trials: Pharmacy 1.25 contact hours or .125 CEUs UAN: 0286-0000-21-031-L04-P; Knowledge

10:00AM-2:30PM

Medical Communications Primer: The Fundamentals of Medical Communications**Session Chair:****Payal Desai, PharmD**, Associate Director, Medical Information and Knowledge Integration, Janssen Scientific Affairs, LLC**Co-Instructors:****Komal Bawa, PharmD**, Evidence Synthesis Scientist, US Medical Affairs Genentech, A Member of the Roche Group**Eddie Carver, PharmD**, Medical Communications Lead, US Immunology Patient Value Unit, UCB Pharmaceuticals**Jennifer Park, PharmD**, Global Medical Information Content Manager, Sanofi**Ellen Whipple, PharmD**, Co-Owner, Scientific Content Solutions, LLC

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

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

WEDNESDAY, MARCH 17

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

THURSDAY, MARCH 18

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

SHORT COURSE | FRIDAY, MARCH 19

9:30AM-11:00PM **Short Course #1:** Medical Communications: Compliance in 2021

Instructors:

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

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

Erik Atkisson, Chief Compliance Officer, Cytokinetics

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

9:30AM-11:00PM **Short Course #2:** Statistics for Non-Statisticians

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 session, 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

1:30-5:00PM **Short Course #3:** Advertising and Promotional Content Review: The Role of Medical Information

Instructors

Anu Randhawa, PharmD, Director, US Medical Information and Review Takeda Pharmaceutical Company

Joel Davis, BSN, Associate Director, US Regulatory Affairs Advertising and Promotion, Abbvie

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 session, 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

1:30-5:00PM

Short Course #4: Lean Authoring

Instructors:

Elizabeth Brown, MS, PMP, Principal Scientist/Managing Medical Writer, Merck & Co., Inc.

Kim Jochman, PhD, Senior Principal Medical Writer, Merck & Co., Inc.

In today's regulatory environment, authors are routinely faced with writing numerous regulatory submission documents involving highly complex studies with overwhelming amounts of data. It is therefore imperative to develop documents that clearly convey the intended key messages to facilitate agency review. This short course will provide an overview of lean authoring, with discussion on the benefits and challenges of this approach. Hands-on activities will offer practical solutions to reduce content redundancy and to improve clarity of regulatory documents, with a focus on key messages. Strategies to help lean authoring succeed at your organization will also be discussed.

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

- Discuss the benefits of implementing a lean, message-based approach to authoring
- Apply techniques for introducing and highlighting the key messages
- Develop documents with the needs and expectations of the target audience in mind
- Identify strategies for implementing lean authoring at their organization

Network with your fellow attendees throughout the forum in the Virtual Conference Site! You will have the ability to schedule 1:1 meetings or group meetings to make new connections or join your long time MASC attendee buddies. Direct messages are also available to all attendees. Our interactive Exhibit Hall allows you to enter virtual booths and participate in live meetings with our exhibitors. We will have additional hosted events to amp up the networking including coffee corners, roundtable discussions, and more!

DAY ONE | MONDAY, MARCH 22

9:50-10:15AM

Welcome, Opening Remarks, and Presentation of Excellence in Service Award

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

Lori Mouser, PharmD, Global Head, Medical Customer Engagement, Roche, Switzerland

David Meats, Associate Director, Global Submissions, Regulatory Services Manager, Synchrogenix, a Certara Company

Excellence in Service Awardees:



Ivy Chang, PharmD, Principal Therapeutic Area Lead, Medical Information, Genentech, Inc., A Member of the Roche Group



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



Craig Klinger, RPh, Global MSL Trainer, The Office of Medical Professional Development, Eli Lilly and Company

10:15-11:00AM

Session 1: Keynote Address: Developing a Positive Mindset in Challenging Times



George Carroll, Business Mastery Representative, Robbins Research International

As we look around, it's easy to be pessimistic and negative about how the world seems to be trending with the pandemic. The truth is, we as individuals have ultimate influence on our mindset, attitude, and action. We cannot control external circumstances, but we can control how we respond to them. We live in a world where the media shines the light on crisis, chaos, and negativity but we have to remember that the information we choose to consume will influence our mental and emotional state. And our mental and emotional state directly influences our performance and production.

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

- Discuss the concept of "garbage in - garbage out"
- Identify how the brain's RAS seeks negative information
- Develop positive habits to find routine in the pandemic
- Describe how to take control of your focus and state of being
- Recognize and dissolve emotional triggers in times of hardship

11:00-11:30AM

BREAK / Visit the Virtual Exhibit Hall

11:30AM-12:30PM

Session 2: BREAKOUT SESSIONS

Track 1: When Virtual Becomes Reality – Maximizing Internal Engagement

Session Chair

Amy Ruffolo, PharmD, Senior Manager, Medical Information, Abbvie

In today's environment, the success of an organization depends heavily on remote employee engagement. This session will focus on understanding the unique challenges experienced by remote teams, adapting to this "new normal", and evolving the ways virtual teams engage. Strategies to drive engagement and accelerate success in a virtual environment will be explored.

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

- Recognize the unique challenges experienced by virtual teams
- Identify strategies to drive engagement in a virtual environment
- Apply techniques for accelerating success in a virtual environment

Speakers

Gladys Dulay, Director of Medical Affairs Strategic Planning and Operations, Myovant

Elizabeth Lathers, PhD, Senior Director, Head NA Medical Strategy & Operations, EMD Serono

11:30AM-12:45PM

Track 2: The Impact of the COVID-19 Pandemic on Medical Writing: What 2020 Taught us About the Way

Session Co-Chairs

Ruggero Galici, PhD, Associate Director, Medical Writing, Pfizer, Inc

David Meats, Associate Director, Global Submissions, Regulatory Services Manager, Synchrogenix, a Certara Company

The COVID-19 pandemic altered the way the public lives and works. This session explores challenges and solutions implemented by the medical regulatory and scientific publications industry during the ongoing COVID-19 pandemic, thus far. Panelists will share their experience and thoughts throughout moderated questions and live interactions with the audience. At the beginning of the session, data from a survey will be presented to stimulate discussion.

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

- Identify potential challenges encountered during the COVID-19 pandemic
- Identify and implement potential solutions and future transformational approaches

Speakers

Adesh Saxena, PhD, Director, Submission Medical Writing, Pfizer, Inc

Demetrius Carter, MBA, Senior Vice President, Regulatory Sciences, Synchrogenix, A Certara Company

11:30AM-12:45PM

Track 3: Life Going Virtual

Session Co-Chairs

Kevin Appareti, MBA, Senior Director, Global Medical Science Liaisons, Royal Philips

J. Lynn Bass, PharmD, RPh, Senior Director, Head of Medical Science Liaisons, Mesoblast Limited

While virtual HCP interactions are not novel, the effects of the COVID-19 pandemic have forced medical science liaison and medical affairs professionals to quickly pivot exclusively to these virtual interactions. With this pivot, new opportunities have been realized and challenges addressed to ensure continuous and open connections with the HCP community. This session will review these opportunities and challenges, share principles of effective virtual engagement, and provide examples of unique innovation for MSLs and medical affairs personnel to apply while working in a virtual environment.

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

- Discuss the challenges and benefits of virtual HCP interactions
- Review Principles of Effective Virtual Engagement (Etiquette, Expectations, Clarity of Objectives, Follow-up, etc.)
- Discuss examples of innovation within Medical Affairs and Medical Science Liaison roles during a pandemic
- Describe how the loss of boundaries can expand internal and external engagements while removing geographical limits

Speakers

Sarah Jarvis, MBA, Global Medical Affairs Lead, ZS

Debbie Yen, PharmD, Medical Science Liaison, Cardiovascular, Sanofi

Kevin Appareti, MBA, Senior Director, Global Medical Science Liaisons, Royal Philips

12:45-1:45PM

BREAK / Visit the Virtual Exhibit Hall

1:45-3:00PM

Session 3: BREAKOUT SESSIONS

Track 1: Medical Information Support in a Virtual World - Adapting to Ensure an Exceptional Customer Experience and Support During a Crisis Situation

Session Chair

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

The COVID-19 pandemic has ushered in unprecedented times forcing us to challenge how Medical Information organizations and contact centers provide support and customer engagement. In this session, we will explore the various factors that have impacted Medical Information services and provide an overview of some solutions that have been identified to ensure an optimal customer experience. You will hear about how medical information teams have rallied to provide innovative content and product support offerings. You will also learn how Medical Information contact centers have adapted to the new virtual environment that has emerged as a result of the global pandemic.

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

- Identify of how Medical Information teams provide product support in a crisis and EUA situation
- Discuss common practices used by Medical Information and contact center teams engage with customers virtually
- Define the concept of a 100% remote working environment and global support models

Speakers

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

Jay Baucom, Senior Vice President of Global Operations, CIO, Alphanumeric

Divyesh Khetia, PharmD, RPh, MBA, Head of Medical Information and Customer Call Centers, Glaxosmithkline

Track 2: Guiding Journal Targeting: Shooting for the Moon may Leave you Lost in Space

Session Chair

Jennie Jacobson, PhD, Medical Director, Cadent Medical Communications, a Syneos Health Company

The saying ‘Shoot for the moon, even if you miss you may land among the stars’ does not apply to targeting journals for biomedical publications. Aiming high sounds good to authors and companies who want the highest status journal possible for their manuscripts but may be the beginning of a costly cycle of rejection and resubmission that significantly delays publication. As medical writers, what is our role in helping publication stakeholders to target realistic journal targets?

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

- Understand the role of the medical writer in recommending target journals
- Discuss and dissect stakeholder motivations for overly optimistic journal choices
- Influence clients and authors to select realistic journals for their manuscripts

Panelists

Jennie Jacobson, PhD, Medical Director, Cadent Medical Communications, a Syneos Health Company

Diane Cleverley, PhD, Senior Regulatory Writer, Synchronix, a Certara Company

Jennifer Zimmer, MD, Senior Medical Advisor, Alzheimer’s Disease Team, Eli Lilly and Company

Meera Kodukulla, PhD, CMPP, Head, Scientific Publications, AstraZeneca

Track 3: COVID-19 Experience from the Field – An HCP Panel

Session Co-Chairs

Lori Mouser, PharmD, Global Head, Medical Customer Engagement, Roche, Switzerland

Paul Minne, PharmD, RPh, Director, MSL Team, Neurocrine Biosciences

This panel discussion will explore the impact of the COVID-19 pandemic on interactions with Health Care Providers (HCPs). A diverse group of HCPs will share their experiences of managing engagements with MSLs, attending virtual congresses, delivering care virtually and provide ideas on how these experiences may shape future approaches.

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

- Discuss the primary challenges facing HCPs in conducting virtual engagements with MSLs.
- List ways that virtual congress engagements have been successful for HCPs to access new data.
- Identify future engagement strategies that meet HCP needs in the post COVID era.

Panelists

Joash Lazarus, MD, Neurologist, Multiple Sclerosis Center of Atlanta

James Pratty, MD, Assistant Clinical Professor, Psychiatry, University of California, Riverside

Melissa Mitchell, PharmD, Senior Clinical Pharmacist – Special Projects, PGY2 Psychiatric Pharmacy Residency Program Director, RUHS-Medical Center

Joshua Sabari, MD, Attending Physician, Thoracic Medical Oncology, Assistant Professor of Medicine, NYU Langone Health, Perlmutter Cancer Center

10:00-11:15AM

Session 4: BREAKOUT SESSIONS

Track 1: Leveraging Technology to Satisfy Shifting Customer Expectations in the Digital Era: Best Practice Examples and Compliance Considerations

Session Chair

Marie-Ange Noue, PhD, Senior Director, Medical Information, EMD Serono, Canada

During this session, panelists will discuss and share best practices, customer insights, experiences, and key learnings related to the adoption of innovative technologies by medical communication teams to disseminate scientific content in a novel and compliant manner.

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

- Identify different innovative content formats for adapting medical information service offerings to the evolving needs of customers in the digital era
- Explain the perceived benefit to HCPs of various content formats
- Develop of internal processes to allow for compliant adoption of innovative formats to better address customers' expectations for accessing medical information

From Traditional to Innovative Content Format and Technologies for Delivering Scientific Information

John Jones, Information Technology SME, PhactMI

Combining Chat Bot and Live Chat to Increase Ease of Access to Product Information: a Case Study

Sandeep Gantotti, CMPP, Senior Director, Medical Solutions, Indegene Lifesystems, India

Regulatory and Compliance Considerations for the Adoption of Innovative Technologies by Medical Information

Stephen Li, MBA, Vice President, Regulatory Affairs, Karyopharm Therapeutics Inc.

Track 2: End-to-End Messaging in Medical Writers

Session Chair

Ruggero Galici, PhD, Associate Director, Medical Writing, Pfizer, Inc

End-to-end messaging ties what we are doing now to what we want to achieve in the end, which is the approved label in the pharmaceutical industry. This session will describe a roadmap and will highlight the key steps and documents that make up the pathway from early drug development to approval. How do our documents contribute to the messaging pathway as knowledge is gained over time? In today's environment, the pressure to accelerate the process means we must plan early and pre-populate submission documents before final data release, then work in parallel to complete them. Understanding the End-to-End messaging pathway and how it relates to decision points during drug development is important for successful regulatory submissions and publications

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

- Describe the basic end-to-end message pathway
- Utilize decision point roadmap
- Recognize where project work lies in the decision point pathway and which documents affect it.
- End-to-end Messaging and the Decision Point Roadmap

Becky Nuttall, BSN, Medical Writer, Director, Pfizer, Inc

Track 3: Augmented Efficiency - Showcasing Field Medical Value through Artificial Intelligence and Natural Language Processing

Session Co-Chairs

Joshua Corriveau, PharmD, MBA, Global Medical Director, LEO Pharma

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

Case study discussion focused on real world examples of integrating Artificial Intelligence (AI) and Natural Language Processing (NLP) into medical affairs organizations to efficiently identify trends and emerging signals from medical insights. Participants will learn innovative ways to analyze medical insights to showcase field medical value and impact medical strategy. Presenters will share candid perspectives to help participants in navigating the growing pains of incorporating AI & NLP into their medical affairs organizations.

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

- Describe role of AI and NLP in analyzing field medical insights to impact medical strategy and showcase medical value
- Identify valuable best practices and tactics shared through the 2 case examples that could be incorporated into their organizations
- Apply learnings to foster innovation and efficiency in their medical affairs organization

Speakers

Avikk Ghose, MBA, CEO, Kernel

Bo Trinh, PharmD, Regional MSL Director, Lundbeck

Kay Uttech, PharmD, MA, RPh, Vice President, Strategic Initiatives, Indegene

William Strickland, PharmD, Senior Director, Medical Affairs Operations & Communications, Elevar Therapeutics

11:15AM-12:15PM

BREAK / Visit the Virtual Exhibit Hall

12:15-1:30PM

Session 5: BREAKOUT SESSIONS

Track 1 and **3**: So You've Got Insights, Now What?

Session Co-Chairs

Dannis Chang, PharmD, Senior Director, Medical Communications and Operations, Myovant Sciences

Joshua Corriveau, PharmD, MBA, Global Medical Director, LEO Pharma

Medical Affairs is uniquely positioned to understand the patient and physician barriers at each step, helping to illuminate needs that can then inform strategic and tactical plans across the organization. Collecting information and generating quantitative metrics is the 'easiest' part of the insight process. Linking the insight to some relevant strategic action is the hardest part—what trends can we anticipate to better exceed the expectations of our key external and internal stakeholders?

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

- Describe how to capture customer insights involving clinical practice dynamics
- Build a cross-functional forum to foster discussion of insights and create clear accountability to implement changes to strategy or new tactics
- Establish common frameworks to consolidate insights across functions to maximize the strategic impact of medical insights

Panelists

Richard Ho, PhD, MS, Co-Founder, Javelin Bioscience

Robin Winter-Sperry, MD, Global Field Medical Lead, Ipsen Bioscience

Mary Alice Dwyer, PharmD, Vice President, US, Syntec Life Sciences

Annette Ogbu, PharmD, MBA, Director, Field Medical Affairs, Lundbeck

Track 2: Labeling Across Borders, Audiences, and Technologies

Session Chair

Dan Benau, PhD, Director, Biomedical Writing Programs, University of the Sciences

This session will provide an overview of labeling for prescription medicines and efforts to expand its audience to patients as well as prescribers. It will highlight the global influences and mechanisms in pharmaceutical product labeling and consider the possible uses of technology.

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

- Identify the changing audiences for labeling of prescription medicines
- Discuss the global influences on essential product information
- Evaluate the promise of certain technology for healthcare product labeling

Adding the Patient to the Audience for Written Information About Prescription Medicines

Cathleen O’Connell, PhD, MS, RPh, Assistant Professor, University of the Sciences

Global Considerations in Pharmaceutical Product Labeling

Cathleen O’Connell, PhD, MS, RPh, Assistant Professor, University of the Sciences, Misher College

Ameesha Batheja, PhD, Director, Regional Regulatory Affairs, Janssen Pharmaceuticals

The Promise Artificial Intelligence in the Drug Labeling Process

Jaquetta Lee, MS, Graduate Student, Medical Writing Intern, University of the Sciences

1:30-2:00PM

BREAK / Visit the Virtual Exhibit Hall

1:40-2:00PM

Q&A Session: Using Type 9 NDA Classification to Accelerate Multiple Approvals for Your Drug Product

Session Chair

David Meats, Associate Director, Global Submissions, Regulatory Services Manager, Synchrogenix, a Certara Company

Have you watched the Using Type 9 NDA Classification to Accelerate Multiple Approvals for Your Drug Product Session On Demand and have questions for the speakers? Now is your chance join the speakers live for interactive questions and answers!

Vibha Kumar, PhD, Associate Principal Regulatory Writer, Synchrogenix, a Certara Company

Elaine Taylor, Vice President, Regulatory Strategy and Policy, Synchrogenix, a Certara Company

2:00-3:15PM

Session 6: BREAKOUT SESSIONS

Track 1: 360 View: Virtual Congresses

Session Chair

Hanady Elhadidy, PharmD, Global Medical Customer Engagement Lead, Bristol-Myers Squibb

This session will provide a holistic view to adapting into a virtual congress environment including perspectives from meeting and events planning, medical inquiry support, medical content, and regulatory/compliance perspective.

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

- Recognize key approaches to adapting to the world of virtual and hybrid conferences
- Consider regulatory and compliance concepts governing virtual interactions
- Identify new ways of working that will enable medical information and content creation in the new environment

Speakers

Katie Koziol, CMP, Director, Business Operations and Client Services, Ashfield Meetings and Events

Colleen Tutella, JD, MSc, Director, Regulatory US Advertising and Promotion, Takeda Pharmaceuticals

Eileen Musser, MBA, Director, USMA Oncology Strategic Operations Genentech

Track 2: Plain Language and Patient Engagement

Session Chair

Sudipta Chakraborty, PhD, Plain Language Summaries Lead, Clinical Trial Transparency Manager, PRA Health Sciences

Current regulatory requirements showcase the global interest in improving clinical trial transparency, including the upcoming implementation of plain language summaries. However, the role of the patient voice should be considered throughout the drug development process. Sponsors may not currently be situated to plan for transparency requirements at earlier stages, including protocol design. In this panel discussion, the audience will hear varying perspectives related to these issues. This will include a scientist who doubles as a patient advocate for her son's rare disease, as well as a non-profit organization geared towards educating the public and patients about the clinical trial process. The panel will also include speakers from 2 major pharmaceutical companies who have set up their organization for success in putting the patient first.

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

- Recognize the importance of patient input earlier and throughout the drug development process
- Identify ways to integrate health literacy and the patient voice into regulatory writing
- Assess how current pharmaceutical companies are already employing patient-forward initiatives

Speakers

Terry Jo Bichell, PhD, MPH, Founder and Director, Consortium for Outcome Measures and Biomarkers for Neurodevelopmental Disorders (COMBINEDBrain)

Laurie Myers, MBA, Global Health Literacy Director, Merck & Co., Inc.

Behtash Bahador, MS, Associate Director, Relationship Management and Development, Center for Information and Study on Clinical Research Participation (CISCRP)

Vivian Larsen, MBA, Associate Director, R&D Patient Engagement Office, Takeda Pharmaceutical Company

Track 3: Mission Launching: Navigating the Challenges to Drive Success

Session Chair

Paul Minne, PharmD, RPh, Director, MSL Team, Neurocrine Biosciences

Almost overnight, working virtually has changed how MSL teams and their leadership tackle medical strategies and initiatives while at the same time keeping their value proposition high. MSLs are frequently shifting gears to build KOL relationships, remap and profile territories, train and certify on new and existing products, and keep up with complex and shifting compliance regulations. This session will take a case series approach to these common tactics and present strategies and practical solutions to overcome barriers to success.

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

- Apply new ways of creating value beyond the face to face meeting
- Develop new ideas and plans for launching new products and team initiatives
- Evaluate priorities around the strategic plan when new challenges arise in the virtual world

Speakers

Kent Christopherson, PhD, Senior National Director, US Medical Affairs, Orchard Therapeutics

Kate Doucette, PhD, Director, MSLs, Amgen, Inc.

Monica Guillory, PharmD, Senior Manager, Medical Affairs Training, Neurocrine Biosciences

3:30-4:30PM

Resident and Fellow Professional Development Session: On Your Mark, Get Set, Innovate!

Session Chair

Stacey Follman, PharmD, Director, Student Affairs, Medical Information, Pfizer, Inc

Innovation is the path to the future. Our organizations/business must continue to evolve in order to stay relevant. New ways of thinking are what help to move our business forward. As a Fellow, your recent education and fresh ideas are welcomed in the industry. At this point in your Fellowship, it is likely that you have been asked to come up with an innovative idea. And it is likely that you felt pressured to deliver something great. When you are called upon to be innovative how do you approach the challenge? Are you able to deliver? Are you praised for your contributions? In this session, using examples from Medical Information, you will establish a practical approach to innovative thinking that you can apply to most any situation.

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

- Use creativity to spark innovation
- Develop a framework that can be used to approach innovative thinking
- Apply innovative thinking to current and future situations

Speaker

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

DAY THREE | WEDNESDAY, MARCH 24

10:00-11:15AM

Session 7: BREAKOUT SESSIONS

Track 1: Podium Pearls

Session Chair

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

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 the clinical impact of medical information, emergency use authorizations, and product launching during a pandemic.

The Clinical Impact of Medical Information: Opinion Survey of Healthcare Professionals

Evelyn Hermes-Desantis, PharmD, Director, Research and Publications, PhactMI

Best Practices for a Global Medical Information Product Launch During COVID-19

Truc Dinh, PharmD, Senior Manager, Medical Information, Gilead Sciences, Inc.

Best Practices for Preparing Medical Information for Emergency Use Authorization (EUA)

Prachee Satpute, Associate Director, Medical Information, Gilead Sciences, Inc.

Track 2: Empowerment: Developing and Retaining Writers Globally

Session Chair

Dan Benau, PhD, Director, Biomedical Writing Programs, University of the Sciences

During the great early 90s writer bolus, companies trained junior writers in house and lost them to enticements from other firms. As these writers age out through retirement, companies are again faced with the expense of training and developing new and less experienced hires. This session will describe thoughts on best practices for maximizing return on this investment.

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

- Differentiate between training and developing junior writers
- Appraise development methods that will help retain newly developing talent
- Plan for maintaining organizational quality through experiential learning and mentoring

Speakers

Mirela Niculita, MD, MSc, Regulatory Services Manager, Synchrogenix, a Certara Company, Canada

Tatyana Wanderer, PhD, Senior Director, Medical Writing, Syros Pharmaceuticals

Nicola Haycock, Manager, Medical Writing, PRA Health Sciences, United Kingdom

Track 3: The New Ecosystem of KOL Engagement

Session Chair

Kevin Appareti, MBA, Senior Director, Global Medical Science Liaisons, Royal Philips

This session will explore the challenges and drivers of a New Ecosystem of Key Opinion Leader Engagement that MSLs and others need to be aware of. We will cover the profound trends transforming healthcare and how these will impact a new approach to identifying KOLs, designing engagement activities, structuring knowledge exchange and ensuring we are aligned with the organization goals and objects. We will look at both Pharmaceutical models as well as Medical Device models of KOL engagement.

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

- Discuss the challenges and drivers of a new ecosystem of Key Opinion Leader Engagement
- Identify ways of identifying KOLs and new designs of engagement activities
- Recognize different KOL engagement models

Speakers

Julia Dmitrieva, MPA, Global MSL and Director of Key Opinion Leader Programs, Royal Philips

Kyle Downey, PharmD, Medical Affairs Executive Director, Seattle/AK Ecosystem, Genentech

Melissa Santiago, PhD, Senior Director, National Lead, Psychiatry Medical Science Liaison Team, Sunovion Pharmaceuticals, Inc.

11:15AM-12:15PM

BREAK / Visit the Virtual Exhibit Hall – View Professional Posters!

11:20-11:40AM

Q&A Session: Writing CSRs and Protocols for Potential Public Release

Session Chair

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

Have you watched the Writing CSRs and Protocols for Potential Public Release session On Demand and have questions for the speakers? Now is your chance join the speakers live for interactive questions and answers!

Pooja Phogat, PhD, Vice President, Head of Development Operations, Kinapse, A Syneos Health Company, India

12:15-1:15PM

Session 8: BREAKOUT SESSIONS

Track 1: Lessons Learned from the AMCP Format

Session Chair

Peter Mollegard, Senior Director, Business Development, Contract Sales and Medical Solutions, IQVIA

In December 2019, the AMCP Format Executive Committee released Format 4.1 after years of assessing how to address the information needs to support pre-approval assessments and budgeting. This important update process included a public comment period during which time stakeholders from the manufacturer, payer, academia, consultancy, and professional association perspectives submitted comments, along with input from the FDA. This Hot Topic session will leave participants with an understanding of the needs behind the recommended updates, and a working knowledge of the differences between 4.0 and 4.1.

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

- Discuss the reasoning behind the AMCP decision to update format 4.0 to 4.1, as opportunities for further improvement
- Recognize the differences between formats 4.0 and 4.1 in the preparation of product dossiers, including the addition of available real-world evidence (RWE) and comparative effectiveness research (CER)
- Plan for the completion of an unapproved product or unapproved use dossier as well as a full AMCP dossier using the 4.1 guidance

Speakers

Katharine Coyle, Senior Consultant, Real-World Insights, Health Economics/Outcomes Research, IQVIA

Paul Petraro, DrSc, MPH, Global Head, Real-World Evidence Analytics Center of Excellence, Boehringer Ingelheim Pharmaceuticals, Inc.

12:15-1:30PM

Track 2: Applying Learning from Rare Disease to Support Diversity in Clinical Trials

Session Chair

Diane Cleverley, PhD, Senior Regulatory Writer, Synchrogenix, a Certara Company

With the advent of patient-focused drug development guidance from the FDA, medical writers can have a hand in crafting protocols and clinical trial materials to include patient advocacy input. The writer will learn how to incorporate advocates' suggestions to enhance patient's ability to enroll and continue to sustain participation in clinical studies, and their quality of experience. Also, to understand how patient input might further benefit special population considerations (cultural, elderly, non-communicative, pediatric, rare-disease, or comorbidities). With a focus on rare disease and application to other special populations based on what we have learned in the rare disease community.

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

- Describe the impact of the patient-focused drug development guidance from the FDA on regulatory medical writing
- Identify special populations that might benefit from patient input
- Apply learnings from rare disease to other special populations for clinical trial registrations

Speakers

Wesley Michael, MBD, President, Rare Patient Voice, LLC

Emily Lemiska, MS, Director of Communication and Educational Programming, US Pain Foundation

Scott Schliebner, MPH, Senior Vice President, Center for Rare Diseases, PRA Health Sciences

Track 3: Why Science Needs More Diversity in Clinical Trials

Session Chair

Lori Mouser, PharmD, Global Head, Medical Customer Engagement, Roche, Switzerland

This session will focus on the scientific rationale for driving for more diversity in clinical trial programs. Ideas for how to ensure more diverse populations of patients have access to clinical trials as an option to treatment will be shared. Presenters will explore the role field teams can play in engaging with clinical trial sites.

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

- Identify examples of where race or gender differences lead to divergent clinical outcomes.
- Identify reasons why broadening the diversity of patients across clinical trial programs is needed.
- Describe how field medical teams can support clinical trial sites in patient screening and enrollment.

Speakers

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

Nicole Richie, PhD, Global Head Health Equity and Population Science, Clinical Development, Genentech

Bethsheba Johnson, MSN, Senior Director, HIV Prevention Field Director Western US, Gilead Sciences, Inc.

1:30-2:00PM

BREAK / Visit the Virtual Exhibit Hall

2:00-2:30PM

Community Update and Closing Remarks

J. Lynn Bass, PharmD, RPh, Senior Director, Head of Medical Science Liaisons, Mesoblast Limited

Ruggero Galici, PhD, Associate Director, Medical Writing, Pfizer, Inc

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

2:30PM

Forum Adjourns

ON DEMAND SESSIONS

In order to remain flexible in this virtual environment, we have decided to pre-record a library of BRAND NEW Sessions that you can view at a time that works for your schedule! If you are an early riser, a night owl, or joining us from a different time zone, our live sessions may not always be convenient for you. Therefore, you can enjoy our On Demand Library at any time! We do encourage you to look through the agenda as there are some On Demand Session Speakers who will be participating in live Q&A throughout the forum. Enjoy! *Please note: No CE is available for On-Demand session recordings.*

On Demand 1 Track 2: The RACE Act: Implications for Pediatric Clinical Development

Session Chair

Sudipta Chakraborty, PhD, Plain Language Summaries Lead, Clinical Trial Transparency Manager, PRA Health Sciences

The Research to Accelerate Cures and Equity (RACE) for Children Act mandates that all sponsors developing targeted cancer treatments in adults must also do so for children with cancer. This act updates the already existing Pediatric Research Equity Act (PREA) by requiring pediatric evaluations when the molecular targets of investigational products are relevant to childhood cancers. The RACE for Children Act also removes the Orphan Designation exemption of pediatric trials. While the RACE for Children Act was enacted in August 2017, it recently went into effect in August 2020. In this on-demand session, the audience will learn more about the implications of the RACE for Children Act on the current landscape of pediatric clinical development. This session will include insights from both a CRO and from the patient advocacy perspective, as collaboration between industry and public partners will be essential to accommodate the shift in oncology drug development due to the RACE Act.

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

- Identify the impact of the RACE Act on oncology clinical development
- Discuss ways that the RACE Act affects medical writing and regulatory affairs
- Recognize the importance of patient advocacy groups and public partners in facilitating the shift in pediatric clinical development due to the RACE Act

Speaker

Jacqui Whiteway, PhD, Senior Director, Center for Pediatric Clinical Development, PRA Health Sciences, Canada

On Demand 2 Track 2: Writing CSRs and Protocols for Potential Public Release

Session Chair

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

Due to the impact of the current global pandemic, clinical trial transparency has become more important than ever. Prior to the COVID-19 pandemic, health authorities were already focused on clinical trial disclosure and transparency initiatives; however, with the pandemic the public-at-large and layperson have become familiar with clinical trial vernacular and are demanding access to clinical trial information. In order to encourage trial participation and successful launch of approved products, access to and transparency in clinical trial documents, particularly the Protocol and Clinical Study Report, have become a critical component in the global public health response. This session will explore the how, when, why, what, and where of disclosing study protocols and trial results to the general public as well as the HRA "Make it Public" initiative and the FDA penalties for not following the regulation.

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

- Understand disclosure regulations and requirements as they relate to clinical trial documents
- Know when and how to submit study protocols and trial results for public consumption
- How to prepare the information to be digested by the average layperson

Bringing Clinical Trial Conduct and Reporting to the Dinner Table

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

Regulations Governing Public Disclosure of Clinical Trial Documents

Pooja Phogat, PhD, Vice President, Head of Development Operations, Kinapse, A Syneos Health Company, India

On Demand 3 Track 2: Using Type 9 NDA Classification to Accelerate Multiple Approvals for Your Drug Product

Session Chair

David Meats, Associate Director, Global Submissions, Regulatory Services Manager, Synchrogenix, a Certara Company

This session describes FDA's policy regarding US NDA classification codes, Types of NDAs, and Type 9 NDAs in specific. Session attendees will learn the submission process of Type 9 NDA submissions compared to other submission types. Furthermore, the benefits and risks associated with the Type 9 NDA process will be discussed.

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

- Recognize the different types of US NDA classification codes
- Understand the risks and benefits of a Type 9 NDA submission
- Judge if a Type 9 submission is right for your product

Speakers

Vibha Kumar, PhD, Associate Principal Regulatory Writer, Synchrogenix, a Certara Company

Elaine Taylor, Vice President, Regulatory Strategy and Policy, Synchrogenix, a Certara Company

Earn while you Lean at the 2021 Medical Affairs and Scientific Communications Forum

There are several opportunities for you to win prizes while exploring the platform, getting to know our exhibitors, and meeting each other. **The best part, you can keep the monetary prize or pay it forward!** If you wish, we will donate to a registered U.S. Charity in your name. You can search [here](#) for eligible organizations.

THREE OPPORTUNITIES TO WIN

#1 - Highest Overall Score

First Prize = \$200 gift card* **Second Prize** = \$100 gift card* **Third Prize** = \$50 gift card*

Keep an eye on the leaderboard to see who is on top!

How To Earn Points:

Action	Occurrence	Points
Meet with an Exhibitor	Every time	10 pts
Participate in a group video meeting	Every time	10 pts
Request Info from Exhibitor	Every time	10 pts
Watch exhibitor/sponsor videos	Every time	10 pts
Download exhibitor/sponsor files	Every time	10 pts
Accept private meeting	Every time	10 pts
Request private meeting	Every time	10 pts
Post photo in forum	Only Once	10 pts
Send private message	Only Once	10 pts
Add profile photo	Only Once	10 pts
Watch a webinar	Every time	5 pts
Post message in discussion	Every time	5 pts
Participate in poll	Every time	5 pts

#2 - Attend Exhibit Sponsored Events - \$125 e-gift card*

Attend an exhibit sponsored event such as Happy Hour, Coffee Corner, Roundtable, Case Study Spotlight. Note that separate sign-ups are required. Each attendance = 1 entry to win. Winner will be drawn at random.

#3 – Leave your Business Card at the Exhibitor Booths! If you “Leave your Card” with an exhibitor you will be entered for a chance to win - \$125 e-gift card*

Each time you leave your card with an exhibitor (1x per booth) you will have another entry to win. Winners will be drawn at random.

EARN POINTS STARTING MARCH 15TH - MARCH 22ND

If you have any questions, please contact [Patti Shaughnessy](#).

NOTE - Exhibitors and DIA staff are not eligible for prizes. The Highest Overall Score will be awarded to the top 3 eligible users.

*Winner can select from the following e-gift cards: Amazon, Apple, Barnes and Noble, Bath and Body Works, Best Buy, Chipotle, Google Play, GrubHub, Lowes, Lyft, Netflix, Starbucks, Uber Eats, Whole Foods. [Click here](#) to view all available e-gift cards available.