• The Westin Boston Seaport District

Mar 10, 2025 8:00 AM - Mar 12, 2025 12:30 PM 425 Summer Street, Boston, MA 02210, USA

Medical Affairs and Scientific Communications Forum

The longest running neutral forum cultivating interdepartmental relationships in medical affairs.



Print Agenda

Day 1 Mar 10, 2025

7:30 AM - 8:00 AM

Grand Ballroom Foyer

Short Course and Executive Forum Registration

8:00 AM - 12:00 PM

Medical Affairs Executive Forum

8:00 AM — 12:00 PM

Short Course: Medical Communications: Compliance in 2025

Speaker(s)



Instructor

Kari Loeser, JD

Vice President, Chief Compliance Officer
Cytokinetics, United States

Kari is Vice President and Chief Compliance Officer for Cytokinetics, Inc., where she provides executive management, direction, and oversight for all aspects of the compliance program, policies, monitoring, training, privacy, and brandlegal advisory. Previously, Kari was the US Healthcare Compliance and Privacy Officer and Senior Corporate Counsel at Vifor Pharma, Inc., and a Senior Director/Senior Compliance Counsel at Jazz Pharmaceuticals. She has extensive experience in providing legal and compliance advice on sales, marketing, promotional and medical materials review, Medical Affairs, managed care, commercial compliance, as well as U.S. Sunshine / aggregate spend and compliance operations.



Instructor

Gary Messplay, JD

Partner
King & Spalding, LLP, United States

Gary Messplay is a Partner in the Washington, D.C., office of King & Spalding. He represents life sciences clients before the Food and Drug Administration (FDA), Drug Enforcement Agency (DEA), and other federal and state agencies. Mr. Messplay's practice includes regulatory and administrative law matters, clinical trials, criminal and civil enforcement matters, healthcare compliance, internal investigations, litigation, liability counseling, and transactional work related to pharmaceutical products. He has written extensively about pharmaceutical compliance issues and is a frequent speaker on regulatory and compliance matters. He is a member of the Food and Drug Law Institute, where he serves on FDLI's Editorial Advisory Board.

11:00 AM — 5:30 PM

Grand Ballroom Foyer

Forum Registration

12:00 PM — 1:00 PM Grand Ballroom AB

1:00 PM — 1:30 PM Grand Ballroom CDE

Welcoming Remarks and Fellow Poster Program Overview

Welcoming Remarks, DIA Community Update, and Fellow Poster Program Overview

Track: General Session

Session Chair(s)

Tamei Elliott, MS Director, Global Scientific Content DIA, United States

Tamei Elliott, MS, serves as the Associate Director of Scientific Programs for the Americas region at DIA. In this pivotal role, she is responsible for identifying and prioritizing content areas and topics crucial to DIA constituents. Tamei assesses the implications of significant regulatory and health policy changes, seamlessly integrating relevant content into the development and advancement of DIA conferences and courses. Her responsibilities extend to overseeing content development and strategy within the Americas region.

Speaker(s)



Speaker

Whitney Hung, PharmD

Director, Medical Information Scientific Engagement J&J Innovative Medicine , United States

1:30 PM — 2:15 PM Grand Ballroom CDE

Session 1: Opening Keynote Address - Bridging the Gap:
Transforming Complex Science into Impactful Digital Public
Health Communications

The digital landscape has revolutionized how scientific information reaches and influences public health decisions. This keynote explores innovative approaches to amplifying scientific messages across social media platforms and digital channels. Drawing from evidence-based strategies and emerging trends, we'll examine how medical affairs professionals can leverage digital tools to transform complex research into engaging, shareable content while maintaining scientific integrity. Attendees will gain practical insights into creating impactful digital narratives that extend reach, foster engagement, and drive meaningful public health outcomes in today's connected world.

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

- Discuss innovative approaches to increase scientific messages across social media
- Recognize the digital tools used to transform complex research into engaging, shareable content while maintaining scientific integrity

Track: General Session

Session Chair(s)



Speaker(s)



Keynote Speaker

Jessica Steier, DrPH, PMP

Founder and Host
Unbiased Science, United States

Dr. Jessica Steier is a public health scientist and health services researcher with expertise in health policy evaluation. She is the CEO of Vital Statistics Consulting, a data science consultancy, and founder and host of Unbiased Science, a science communication brand. She is also the executive director of The Science Literacy Lab, a non-profit organization aimed at improving health and science literacy and empowering people to make informed decisions that impact their well-being. Dr. Steier received her Master of Public Health (Evaluative Sciences) at SUNY-Stony Brook University and her Doctor of Public Health degree from the Graduate Center at the City University of New York (CUNY).

2:15 PM — 3:00 PM Grand Ballroom AB

Networking Break in the Exhibit Hall

Hosted Session/Non-CE: Case Study Spotlight hosted by Alliant: Al and Medical Affairs: Tactical Ways Al Can Help Your Day to Day

Join alliant leaders Amy Flynn and Chris Stephenson as they show you practical ways to use AI and automation to support medical affairs activities. You'll see how AI tools can make your daily work easier, developing, managing and analyzing content medical content. Learn how these tools can help medical writers get started faster, find information more easily, and cut down on repetitive tasks.

They'll share solutions you can use right away across your organization to streamline work and make better decisions. DIA Members will leave with practical ways to use AI for documentation, analysis, and planning that will save time, work better, and show clear benefits.

Featured Topics

Accelerate medical writers' content development with Al-powered frameworks and templates that provide robust foundations for new projects and documentation

Transform information gathering through intelligent search capabilities that quickly surface relevant medical content, research, and educational materials from diverse sources

Streamline workflows by automating time-consuming routine tasks while enabling sophisticated analysis of medical data and content, allowing writers to focus on high-value strategic work

Track: Hosted Session

Session Chair(s)



Sponsored Sessions

United States

Speaker(s)



Speaker Amy Flynn

Managing Director Alliant, United States

Speaker

Chris Stephenson



3:00 PM — 4:00 PM Grand Ballroom CDE

Session 2 Track 1: Elevate and Lead: Upskilling Medical Information Professionals for Dynamic Career Growth

This insightful session will focus on empowering medical communication professionals to navigate and overcome contemporary challenges in their field. This session will delve into strategies for career development amidst evolving industry landscapes, fostering essential leadership skills, and leveraging personal strengths and values to drive professional growth. Attendees will gain practical tools and knowledge to enhance their capabilities, ensuring they remain agile and effective in their roles.

Learning Objective:

- Identify current career development challenges faced by medical communications team and strategies/tools to
 address
- Describe insights and best practices for professional growth in a rapidly changing industry
- Illustrate the development of leadership skills by helping participants understand and leverage their personal strengths and values

Track: Medical Communications

Session Chair(s)

Elizabeth Froom, PharmD, RPh
Senior Director, Medical Writing and Healthcare Communications
PPD, United States

Elizabeth C. Froom, PharmD, is a Senior Director in the Medical Writing and Healthcare
Communications team at PPD. She has over 20 years of medical information and writing
experience. In her role she provides strategic direction and oversight to a global team of medical writers who deliver
medical information services including standard response documents, custom responses, Academy of Managed Care
Pharmacy (AMCP) dossiers, infographics, and promotional review. Her educational background includes a BS in
pharmacy and a PharmD from the University of South Carolina College of Pharmacy.

Speaker(s)



Elevate and Lead: Upskilling Medical Professionals for Dynamic Career Growth

Purvi Dunn, MEd, MPA, PMP

Director, Capability Building Leadership Excellence EMD Serono, United States

As the Director of Leadership Excellence, Purvi builds leadership capability within medical and commercial teams at EMD Serono, a critical investment in enhancing current and future leaders' skills, abilities and confidence. Purvi brings 20+ years' experience, most recently 7 years as a Senior Executive Consultant at the FDA, helping the agency develop their leadership development strategy and approach. As an ICF-certified coach, Purvi has worked with leaders at all levels, helping them gain important insights and empowering them to operationalize who they want to be as leaders. Purvi holds a BS in Health Science from the Univ. of Texas HSC, a MEd in Public Health Ed from Univ. of Houston, and a MPA from George Mason Univ.



Challenges and Tools

Dave Bezick, RN

Senior Director Medical Information
Propharma, United States

Dave brings over 14 years of Medical Information Contact Center Management and Operations experience. A licensed Registered Nurse, he began his career as a front-line Medical Information Specialist and has continually advanced into roles of increasing responsibility within the Medical Affairs industry. He is currently the Senior Director, Medical Information Service Delivery (Operations and Account Management) at ProPharma. Dave's passion for the patient and HCP experience is evident in his approach to staff selection, employee development and operational excellence of his teams.

3:00 PM - 4:00 PM

Commonwealth Ballroom C

Session 2 Track 2: Strategic Protocol Design and Patient Engagement in Clinical Research

This session will focus on the critical aspects of writing clinical research protocols while discussing the increasing importance of patient engagement in the process. Attendees will explore strategic protocol design that incorporates clinical program considerations, regulatory compliance, and patient advocacy, all aimed at optimizing clinical study outcomes.

We will first take a general look at how cross-functional collaboration, including research and development, clinical, regulatory affairs, and patient advocacy groups can result in the development of a robust, regulatory-compliant study design, while enhancing protocol efficiency and increasing the probability of success. Then we will take a deeper dive into the practical application of one regulatory guidance in particular, FDA's Patient-Focused Drug Development Guidance, showcasing how incorporating patient input can mitigate enrollment challenges and lead to more effective clinical trials.

A case study describing the use of Patient Advisory Groups (PAGs) will demonstrate the tangible impact of patient perspectives on study design. Attendees will leave with practical tools and strategies to enhance their protocol writing and foster patient engagement in clinical research.

Learning Objective:

- Demonstrate how to effectively integrate clinical program considerations, regulatory requirements, and patientcentered approaches
- Discuss methods for fostering collaboration between research and development, clinical, regulatory affairs teams, and patient advocacy groups
- Describe key aspects of the FDA's Patient-Focused Drug Development Guidance series
- Identify strategies to enhance patient engagement

Track: Medical Writing

Session Chair(s)

Elizabeth Brown, MS, PMP

Executive Director, Medical Writing & Disclosure

Merck & Co., Inc., United States

Elizabeth Brown is an Executive Director in Medical Writing & Disclosure at Merck & Co, Inc. near Philadelphia, PA. She has led regulatory projects and initiatives in the pharmaceutical industry for 20+ years, as a laboratory scientist, a clinical researcher, a medical writer and an organizational leader. With her project and people management focus, she has developed a passion for developing people, advising teams, and providing strategic guidance how to create efficient, effective, and high-quality scientific communication deliverables.

Speaker(s)



Strategic Protocol Design: Clinical Program
Considerations, Regulatory Compliance, Patient
Advocacy, and Efficient Writing

Ana Magalhaes

Senior Manager, Medical Writing, Clinical Business Solutions Precision for Medicine, United States

Ana Magalhaes is a Senior Manager of Medical Writing at Precision for Medicine with over a decade of clinical trial experience, specializing in documentation and regulatory compliance. Leveraging an academic foundation in clinical research, health sciences, and statistics, Ana optimizes clinical trial processes through the development of regulatory documentation, ensuring consistency and efficiencies from study initiation to completion. Ana has a proven track record in translating complex scientific data into clear and concise protocols that are tailored to address the unique challenges of oncology and rare indications, meet regulatory requirements, and facilitate successful study execution.



From Guidance to Practice: Enhancing Patient Engagement and Clinical Trial Design with FDA Guidance

Samantha Winders, BSN, PhD, RN

Regulatory Medical Writer Aroga Biosciences, United States

Samantha Winders is a Regulatory Medical Writer at Aroga Biosciences, dedicated to advancing symptom management and enhancing scientific communication. She holds a PhD in Nursing Science from the University of Florida and completed a postdoctoral fellowship at the University of Washington. During her fellowship, her research focused on self-management strategies for individuals with Inflammatory Bowel Disease (IBD), with an emphasis on factors affecting sleep and overall well-being in this population.

3:00 PM - 4:00 PM

Commonwealth Ballroom B

Session 2 Track 3: Demonstrating Value and Impact

To create both value and impact, individuals or teams must focus on achieving results that deliver immediate benefits (value) while also driving long-term, transformative outcomes (impact). Striking a balance between delivering exceptional results now and shaping future success is key. By dedicating efforts to meaningful work that addresses current needs while aligning with long-term goals, committing to continuous growth, and fostering strong relationships, individuals can amplify their contributions and influence. In this session, we will explore how the value you provide today can lead to lasting impact.

Learning Objective:

- Evaluate the existing methods for measuring value and impact within the Field Medical Affairs Team, considering both individual and team-level approaches
- Discuss best practices for revolutionizing the measurement of value and impact of Field Medical Affairs Teams
- Identify possibilities to advance the development of immediate and long-term goals to advance this profession- where should we focus in the future

Track: Field Medical

Session Chair(s)

J. Lynn Bass, PharmD, RPh Medical Affairs Lead Mesoblast, United States

In her 25+ years of industry experience, Lynn has served in both individual and leadership positions within Medical Affairs at both large and start-up companies. She is currently Sr. Director, Medical Science Liaisons at BridgeBio, where she is building and leading a field medical team in the rare cardiovascular

therapeutic area. Lynn is a transformative leader with proven excellence in building & developing high performing teams. Along with her leadership positions, Lynn is very active in growing/expanding the MSL profession across the industry and is a frequent invited speaker. She has also authored/ co-authored several MSL surveys highlighting and assessing the MSL role.

Speaker(s)



Speaker

Robin Winter-Sperry, MD

Global Medical Affairs
Scientific Resilience, United States

Dr. Robin Winter-Sperry is currently the Field Medical Excellence, International / Oncology Lead at Pfizer. With roles of increasing responsibility, she was the Global MSL Lead at Ipsen. Prior to joining Ipsen, she was Head, Global Field Based Medical Excellence and Insights at Sanofi Genzyme after joining as VP, Strategy, MS. With extensive consulting experience as President of Scientific Advantage, she's been instrumental in Medical Affairs strategy, operations including mergers, transitions and organizational design. She has pioneered the recognition of MSLs as a specialty in the biopharmaceutical and device industry, responsible for creating and developing many of the industry's leading Medical Affairs and Field Medical teams.



Speaker

Peg Crowley-Nowick, PhD, MBA

President, Medical Affairs Consulting and Head of Medical Affairs
Lumanity, United States

Dr. Crowley-Nowick, is a respected expert in the pharmaceutical industry, bringing nearly 15 years of experience in medical affairs and clinical research. In 2008, Dr. Crowley-Nowick founded Zipher Medical Affairs, Co., LLC., a leading provider of medical affairs strategic consulting & MSL services. She has successfully led late stage biotech & pharma companies through multiple product launches across several therapeutic areas, such as oncology, cardiovascular, and diabetes. Dr. Crowley-Nowick's patient-centric view & drive for improved patient care & outcomes have propelled her to shape the organization based on not only scientific integrity but also continual collaboration with emerging medical stakeholders.



Speaker

Ann Clark, PharmD

Field Director, Ophthalmology Medical Science Liaisons
Genentech, Inc., United States

Ann joined Roche in 2008 and became the Field Director of the Ophthalmology Medical Science Liaisons in 2020. Her first leadership role was in 2017 as Associate Director of the Surgical Devices Liaison Team after the Roche acquisition of Forsight Vision4. The team expanded from 5 to 12 and completed Phase II and III trials for the Port Delivery System with ranibizumab, Genentech's first surgically implanted device. Ann established the team's infrastructure, including Onboarding and training, case support documentation, and KPIs. Before this, she served as

an MSL for the CV/Metabolism and Ophthalmology teams and worked in Medical Communications at Janssen and as an MSL at Bristol-Myers Squibb.

4:10 PM — 5:10 PM Grand Ballroom CDE

Session 3 Track 1: Enhancing Patient Engagement: Developing Toolkits and Digital Approaches

In an era where patient-centricity is paramount, this dynamic session explores cutting-edge strategies to enhance patient engagement, advocacy, and communication, with a special focus on underserved populations. Our expert speakers will delve into the development of practical tools for patient response, innovative digital engagement approaches, and targeted health literacy initiatives. Attendees will gain insights into co-creating materials with diverse patient groups and learn how to effectively bring vital health information directly to communities in need. Join us for an inspiring and informative session that promises to revolutionize your approach to patient communication and advocacy.

Learning Objective:

- Recognize how to effectively implement a comprehensive Patient Response Document Toolkit and leverage digital channels to enhance patient engagement
- Discuss ways to design and execute tailored health literacy and disease awareness programs, co-creating materials
 with diverse patient groups to ensure accessibility and relevance
- Evaluate the impact of innovative patient engagement strategies on health outcomes and satisfaction

Track: Medical Communications

Session Chair(s)

Maria Paula Bautista Acelas, MSc Senior Scientific Project Manager DIA, United States

Maria Paula offers expert scientific content guidance and project management support for DIA's global consortium initiatives and specialty meetings. She is dedicated to ensuring the development and delivery of impactful, patient-centric scientific content that generates evidence to facilitate the integration of innovation in medical product development. She brings experience in public health, patient engagement, and research management. She holds a Master of Science in Health Care Management from Marymount University and a Bachelor of Science in Microbiology and Bioanalysis from Universidad Industrial de Santander, Colombia.

Speaker(s)

Development of a Patient Response Document Toolkit Meera Patel, PharmD

Head of Global Medical Information, Content Bayer, United States

Meera serves as the Head of Global Medical Information, Content at Bayer in Whippany, NJ, where she leads a large, global team responsible for medical information, content strategy and communication, of Bayer's complete pharmaceutical portfolio. Her leadership has driven innovation, including the creation of a dedicated group within Bayer Oncology focused on cutting-edge content and medical insights. Building on over 20 years of pharmaceutical experience, including roles at Johnson & Johnson and Schering-Plough, Meera has participated as a speaker at industry conferences such as DIA Annual and MASC.



Approaches to Enhance Patient Engagement Through Digital Channels

John M. Shea, MD, PhD

Associate Director, Medical Information EMD Serono, United States

John Shea is an Associate Director of North America Medical Information at EMD Serono, focusing on Oncology products and pipeline. He received his MD/PhD from the Medical University of South Carolina, where his research focus was the role of sphingolipids in signaling in the intersection of pathogens and the immune system. After a residency in Emergency Medicine in Pittsburg, PA, John gravitated towards Medical Communication with particular interests in improving patient health literacy and improving quality and impactful communications among patients, caregivers, and healthcare providers. He's written several nonfiction books on science, heath, and history for grade schoolers and teenagers.

4:10 PM - 5:10 PM

Commonwealth Ballroom C

Session 3 Track 2: Writing for Regulatory Agencies: Leadership in Collaborative Authoring & Interpreting Clinical Study Results

This session explores the complexities involved in writing clinical research results for regulatory submissions, emphasizing the importance of both effective collaborative authoring and accurate interpretation of efficacy data. First, we will provide insights into the leadership role that medical writers must assume in collaborative authoring environments, where tools like SharePoint and Veeva are utilized for document development across functions. Attendees will learn about common pitfalls and strategies for maintaining document quality through effective leadership and communication. Then, we will delve into navigating efficacy data interpretation under the ICH E9 (R1) framework, highlighting how the treatment policy estimand can lead to confounding results. By examining case studies, participants will gain a clearer understanding of how to assess various estimands and their implications for clinical trial outcomes. Overall, this session aims to equip medical writers with practical skills to improve document quality and efficacy data analysis critical for regulatory submissions.

Learning Objective:

- Recognize the common pitfalls of collaborative authoring and propose strategies for effective workflows
- Describe the essential leadership qualities required for medical writers to maintain high-quality, on-time deliverables
- Identify when application of the ICH E9 (R1) preferred estimand (Treatment Policy) leads to confounding of results
- Discuss practical solutions to enhance collaborative authoring processes

Track: Medical Writing

Session Chair(s)



Elizabeth Brown is an Executive Director in Medical Writing & Disclosure at Merck & Co, Inc. near Philadelphia, PA. She has led regulatory projects and initiatives in the pharmaceutical industry for 20+ years, as a laboratory scientist, a clinical researcher, a medical writer and an organizational leader. With her project and people management focus, she has developed a passion for developing people, advising teams, and providing strategic guidance how to create efficient, effective, and high-quality scientific communication deliverables.

Speaker(s)



Strategic Result Reporting: Medical Writing Process Leadership for Effective Collaborative Authoring Meagan Eldridge, MS

President
Eldridge Writing & Consulting LLC, United States

Prior to starting Eldridge Writing and Consulting in 2023, Meagan served in medical writing positions of increasing responsibility across both the contract and sponsor sides of the industry. Meagan finds her greatest career joys in ongoing partnerships with collaborative teams to produce high-quality clinical and regulatory documents. In addition to writing for any phase of drug development, her growing company is focused on agile medical writing leadership to optimize the document development process, help clients reach their submission goals, and ultimately bring lifechanging therapies to patients.



From Guidance to Practice: How to interpret efficacy data when significance varies by estimand under ICH E9 (R1)

Rebecca Pogue, PhD

Consultant, Regulatory Medical Writing Pogue Writing Solutions LLC, United States After earning her PhD in Immunology and working at an immunotherapy start-up, Rebecca started her medical writing career in 2006. Since then, she has contributed to drug or biologic clinical development programs through a number of medical writing positions across contract research and sponsor organizations. Rebecca particularly enjoys strategic writing, efficacy, submission management, and the collaborative nature of the work. She partners with project teams to produce clear, high-quality regulatory documents with consistent messaging. With over 18 years of experience, Rebecca recently started Pogue Writing Solutions LLC in 2025.

4:10 PM - 5:10 PM

Commonwealth Ballroom B

Session 3 Track 3: Technology: What is New and How Can it make My Job Easier?

This session will review some of new technology and applications field medical can utilize to stay up to date on content within their therapeutic area as well as provide quick responses to thought leaders. We will also explore potential tools to make scheduling and territory management more streamlined. The use of AI will also be explored in how field medical can utilize these tools to generate accurate content for responses.

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

- Identify the applications available to help field medical meet thought leader needs quickly
- Demonstrate tools to streamline business processes
- Recognize and evaluate technology trends to improve responses to requests

Track: Field Medical

Session Chair(s)

Craig Klinger, RPh

Retired Director - Global MSL Trainer, The Office of Medical Professional Develo Eli Lilly and Company, United States

In Craig's more than 30 years working at Lilly, he has successfully worked in various positions in multiple therapeutic areas including neuroscience, diabetes and osteoporosis. Craig is a founding member of the Medical Science Liaison (MSL) program at Lilly where he worked in the New York City Metropolitan area for over 13 years in this field role. Craig spent 6 years as the MSL Trainer for Lilly USA and in 2017 became part of the Office of Medical Professional Development where is he assumed the role of the Global MSL trainer. Craig has been very active in developing benchmarking survey data on MSL standards across the pharmaceutical industry. Craig received the DIA Excellence in Service award in 2021. Craig retired from Lilly in 2024.

Iris Tam, PharmD

Senior Vice President and Head, Medical Affairs and HEOR COEUS, United States



AMCP Format Executive Committee which oversees the AMCP Format for Formulary Submissions for dossier development, including serving as the Chair.

Speaker(s)



Speaker
Preeti Sule, PhD
Director, Global Scientific Communication

Moderna, United States

With 15+ years in disease pathogenesis and scientific research, Preeti Sule leads scientific communication initiatives to make science clear, engaging, and accessible. She specializes in translating complex data into impactful strategies, ensuring innovative therapies reach the right audiences. Passionate about science for all, she believes it should inform, inspire, and empower. Outside work, Preeti enjoys painting and cooking—and once attempted a three-tier cake that became an abstract masterpiece!



Speaker Tim Jones

Vice President, Strategic Operations, Deployment Solutions Syneos Health, United States

Tim brings more than 18 years of success in corporate strategy, project management, and market research. At Syneos Health, he drives the strategy for customers on how they can utilize data, analytics, and technology to operate more efficiently. Tim spearheads innovation initiatives at Syneos Health to provide cutting edge technology solutions to our customers. He has an excellent history of applying marketing methodologies and data analytics to shape operational strategies and reduce customer costs.

5:10 PM — 6:30 PM

Poster Reception in the Exhibit Hall - View Fellow Posters!

7:30 AM — 8:00 AM Grand Ballroom AB

Networking Breakfast in the Exhibit Hall

7:30 AM - 5:00 PM

Grand Ballroom Foyer

Registration

8:00 AM - 8:20 AM

Grand Ballroom CDE

Welcome Presentation of the Excellence in Service Awards, and DIA Community Update

Congratulations to our three 2025 Excellence in Service Awardees!

Evelyn Hermes-DeSantis, PharmD, Director, Research and Publications, phactMI

Stacey Fung, PharmD, Head, Global Medical Information, Gilead Sciences

Diane Cleverley, PhD, Associate Principal Regulatory Writer, Certara

Track: General Session

Session Chair(s)

Tamei Elliott, MS Director, Global Scientific Content DIA, United States

Tamei Elliott, MS, serves as the Associate Director of Scientific Programs for the Americas region at DIA. In this pivotal role, she is responsible for identifying and prioritizing content areas and topics crucial to DIA constituents. Tamei assesses the implications of significant regulatory and health policy changes, seamlessly integrating relevant content into the development and advancement of DIA conferences and courses. Her responsibilities extend to overseeing content development and strategy within the Americas region.

Speaker(s)



Jenny has over 19 years of experience in providing global, multilingual Medical Information and Pharmacovigilance contact center services; holding various roles within Operations, Client Services, Management, and Leadership. Much of her career has focused on designing and delivering Medical Information teams across Europe, MEA, the Asia-Pacific region, and the Americas. Working directly with clients to enable, expand, and evolve services and strategies and was involved with integrating several Pharmacovigilance (PV) acquisitions in Europe and supported the globalization of PV functionality. Jenny obtained her Bachelor of Science (BSc) in Biological Sciences from Bristol University and has lived and worked globally throughout her career.



Speaker

Nimita Limaye, PhD

Research VP, Life Sciences R&D Strategy and Technology, at IDC IDC, United States

Dr. Nimita Limaye leads R&D Strategy and Technology at IDC Health Insights, providing research-based advisory and consulting services on the Life Sciences industry. She represents Healthcare and life science on IDC's AI Council. She is an executive business leader with more than two decades of life sciences leadership experience in the pharma/CRO/tech consulting industry. She focuses on the role of data and technology in transforming drug development, RWD, synthetic data and analyzing and predicting evolving trends in the life sciences industry. Nimita was the chair of the SCDM board, chaired several conferences roundtables, given keynote talks, participated in fireside chats, and authored close to a 100 thought leadership papers.



Speaker
Robin Winter-Sperry, MD
Global Medical Affairs
Scientific Resilience, United States

Dr. Robin Winter-Sperry is currently the Field Medical Excellence, International / Oncology Lead at Pfizer. With roles of increasing responsibility, she was the Global MSL Lead at Ipsen. Prior to joining Ipsen, she was Head, Global Field Based Medical Excellence and Insights at Sanofi Genzyme after joining as VP, Strategy, MS. With extensive consulting experience as President of Scientific Advantage, she's been instrumental in Medical Affairs strategy, operations including mergers, transitions and organizational design. She has pioneered the recognition of MSLs as a specialty in the biopharmaceutical and device industry, responsible for creating and developing many of the industry's leading Medical Affairs and Field Medical teams.

8:20 AM — 9:20 AM Grand Ballroom CDE

Session 4: Plenary Session: Reimagining the World of Medical Writing, MedCom, and Field Medical: AI/GenAI as the Game Changers

This session will discuss how technology players, CROs, and life sciences companies are leveraging Al/GenAl to transform Medical Writing, MedCom, and Field Medical operations. It will dig into some of the implementation challenges, the Al identity threat, change management, key strategies for driving success, and the outcomes achieved.

Learning Objective :

- Identify ways to address challenges in trying to embed AI/GenAI in Medical Writing, MedCom, and Field Medical operations
- Recognize the AI identity threat and how to address the threat
- Identify key strategies for driving success and outcomes achieved

Track: General Session

Session Chair(s)

Nimita Limaye, PhD

Research VP, Life Sciences R&D Strategy and Technology, at IDC IDC, United States

Dr. Nimita Limaye leads R&D Strategy and Technology at IDC Health Insights, providing research-based advisory and consulting services on the Life Sciences industry. She represents Healthcare and life science on IDC's AI Council. She is an executive business leader with more than two decades of life sciences leadership experience in the pharma/CRO/tech consulting industry. She focuses on the role of data and technology in transforming drug development, RWD, synthetic data and analyzing and predicting evolving trends in the life sciences industry. Nimita was the chair of the SCDM board, chaired several conferences roundtables, given keynote talks, participated in fireside chats, and authored close to a 100 thought leadership papers.

Sarah Jarvis, MBA
Global Medical & Evidence Lead
ZS, United States

Sarah Jarvis leads our Global Medical & Evidence consulting space at ZS. Based now in San Francisco, California, Sarah has worked in the lifesciences industry for over 25 years and has focused exclusively on working with medical affairs clients for the past 15 years at ZS. ZS has worked with more than 100 companies' Medical Affairs organizations. Sarah also previously worked at Genentech in a variety of different roles on products that spanned therapy areas and phases of the lifecycle. With COVID acting as an accelerator on the medical function, ZS is partnering with clients to support the growth and change needed to meet global demands - in the field and in headquarters - through strategy, advanced analytics, and operations projects.



Speaker Sidd Bhattacharya, MBA

Partner, Generative AI Leader, Pharma and Life-Sciences PwC. United States



Speaker

Donna A. Holder, PharmD

Executive Director, Head of Digital Strategy and Innovation

Daiichi Sankyo, Inc., United States

Donna Holder has over 30+ yrs experience in the pharma. She is the Executive Director & Head of Digital Strategy and Innovation in Global Oncology Medical Affairs at Daiichi Sankyo where she focuses on implementing digital technology, platform and processes. Previous to that she led Global MSL Excellence at Daiichi Sankyo, Merck & Co, and AstraZeneca. In these roles she drove consistency, standards and the development of tools & processes in Field Medical. Donna has spent the majority of her career in Medical Affairs leading teams across multiple functions. Donna is a PharmD graduate of the University of Michigan.



Speaker
Woo Song
CEO
Xogene, United States

As a seasoned technology entrepreneur and business builder, Woo oversees Xogene's strategic direction as well as the services and technology divisions. Prior to Xogene, Woo co-founded Intrasphere, a technology and services provider to the biopharmaceutical industry, which was acquired by Deloitte Consulting. Woo also co-founded PharmaCM, a leading clinical disclosure platform, now acquired by Citeline. A former derivatives trader, Woo is also a founder of Reval, a global leader of SaaS platform for treasury and risk management with clients and employees in North America, EMEA, and the Asia Pacific, now a part of Ion Group.



Speaker

Jennifer Ghith, MBA, MS

Senior Director, Channel Integration and Innovation Lead, Global Scientific Comm GlaxoSmithKline, United States

Jenny is the Senior Director, Channel Integration and Innovation Lead for the Global Scientific Communications Team at GSK. She drives omnichannel engagement, generative AI advancements, and analytics to transform scientific communications. Previously, Jenny led the Generative AI Content and Innovation Team at Pfizer, pioneering AI-driven content development. Her work resulted in peer-reviewed publications, international presentations, and innovative AI tools. She also developed digital content strategies and health literacy initiatives. Jenny holds an MS in Biology and Immunology and an MBA in Innovation and Leadership. She serves on the ISMPP Board of Trustees and the MAPS Digital Focus Area Working Group.

Session 5 Track 2: How Generative AI is Transforming Medical Writing

This session will discuss how technology players, CROs, and life sciences companies are leveraging Al/GenAl to transform Medical Writing. It will discuss the key use cases that are being implemented, examine the ROI that can be generated, dig into some of the implementation challenges, explore regulatory considerations, change management issues, and how GenAl will completely transform medical writing operations over time.

Learning Objective :

- Discuss which are the use cases that show promise for the implementation of GenAl in Medical Writing
- Describe how to address some of the implementation challenges related to leveraging GenAl in Medical Writing
- Identify how new business models for medical writing will be structured
- Recognize the key strategies for driving and scaling adoption of GenAI in Medical Writing

Track: Medical Writing

Level: Intermediate

Session Chair(s)



Nimita Limaye, PhD

Research VP, Life Sciences R&D Strategy and Technology, at IDC IDC, United States

Dr. Nimita Limaye leads R&D Strategy and Technology at IDC Health Insights, providing research-based advisory and consulting services on the Life Sciences industry. She represents Healthcare and life science on IDC's AI Council. She is an executive business leader with more than two decades of life sciences leadership experience in the pharma/CRO/tech consulting industry. She focuses on the role of data and technology in transforming drug development, RWD, synthetic data and analyzing and predicting evolving trends in the life sciences industry. Nimita was the chair of the SCDM board, chaired several conferences roundtables, given keynote talks, participated in fireside chats, and authored close to a 100 thought leadership papers.

Speaker(s)



Speaker

Julia Forjanic Klapproth, PhD

Senior Partner

Trilogy & Consulting GmbH, Germany

After receiving her PhD in Developmental Neurobiology, Julia became a medical writer in 1997. In 2002, she cofounded Trilogy Writing & Consulting, a company specialized in medical writing of regulatory documentation. She has twice been President of the European Medical Writers Association (EMWA), is an experienced trainer of medical writers, and runs workshops for EMWA, AMWA, DIA, and pharma companies around the world.



Speaker

James Wolfe, PhD, MS

Vice President, Medical Writing Services
PAREXEL, France

> 10 years experience of writing in the pharmaceutical industry. Before joining PAREXEL Medical Writing Services in Jan 2003 he was the Deputy Executive Editor for IMS Health's R&D Focus. James completed a PhD in apoptosis, and then did a Post-Doc in the role of apoptosis in endometriosis.



Speaker

Erica Cave, PhD, MSc

Director, Medical Communications Writing
IQVIA, United Kingdom

Erica is a seasoned leader in medical communications with over 15 years of experience partnering with global medical affairs clients. As the Director for Medical Communications Writing at IQVIA, she spearheads the integration of GenAl across her team of medical writers and strategists, driving advancements in compliance, quality, and efficiency. Erica has a passion for publications, and as well as carrying a CMPP accreditation, she is a member of the ISMPP Publication Practices steering committee. Her combined expertise and innovative approach position her as a pivotal figure in revolutionizing medical communications through cutting-edge technologies.

9:30 AM — 10:45 AM Grand Ballroom CDE

Session 5 Tracks 1 and 3: Revolutionizing Medical Communication: The Power of Artificial Intelligence, Natural Language Processing, and Machine Learning

Dive into the future of medical communication with this cutting-edge session exploring the transformative potential of AI, NLP, and ML technologies. Our expert speakers will guide you through the innovative use of AI in creating medical information content, navigating copyright challenges in an AI-driven world, and mastering the art of crafting precise generative AI prompts. Join us to discover how these technologies can enhance efficiency, accuracy, and creativity in medical communications, positioning you at the forefront of the industry.

Learning Objective :

- Discuss implementing Al-driven tools to streamline the creation of medical information content
- Identify ways to apply best practices for managing copyright issues in Al-generated medical communications

 Recognize how to design and utilize precise generative AI prompts to enhance the clarity and accuracy of medical content

Track: Med Com/Field Medical

Session Chair(s)

John Jones, MBA
Technology Director
PhactMI, United States

John Jones is an experienced IT Strategist focused on developing innovative technology solutions for unmet business needs in Life Sciences. John is currently the Founder and CEO of Entitech Solutions, a Life Sciences focused IT Software and Consulting firm. Prior to starting his company, John led Quintiles' IT Consulting Division from 2010 – 2015 focusing on IT Advisory and Implementation services in Life Sciences. John has more than 20 years experience in developing and delivering IT Solutions for various companies, and has extensive experience in the clinical, regulatory, and commercial areas.

Speaker(s)



Harnessing AI to Revolutionize Medical Information
Content Creation
Stephanie Vezina, PharmD

Medical Information Director, I&I Category Lead/Gen Al Content Lead Pfizer Canada, Canada

Stephanie Vezina is Director of Medical Information at Pfizer, where she currently leads the Inflammation and Immunology Category and is the Gen AI Content Lead. With over 25 years of experience in pharmacy practice and the pharmaceutical industry, Stephanie has gained extensive experience leading teams capable of delivering high-quality, compliant, and customer-focused medical information services. In her current role, she also contributes to the implementation of global Medical Information strategies. As the Gen AI content lead, she focuses on advancing GenAI content transformation and overseeing the development of AI capabilities dedicated to optimize efficiency within her organization.



Copyright for Medical Communications in an AI World Lauren Tulloch

Vice President and Managing Director CCC (Copyright Clearance Center), United States

Lauren Tulloch is Vice President & Managing Director at CCC. In that role, she is responsible for the Corporate Business Unit which includes copyright licenses, the RightFind product suite, and managed knowledge services. Prior, Tulloch held several product management leadership roles in the organization. Before joining CCC, she served as a group publisher at a healthcare education & training company. Tulloch began her career as a newspaper reporter and editor. She holds Bachelor's degrees in journalism and political science from Boston University.



Al for Custom Responses by Medical Information and Field Medical

Simon Johns

Director, Medical Information and Local Affiliate Product Services IQVIA, United Kingdom

Simon Johns has over 25 years of experience supporting global pharmaceutical customer projects. As Director of Medical Information (MI) and Marketed Product Safety at IQVIA, he manages global MI projects focused on process optimization and technology enablement to drive enhanced efficiency and customer engagement. Simon is a member of the European DIA Medical Information and Communications Training Team, advising pharmaceutical companies on best industry practices, innovation and automation. He speaks regularly on topics ranging from combined human and AI conversational agent models for MI to the benefits and increased value of integrating MI and pharmacovigilance.

10:45 AM — 11:30 AM Grand Ballroom AB

Networking Break in the Exhibit Hall

11:30 AM — 12:30 PM Grand Ballroom CDE

Session 6 Track 1: Transforming Engagement: Innovations, Strategies, and Regulations for the Future of Medical Communications

Join us for an engaging session on the future of customer and stakeholder engagement, where experts will share transformative insights into modernizing contact centers, scaling workforce operations and navigating complexities in payer communications. This session will cover groundbreaking advancements in automation and AI, strategic workforce solutions for maintaining excellence amid high call volumes, and the critical regulations that shape communication practices with payers. Attendees will gain a comprehensive understanding of how to optimize operations while prioritizing customer-centric approaches.

Learning Objective:

- Describe the key advancements in contact center technology and explain how these technologies improve customer engagement and operational efficiency
- Outline effective strategies for managing high call volumes, including call deflection and training enhancements, and develop an action plan to apply these techniques in their own organizations
- Discuss key laws and regulations impacting manufacturer-payer communication

Track: Medical Communications

Session Chair(s)

Yvonne Mehta, PharmD Director, Global Medical Information Gilead Sciences, Inc, United States

Yvonne joined Gilead Sciences, Inc in 2011 and currently the Director, Strategic Capabilities lead for Global Medical Information. In this role, she drives strategic planning, business performance, and resource management while ensuring alignment across key stakeholders. She leads a global team to enhance operational excellence, support business innovation and oversee inspection and audit readiness.

Speaker(s)



Evolution of Medical Information Contact Center

Dave Bezick, RN

Senior Director Medical Information

Dave brings over 14 years of Medical Information Contact Center Management and Operations experience. A licensed Registered Nurse, he began his career as a front-line Medical Information Specialist and has continually advanced into roles of increasing responsibility within the Medical Affairs industry. He is currently the Senior Director, Medical Information Service Delivery (Operations and Account Management) at ProPharma. Dave's passion for the patient and HCP experience is evident in his approach to staff selection, employee development and operational excellence of his teams.



Can You Hold Please? Scaling Success: Strategies for Medical Contact Centers Facing High Demand Courtney Phillips, PharmD

Associate Director
Thermo Fisher Scientific, United States

Propharma, United States

Courtney Phillips, PharmD, is an Associate Director on the Medical Communications Operations team at PPD, part of Thermo Fisher Scientific. With over 6 years at the company, she has extensive experience managing small, medium and large medical information contact center programs. In her role, Courtney offers strategic direction and oversight to an operations management team, ensuring that client deliverables and expectations are consistently met.

Courtney received her PharmD from Campbell University College of Pharmacy & Health Sciences.

Demystifying Manufacturers' Communications to Payers



Iris Tam, PharmD, FAMCP, is Senior Vice President & Head of Medical Affairs and HEOR at COEUS Consulting with 34 years of experience in health care, including hospital pharmacy, managed care pharmacy, and the biopharmaceutical industry. In previous industry roles, she led Medical Affairs strategies and tactics that support market access, product value, and patient access, including accountabilities for medical communications, HEOR, AMCP dossiers, compendia submissions, guideline bodies engagement, and payer communications. From 2008 to 2021, Iris served on the AMCP Format Executive Committee which oversees the AMCP Format for Formulary Submissions for dossier development, including serving as the Chair.

11:30 AM - 12:30 PM

Commonwealth Ballroom C

Session 6 Track 2: Optimizing Collaborations: Successes and Learning Opportunities in Medical Writing Partnerships between Sponsors and CROs

This session will provide participants with the essential strategies and tools needed to build and sustain effective partnerships. Whether you are forming a new partnership or looking to strengthen an existing one, this session will help develop practical insights and actionable steps to ensure a successful collaboration.

Learning Objective :

- Define specific roles and responsibilities of a sponsor and a CRO in collaborative partnerships
- Identify ways of fostering trust, respect, and open communication

PPD, United States

 Discuss the importance of establishing processes for resolving disagreements, addressing conflicts early and constructively

Track: Medical Writing

Level: Basic

Session Chair(s)

Elizabeth Olbrich, MS, RN Associate Director

Elizabeth Olbrich, RN, MS, is known for engaging teams through hands-on leadership and conviction to do what it takes to produce quality output and achieve milestones. She has earned reputation for fostering positive vendor/client relationships, establishing and leading teams, and vendor performance turn-around. Elizabeth has provided strategic leadership for global medical writing, CRO partnerships, and quality

control activities. She currently oversees a global medical information program involving 12 medical writers and editors who deliver over 1,000 annual documents while exceeding client KPIs.

Speaker(s)



Partnerships in Medical Writings Sponsor and Consultant Representatives Maureen Piotrowski, MBA

Medical Writer and Consultant
Whitsell Innovations, Inc., United States

Maureen Piotrowski is a Senior Medical Writer and Consultant with Whitsell Innovations. She has over 20 years of biotech and pharmaceutical experience, including clinical trial management, orphan drug development, and regulatory writing. In the 10 years she has been with Whitsell Innovations, Maureen has worked with many bio and pharma clients on regulatory documents, from short term projects to years long collaborations.



Speaker

Krista Crenshaw, MS

Director, Clinical Writing & QC

Alcon, United States

Krista is the Director of Clinical Writing & QC at Alcon in Fort Worth, TX. She leads a global team of medical writers and QC specialists supporting Alcon's clinical trials and submissions for devices and pharmaceuticals. With over 25 years of industry experience and a background in statistics, Krista transitioned to medical writing 10 years ago. She played a key role in moving Alcon from a fully outsourced model to a mixed model for medical writing and QC services. Krista is excited to lead this team into the future with quality and excellence, creating lean processes and utilizing breakthrough technologies to deliver high-quality, regulatory-compliant documents that effectively communicate complex data in a clear and concise manner.

11:30 AM - 12:30 PM

Commonwealth Ballroom B

Session 6 Track 3: Unlocking the Power of Medical Insights to Inform Strategy and Take Action

To help accelerate implementation of clinical evidence into clinical practice, medical insights capabilities must evolve to realize the true value to the healthcare ecosystem. Most organizations can find it a significant challenge to identify real insights and link them to actions to demonstrate their impact. Optimizing data and advanced analytics, along with staff training, will be critical to driving data-driven decisions based upon meaningful insights. In this session, we will explore

how a successful insights capability has the power to create real impact that leverages actionable insights to drive patient outcomes.

Learning Objective:

- Identify ways to evaluate the current methods utilized for collecting and analyzing medical insights within Medical Affairs
- Discuss best practices and inherent challenges when collecting and evaluating medical insights and linking them to actionable data-driven decisions
- Identify areas in the process where technology can help and areas where human touchpoints are needed to contextualize and create meaningful impact

Track: Field Medical

Session Chair(s)

Jim Wilkinson, PhD

U.S. Medical Affairs Lead (Immunology & Payer), Medical Affairs & Evidence Gener Argenx, United States

Jim Wilkinson, PhD is an executive leader in global and US Medical Affairs, with over 20 years in the biopharma industry. Currently at Argenx, his experience includes leading Global/US Medical Information, Global Publications, Global/US Medical Communications, Global Field-Based Medical, and US Medical Science Liaison (MSL) teams. Jim has worked in multiple therapeutic areas while also launching multiple products throughout the course of his career. He has extensive working knowledge of the commercialization process, compliance, product launches, company/product acquisition and integration, legal and regulatory guidelines, operations, digital, and promotional review. Jim received his B.S. from UW-Madison and his Ph.D. from UM-Minneapolis.

Speaker(s)



Speaker
Rico Calara, PhD
Director, Medical Analytics and Insights

Argenx, United States

Rico Calara is a scientist by training with a PhD in Medical Sciences from the Karolinska Institute in Stockholm, Sweden. With 25 years of experience, he has held positions in Target Discovery, Clinical Development, and Medical Affairs. Rico is focused on developing advanced analytics and insights frameworks aimed at enhancing the integration of clinical evidence into practice. He collaborates cross-functionally with teams in Pre-Clinical to Medical Affairs, utilizing AI tools to uncover meaningful insights from complex datasets. His work is instrumental in informing and refining strategic initiatives while simplifying the communication of the value and impact of functional activities to uncover meaningful insights from complex datasets.

Seth Tyree, MS

Senior Director, Product Management Sorcero, United States

I have 18 years experience in healthcare data and analytics, working to generate intelligence across providers, payers and pharma, always with the goal of driving better health outcomes. In my current role at Sorcero, I help Med Affairs teams around the world utilize AI to optimize engagement and drive better care for patients. At GSK, I was Director of Data Science, US Med Affairs. While there, I built a Center of Excellence for Data Science to develop and apply ML and NLP capabilities to accelerate the very manual process of mining unstructured data for insights on customers and patients. As Head of Product at Stratifyd, my remit is to grow our text analytics platform to meet market needs, with a key focus on Medical Affairs.



Speaker

Jason Howard, PhD

Medical Digital Lead
Sanofi, United States

Dr. Howard is currently the Global Medical Digital Lead in the Medical Operations and Effectiveness group in Sanofi Specialty Care. In this capacity, he is responsible for leading a team to evaluate and develop novel digital platforms and processes to support a fully realized Medical Omnichannel strategy. Specifically, these projects have internal impact, such as NLP insight analysis and social media monitoring, or external impact to facilitate HCP access to the right content, on the right channel, at the right time. Every project is informed by his prior experience in the field as an Oncology MSL with a keen focus on improving field efficiency and maximizing HCP value.

12:30 PM — 1:45 PM Grand Ballroom AB

Networking Luncheon in the Exhibit Hall

12:30 PM - 1:45 PM

Commonwealth Ballroom A

Resident and Fellow Professional Development Luncheon: Mastering Effective Communication for Career Success

Join us for an engaging session designed specifically for industry fellows. This session will equip you with essential communication skills to excel in your career transition and beyond. We will focus on the communications around navigating job transitions, time management, and networking. By the end of this session, you'll have practical tools and strategies to communicate confidently and effectively, paving the way for a successful career in the pharmaceutical industry.

Session Chair(s)



Whitney Hung, PharmD

Director, Medical Information Scientific Engagement J&J Innovative Medicine , United States

Robert Tamburri, PharmD, MBA

Director, Medical Information Johnson & Johnson, United States

Rob is a Director of Medical Information at Johnson & Johnson responsible for the overall leadership of the Heme Oncology Medical Information team. His team has a focus on developing responses to medical information requests from HCPs and the provision of medical review for scientific and promotional materials. In addition to his 17 years of pharmaceutical industry experience, Rob also has 11 years of experience as a practicing pharmacist in various pharmacy settings. Rob earned his Bachelor of Science in Pharmacy from Temple University, his Doctor of Pharmacy degree from Shenandoah University, and his MBA from Drexel University.

1:45 PM — 3:00 PM Grand Ballroom CDE

Session 7 Track 1: Podium Pearls

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

Learning Objective:

- Discuss implementing innovative strategies to enhance medical information (MI) contact center operations using AI
- List best practices for posting compliant drug safety communications and drug approvals
- Describe how to develop and utilize databases to provide current ingredient and product-specific information
- Explain ways to evaluate the use of generative AI to assist in the creation of plain language summaries

Track: Medical Communications

Session Chair(s)



Darshan Kulkarni, JD, PharmD, MS

Principal Attorney
The Kulkarni Law Firm, United States

Dr. Kulkarni is Principal Attorney for the Kulkarni Law Firm which focuses on providing legal and regulatory solutions to pharmaceutical companies and their providers. He is a pharmacist & lawyer and advises clients on bringing their product to market, focusing on post IND thru commercialization and genericization.

Christina Nixon, PhD
Senior Director, Medical and Scientific Communications
Alphanumeric, United States

As ever-questioning medical communication professional with an international reputation, I have been communicating science to children, grandmothers, business professionals, government agencies, and scientific experts for more than 15 years. My technical areas of expertise span across infectious disease, immunology, oncology, and vaccines and include content deliverables at all stages within a product's lifecycle.

Speaker(s)



Revolutionizing Customer Experience: Role of AI in Enhancing MI Contact Center Operations

Carolyn Quon, PharmD

VP, Global Medical Information Strategic Operations & Digital Solutions EVERSANA, United States

Carolyn Quon, PharmD is the Vice President of Global Medical Information Strategic Operations & Digital Solutions at EVERSANA. With over two decades of experience in medical information call centers, project management, and client onboarding, she specializes in delivering effective, efficient solutions and exceptional support to pharmaceutical clients. Her expertise includes global medical information strategies, regulatory compliance, medical information systems, performance metrics, customer service, quality programs, and call center development. Carolyn earned her PharmD from USC and completed a specialized residency in drug information at Stanford University. She also holds a bachelor's degree in biochemistry from UC San Diego.



Development of a Database Providing Current Ingredient and Product-Specific Information for Responses to Medical Inquiries

Marc Cataldo, PharmD, RPh

Director, Medical Communications and Stategy Purdue Pharma, United States

The Use of Generative AI to Assist in Authoring of Plain Language Summaries



1:45 PM - 3:00 PM

Commonwealth Ballroom C

Session 7 Track 2: Transparency in Action: Navigating Regulations and Plain Language in Clinical Trial Disclosure

This session explores the evolution of transparency and disclosure regulations, including the newer role of plain language through the recent implementation of the European Union Clinical Trial Regulation 536/2014 (EU-CTR). First, we will provide an overview of transparency and disclosure regulations and how they have evolved over the last decade. Through case studies and lessons learned, attendees will also learn about the challenges of estimating a primary completion dates, in addition to the complexities behind disclosure of innovative trial designs (like an Umbrella trial). Then, we will delve into a discussion on current industry guidelines and best practices related to plain language use in transparency and disclosure deliverables. Overall, this session aims to equip medical writers with a general understanding of current global clinical trial regulations related to transparency and disclosure commitments, including the invaluable use of plain language in driving patient-centric trial communications.

Learning Objective:

- Describe key global regulations related to CTD and disclosure, including the more recent implementation of plain language writing
- Recognize the challenges these present in driving federal and global compliance
- Identify current industry standards and best practice strategies for effectively using plain language in disclosure deliverables in a manner that prioritizes the patient voice

Track: Medical Writing

Session Chair(s)



While working on her PhD, Sudipta discovered her passion for helping the public better understand science. In her first position as a medical writer, Sudipta learned of the new requirements for patient-friendly summaries of clinical trial results. Since then, Sudipta has worked with over 20 sponsors in developing a pipeline of plain language deliverables. She has also built teams that effectively use health literacy and patient-focused strategies in their communications. Currently, Sudipta is a Senior Manager of Clinical Trial Transparency at Biogen, where she oversees transparency commitments and leads initiatives to help Biogen become more patient-centered in their communications.



Navigating Evolving Transparency Regulations:
Challenges and Best Practices as Medical Writers Face
These Complexities

Ritama Gupta Dempsey, PhD

Associate Director, Medical Writing and Disclosure Merck & Co., Inc., United States

Ritama Gupta Dempsey is an Associate Director of Disclosure Medical Writing at Merck & Co., Inc. As the operational head for clinical trial disclosures, she is dedicated to establishing long-term strategies within the evolving transparency landscape. Ritama is passionate about developing talent and building cross-functional relationships with diverse stakeholders to enhance disclosure initiatives. She has a background in academic scientific research and holds a PhD in Immunology and Microbial Pathogenesis from Weill Cornell Graduate School of Medical Sciences.



The Importance of Plain Language Writing in Clinical and Medical Communication
Oladayo Oyelola, PhD

Senior Director and Head Global Clinical Trial Information Disclosure Daiichi Sankyo, Inc. , United States

Dr. Oladayo Oyelola is Senior Director and Head, Clinical Trial Information Disclosure at Daiichi Sankyo. He oversees corporate clinical trial transparency/data sharing strategies and compliance activities; coordinates internal disclosure operations' training, process improvements and trial transparency policy intelligence. He holds a PhD in Clinical Chemistry from Obafemi Awolowo Univ. Ile-Ife, Nigeria, 1990 and received The Rockefeller Foundation Postdoctoral Fellowship, 1991 and National Mentor Role Model Award of Minority Access Inc/Office of Minority Health, NIH, 2001. Dr. Oyelola has over 35 years' experience in biomedical R&D, and certifications by National Registry of Certified Chemists and American Society for Clinical Pathologist

1:45 PM - 3:00 PM

Commonwealth Ballroom B

Session 7 Track 3: Innovation in Medical Affairs: Leveraging Digital Solutions for Data-Driven Decision Making

In an era where data is paramount, Medical Affairs teams are exploring innovative ways to utilize digital capabilities (e.g., Al-powered insights mining, dynamic impact measurement, etc.) to enhance decision-making processes. This session will explore how Medical Affairs teams are using data to identify care gaps, understand Key Opinion Leader (KOL) influence networks, and generate insights to inform engagement planning. We will delve into success stories and challenges faced

by industry leaders on the evolving landscape of digital integration in medical decision-making. The session will culminate in an interactive discussion, where participants will collaboratively address key challenges, explore data utilization strategies, and anticipate future trends that will shape how Medical Affairs increases efficiencies in decision-making.

Learning Objective:

- Identify innovative digital strategies employed by Medical Affairs teams to drive data-driven decision-making
- Discuss real-world success stories and challenges faced by industry leaders in leveraging digital capabilities

Track: Field Medical

Level: Basic

Session Chair(s)



Sanaa Nagji, MD zs, United States

Speaker(s)



Speaker

Calvin Chan, MS

Global Head of Medical Affairs, Insights, Digital, Analytics
Gilead, United States



Speaker

Aaron Tarkinson, MBA

Head of Medical Strategy, Operations & Excellence (North America)
Biogen, United States

Aaron is a seasoned leader in strategy development, program management, and operational excellence. He leads strategic planning and medical excellence for Medical in the U.S. and Canada. He and his team drive key initiatives such as a Generative AI platform for medical insights and impact measurement and a Strategic Territory Planning framework for MSLs. With leadership experience at Biogen and Genzyme, he has led high-impact initiatives, from quality system remediation under FDA consent decree to co-developing three-year medical success horizon strategies. Aaron holds an MBA from Northeastern University and a dual B.S. in Chemical Engineering and Science, Technology & Society from Rensselaer Polytechnic Institute.

3:00 PM — 3:45 PM Grand Ballroom AB

Networking Break in the Exhibit Hall - View Professional Posters

3:45 PM - 5:00 PM

Commonwealth Ballroom C

Session 8 Track 2: The Power of Plain Language: How to Create Clear and Understandable Clinical Trial Communications

With the implementation of recent regulations, the role of plain language in communicating clinical trial information to patients, the public, and regulators has risen to the forefront of transparency and disclosure commitments. From plain language summaries of results and of publications to the new kid on the block (plain language protocol synopses), medical writers must be equipped with the knowledge and skill set to translate technical information into plain language that serves a variety of audiences. In this session, we will explore the ways to effectively produce plain language documents that are fit-for-purpose. Attendees will learn key health literacy principles that highlight the difference between writing for patients and writing for regulators, including challenges in explaining complex ideas like benefit and risk to a lay audience. Then, we will dive into recent updates to regulatory guidances related to informed consent forms (ICFs). This will include tips and tricks to transform ICFs from a legal formality to a meaningful and understandable document that builds trust and empowers patients at the start of their clinical trial journey. Finally, the session will conclude with practical strategies to support the integration of health literacy best practices into the creation of any participant-facing material, as well as an introduction to select resources that advance clear clinical research messaging. Overall, this session aims to empower medical writers with the understanding and skill set required to produce clear, meaningful, and patient-centered clinical trial communications.

Learning Objective :

- Describe key health literacy principles that aim to improve the understanding of clinical trial information
- Discuss how to employ best practices that integrate patient perspectives and readability improvements into documents
- Apply the updated FDA guidance on informed consent documents in a way that positively impacts clinical trial development
- Identify supportive resources that advance the communication of clear clinical research information

Track: Medical Writing

Session Chair(s)



Sudipta Chakraborty, PhD Clinical Trial Transparency Strategy Lead Biogen, United States

While working on her PhD, Sudipta discovered her passion for helping the public better understand science. In her first position as a medical writer, Sudipta learned of the new requirements for patient-friendly summaries of clinical trial results. Since then, Sudipta has worked with over 20 sponsors in developing a pipeline of plain language deliverables. She has also built teams that effectively use health literacy and patient-focused strategies in their communications. Currently, Sudipta is a Senior Manager of Clinical Trial Transparency at Biogen, where she oversees transparency commitments and leads initiatives to help Biogen become more patient-centered in their communications.

Speaker(s)



Communicating with Patients: Challenges and Considerations

Lisa Chamberlain-James, PhD

Senior Partner
Trilogy Writing & Consulting, United States

Lisa Chamberlain James is a Senior Partner and Chief Executive Officer of Trilogy Writing & Consulting. Aside from management activities, she also leads client projects, with extensive experience in a variety of documents and a special interest in drug safety and patient information. After receiving her Ph.D. in Pathology, Lisa began her medical writing career in Cambridge in 2000. Since then, she has been heavily involved in the EMWA on the Education Committee and as a workshop leader, is a visiting lecturer for King's College London, initiated and chaired the EMWA PV and Communicating with the Public SIGs, is chair of the Geoff Hall Scholarship Committee, section editor for Medical Writing, and a Fellow of the Royal Society of Medicine.



Revolutionizing Informed Consent: Empowering Medical Writers to Drive Patient-Centered Change Marialena Davis, PhD, MS

Regulatory Medical Writer Aroga Biosciences, United States



Integrating Health Literacy Concepts into Materials for Participants: Strategies and Resources

Sylvia Baedorf Kassis, MPH

Program Director MRCT Center of Brigham and Women's Hospital and Harvard, United States

Sylvia Baedorf Kassis, MPH has over 25 years of clinical research experience. She currently serves as Program Director at the Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard. Her main foci over the past seven years has been on health literacy, return of results, and patient engagement. Her clinical research interests include integrating study participant experiences into research, supporting research coordinators through networks and training, and ensuring researchers have access to vital information that supports the ethical and

compliant research conduct. Sylvia earned her MPH in Global Health at Boston University School of Public Health (2008) and a BSc at the University of Toronto (2001).

3:45 PM — 5:00 PM Grand Ballroom CDE

Session 8 Tracks 1 and 3: Unlocking Omnichannel Success: Bridging Gaps in Medical Communication and Strategy

This session brings together speakers from Biotech/Pharma, Consulting, and Medical Communications Agencies to explore strategies for successful medical omnichannel transformation. Discussions will focus on the integration of people, processes, and technology to enhance engagement with healthcare providers. Attendees will gain actionable insights to build capabilities, break down siloes, and drive impactful communication and collaboration.

Learning Objective :

- Recognize the people, process, and technology aspects of the strategy to achieve the medical omnichannel transformation
- Identify actionable pathways to advancing medical omnichannel engagement capabilities
- Integrate omnichannel ways of working in day-to-day engagements and collaborations

Track: Med Com/Field Medical

Session Chair(s)



Rachel Kennedy
Sr Dir, Head of Scientific Communications
Moderna Tx, United States

Speaker(s)



Break Down Siloes: Building a Winning Medical

Omnichannel Strategy to Transform HCP Engagement

Jones Jaick, MBA

Associate Principal ZS Associates, United States

Jones is an Associate Partner at ZS Associates, a Global Healthcare Management Consulting Firm and leads the Medical Omnichannel / Digital Transformation Domain. He has over a decade of experience and worked with 20+ pharma organizations across omnichannel / digital domains spanning strategy, technology and analytics. He has supported organizations in areas like digital and omnichannel strategy & roadmapping, technology ecosystems,

digital blueprint and activation, engagement process redesign, omnichannel orchestration, digital analytics and reporting Jones holds an MBA from Washington University in St. Louis and a Bachelors Degree in Electronics and Communication Engineering from Cochin University, India



From Mountain to Molehill: Designing Grassroots Strategies for Medical Omnichannel Transformation Tim Mitchell, PhD

Managing Director, Medical Communications & Innovation Klick Health, United States

Dr. Tim Mitchell is Managing Director of Medical Communications & Innovation at Klick. With a PhD in pharmacology and an honors degree in psychology, he previously conducted and published industry-sponsored research at King's College London before co-founding a global medical communications agency, later acquired. His leadership experience spans Chief Medical Officer roles and oversight of technology, UX, analytics, and engagement strategy teams. Since joining Klick in 2021, he has led the development of high-tech, high-science solutions that transform medical engagement, partnering with global and US medical affairs teams to advance their omnichannel and digital engagement strategies.

Day 3 Mar 12, 2025

8:00 AM — 8:30 AM Grand Ballroom AB

Networking Breakfast in the Exhibit Hall

8:00 AM — 12:30 PM Grand Ballroom Foyer

Registration

8:30 AM — 9:30 AM Grand Ballroom CDE

Session 9 Track 1: The Future of Medical Communication

Join us for an enlightening panel discussion that explores the future of medical communication by breaking down borders and enhancing accessibility to credible medical information for healthcare professionals (HCPs) and patients worldwide.

Discover how MILE (Europe), PVN-MI (Canada), and PhactMI (US) are tackling similar challenges and developing innovative frameworks to improve access to reliable information. Our expert panelists will share their unique perspectives, discuss collaboration opportunities, and offer insights into what the future holds for global medical communication.

Learning Objective:

- Discuss the shared challenges faced in accessing credible medical information across the USA, Canada, and Europe
- Recognize ways to analyze the frameworks developed by MILE, PVN-MI, and PhactMI, and evaluate how these can be adapted or integrated to enhance global access to medical information
- Describe how to formulate strategies for fostering international collaboration

Track: Medical Communications

Session Chair(s)

Joanna Rizos, MBA, RPh Director, Medical Information Eli Lilly Canada Inc., Canada

In her current role, she provides strategic leadership and oversight for activities related to Medical Information and Medical Information Digital solutions. She began her career as a community pharmacist, before joining the Pharmaceutical Advertising Advisory Board (PAAB) as an Assistant Commissioner. She joined Lilly, 25 years ago, first supporting Medical Information before holding various roles in Legal, Sales, Compliance and Medical Affairs. Joanna obtained her B.Sc. in pharmacy from the University of Toronto and her MBA from the Schulich School of Business. Joanna is also a board member of the Pharmacovigilance and Medical Information Network (PVN-MI) Canada.

Speaker(s)



Collaboration Beyond Borders to Make Medical
Information More Easily Accessible Online to HCPs and
Patients Worldwide

Mary K. Sendi, PharmD

Medical Information, Global Content Strategy and US Regional Lead Pfizer Inc, United States

Mary is the Global Content Strategy and US Regional Lead for Pfizer Medical Information [MI]. Mary earned both a Bachelors and Doctorate degree in Pharmacy. Mary has greater than 20 years pharmaceutical industry experience specific to medical information. Outside of Pfizer, Mary is active in advancing the medical information profession through her leadership/collaboration roles in the Drug Information Association and phactMI [Pharma Collaboration for Transparent Medical Information]. Mary is currently serving on the phactMI board of directors for the term 2019-2020.



Breaking Barriers: Global Collaboration for Accessible Medical Information

Michelle Bridenbaker, BSN, MBA, MS

Vice President Medical Information Leaders in Europe Recordati, Switzerland

Michelle is currently the Global Head of Medical Information at Recordati Rare Diseases. She is an advanced practice nurse, toxicologist, and earned her Executive MBA in 2022 and has worked in industry for nearly 20 years in roles including: Medical Device Sales, Med Info, Pharmacovigilance and Medical Affairs. Her most recent areas of interest include increasing the uptake of AI in Med Affairs and in social media strategy for health communication. Michelle is very passionate about Med Info & Med Affairs and is highly motivated by innovative, customer centric ways to support healthcare and non-healthcare professionals around the world to ensure the safe and effective use of medicines.

8:30 AM - 9:30 AM

Commonwealth Ballroom C

Session 9 Track 2: The Future Medical Writer: Adapting, Evolving, Excelling

This interactive workshop explores the evolving role of medical writers in a changing landscape. Through group discussions and hands-on activities, participants will gain insights into emerging trends, new responsibilities, and essential skills for the future medical writer. The session emphasizes the importance of adaptability, continuous learning, and strategic thinking in navigating the evolving field. Participants leave with a clearer understanding of future challenges and opportunities, along with actionable plans to develop/strengthen skills for the new role.

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

- Recognize the evolving role of the medical writer
- Identify key skills essential for future medical writers
- Identify challenges and outline strategies to develop/strengthen skills for the new role

Track: Medical Writing

Session Chair(s)



Fabiana Ebihara has over 19 years of extensive experience in the field of medical writing, with a particular focus on leadership and regulatory medical writing. Throughout her career, Fabiana has held several key leadership positions at Parexel International, where she has played a pivotal role in managing medical writing partnerships with pharmaceutical companies. She provided financial and operational oversight and

led projects covering a range of therapeutic areas. Fabiana has successfully collaborated with her clients, implemented process improvements, and mentored cross-regional teams.

Speaker(s)

8:30 AM - 9:30 AM

Commonwealth Ballroom B

Session 9 Track 3: Field Medical and Engagement with Payers

Session speakers will navigate the journey of a product from clinical development through commercialization, highlighting the diverse responsibilities and critical activities of medical field personnel in driving product value and market access. This session will cover strategies and insights from pre-launch through post-launch and throughout the product lifecycle. Ideal for therapeutic medical science liaisons seeking to enhance their understanding of payer interactions or explore career pathways into field medical market access roles, as well as professionals responsible for shaping medical affairs strategies.

Learning Objective:

- List and explain two essential tools developed by Medical Affairs to effectively communicate product value to payers
- Describe critical topics or activities that Medical Affairs field teams should prioritize to support payer engagement during the pre-approval phase of a pipeline product
- Discuss key strategies for field medical teams to successfully engage with payers and support market access during the launch of a new product and throughout its life cycle

Track: Field Medical

Session Chair(s)

Iris Tam, PharmD
Senior Vice President and Head, Medical Affairs and HEOR
COEUS, United States

Iris Tam, PharmD, FAMCP, is Senior Vice President & Head of Medical Affairs and HEOR at COEUS Consulting with 34 years of experience in health care, including hospital pharmacy, managed care pharmacy, and the biopharmaceutical industry. In previous industry roles, she led Medical Affairs strategies and tactics that support market access, product value, and patient access, including accountabilities for medical communications, HEOR, AMCP dossiers, compendia submissions, guideline bodies engagement, and payer communications. From 2008 to 2021, Iris served on the AMCP Format Executive Committee which oversees the AMCP Format for Formulary Submissions for dossier development, including serving as the Chair.

Speaker(s)



Field Payer Engagement: During the Pre-Approval

Period

Patricia Bourne, PharmD

Senior Director, Medical Sciences Cytokinetics, United States

Patricia Bourne, PharmD, Senior Director, Medical Sciences at Cytokinetics has over 25 years of industry experience leading both therapeutic and managed care field teams. At Cytokinetics, Patricia is responsible for leading the development of medical strategies that support market access and driving field tactics with a goal of patient access and improving patient outcomes. She has owned a retail pharmacy, worked as a clinical pharmacist and Director of Pharmacy Services at a managed care organization giving additional perspectives in healthcare. Before joining Cytokinetics, she led the Medical Affairs' market access strategies at Gilead Sciences across a range of therapeutic areas and population-based decision maker teams.



Account Prioritization and Engagement Strategy

Lee Ding, PharmD, RPh

Senior Director, Medical Value and Outcomes BeiGene, United States

Lee Ding, PharmD, is Senior Director of Field Health Economic Outcomes Research at BeiGene, with over 25 years of managed care experience across health plans, health systems, and the biopharmaceutical industry. He engages with payers, PBMs, and integrated delivery systems to communicate scientific, health economic, and real-world data, aiming to optimize patient access and outcomes. Previously, he spent 18 years at Genentech/Roche, contributing to 10+ NME launches in multiple therapeutic areas. His experience also includes roles at a Blue Cross Blue Shield plan and an integrated delivery system-owned health plan.



Creative Value Story and Evidence Generation Stuart O'Brochta, PharmD

Executive Medical Value and Evidence Liasion, US Medical Affairs Gilead, United States

9:30 AM — 10:15 AM Grand Ballroom AB

Networking Break in the Exhibit Hall

10:15 AM — 11:30 AM Grand Ballroom CDE

Session 10 Track 1: From Misinformation to Clarity: Scientific Storytelling in the Digital Era

In an age of information overload, communicating scientific data in an appealing way that supports understanding is a valuable skill. Through scientific storytelling, medical communications professionals have an effective tool to combat misinformation, foster trust, and expand reach to a broader audience.

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

EVERSANA, United States

- Define the elements needed for an impactful scientific story
- Describe ways to apply principles of scientific storytelling to content development workflows
- Identify opportunities to correct misinformation

Track: Medical Communications

Session Chair(s)

Christina Nixon, PhD
Senior Director, Medical and Scientific Communications
Alphanumeric, United States

As ever-questioning medical communication professional with an international reputation, I have been communicating science to children, grandmothers, business professionals, government agencies, and scientific experts for more than 15 years. My technical areas of expertise span across infectious disease, immunology, oncology, and vaccines and include content deliverables at all stages within a product's lifecycle.

Speaker(s)



Misinformation and What Medical Information Can Do Michael DeLuca, PharmD, MBA, MS, RPh

Executive Vice President, Global Medical Affairs & Medical Information

Michael is the Executive Vice President of Global Medical Affairs and Medical Information at EVERSANA and has 20+ years of healthcare and pharmaceutical industry experience in multiple leadership roles at several pharmaceutical companies. He has extensive experience in medical information, medical communications and in supporting medical review of promotional / non-promotional materials. Throughout his career, Michael has supported multiple product launches, and he has led MI activities from both a US and global perspective. He has led and grown established MI teams and has built a MI department and services from the ground up. His educational background includes Doctor of Pharmacy, MBA, and Master of Science in Regulatory Affairs degrees.



From Complexity to Clarity: Using storytelling for Clear Communication and Combating Misinformation Pooja Srivastava Banerjee, MPharm

Senior Director Krystelis Ltd, India

With 18+ years of experience, Pooja holds a Master's degree in pharmaceutical chemistry and a postgraduate diploma in health communications. She currently leads Medical Communications at Krystelis, managing publications, medico-marketing, and medical education. Pooja specializes in strategic communication for pharma and biotechnology, having worked on public health campaigns, advisory boards, RWEs, and developing consensus statements and clinical guidelines. She has worked with top pharma clients, and other healthcare stakeholders. Pooja is also a published author, having received the PRS Global Open "Best International Collaboration-Gold Award" in 2020. Actively involved as a faculty member in workshops and conferences.



Digital Storytelling for HCPs

Nga Tong, MPH

Director, Medical Information, Communications, and Operations Dynavax, United States

Nga has over 13 years of industry experience ranging from large to medium to small pharma. She had her start in publication writing, and has since then expanded to medical communications and medical information. Her training and background is in public health and prior to joining industry, she was involved in community health in Boston and also spent some time at the WHO in Geneva. She has been involved with the development and commercialization of several vaccines over the course of her industry career and is embracing the challenges in this current environment where vaccines and public health intersections are more important than ever.

10:15 AM - 11:30 AM

Commonwealth Ballroom C

Session 10 Track 2: Bridging Medical Writing Expertise with Technology, Guidelines, and Soft Skills

In this forward-looking session, we will share considerations to developing the future medical writer in an era of automation. We will learn the critical role of seasoned medical writers in harnessing the power of Generative AI (GenAI) and how essential it is to effectively translate their medical writing expertise into machine-friendly prompts, recognizing where AI can effectively be applied in the medical writing process. We will discuss a considerations document for the use of AI in creating plain language trial results summaries, including recommended practices and level of human involvement. This document was developed by representatives from over 15 organizations who have expertise in medical writing, technology, clinical operations, plain language, and patient engagement. During this session we will also learn about the human element and essential soft skills to ensure that AI's output is not only accurate, but also relevant and meaningful. Real-life triumphs and tribulations will be shared to illustrate how navigating prompt writing challenges and bridging communication gaps with programmers relies on these essential soft skills.

Learning Objective:

- Discuss the pivotal role of medical writers translating their expertise into machine-friendly prompts
- Recognize where AI can effectively be applied in the medical writing process
- Identify key considerations to help ensure accurate and appropriate use of AI in creating plain language trial results summaries
- Discuss the interplay between human judgment, soft skills, and AI tools

Track: Medical Writing

Session Chair(s)



Fabiana Ebihara, MSc Director, Medical Writing Services Parexel International, United States

Fabiana Ebihara has over 19 years of extensive experience in the field of medical writing, with a particular focus on leadership and regulatory medical writing. Throughout her career, Fabiana has held several key leadership positions at Parexel International, where she has played a pivotal role in managing medical writing partnerships with pharmaceutical companies. She provided financial and operational oversight and led projects covering a range of therapeutic areas. Fabiana has successfully collaborated with her clients, implemented process improvements, and mentored cross-regional teams.

Speaker(s)



Scaling Up Medical Writers: Effective Strategies to Apply GenAl for Medical Writers Vladimir Penkrat, MBA

Associate Vice President - Regulatory Affairs Indegene, United States

Vladimir Penkrat is AVP of Regulatory Affairs at Indegene. With an MBA in International Business, Vladimir has provided strategic leadership throughout his career across clinical development, biometrics, biostatistics, medical writing, pharmacovigilance, and regulatory affairs. Over the past three decades Vlad worked across top pharma, biotech startups, CROs, and consulting firms. Within the recent 10 yrs, Vlad's passion for regulatory excellence has established process leadership in Regulatory Writing, Submissions Management, Publishing, Labelling, CTT, Consulting, & GenAl innovation as a business. Vlad's leadership has enabled businesses to prepare for digital adeptness & as a business leader he has scaled R&D operations to >500 FTE.



Considerations for the Use of AI in Plain Language Summary Creation

Kimbra Edwards, PhD

Senior Director, Health Communication Services Center for Information & Study on Clinical Research Participation (CISCRP), United States Kim Edwards is the Senior Director of Health Communication Services at the Center for Information and Study on Clinical Research Participation (CISCRP). CISCRP is a non-profit organization focused on increasing awareness and understanding of clinical research participation. Kim oversees the creation of easy-to-understand trial resources for patients, participants, and the public. Kim earned her BS in Neuroscience from Trinity College and PhD in Developmental and Brain Sciences from University of Massachusetts Boston.



Closing the Loop: The Strategic Role of Soft Skills in Al-Driven Storytelling
Jeanette Towles, MA

President and CEO Synterex, Inc., United States

Jeanette Towles, MA, RAC, is the CEO of Synterex, Inc., a woman-owned, disability-owned clinical and regulatory consulting firm specializing in agile-based project management methodology, automation, and AI-driven technologies. Prior to that, she held in-house consulting and FTE medical writing and clinical science positions at both small- and large-size companies, including managing a group of programmers and vendors working on automated documents, with cumulative industry experience of nearly 20 years. She lives in the Boston area with her husband, 2 children, and dog.

10:15 AM - 11:30 AM

Commonwealth Ballroom B

Session 10 Track 3: KOL Engagement Strategies: Best Practices in External Engagement

Field Medical teams are expected to engage external stakeholders to help companies understand and shape clinical understanding and decision making. Expectations of MSL impact shift with lifecycle management changes, from developing opinion leader relationships prior to approval, to managing deeper local HCP engagement in the years post-launch. This session will delve into bast practices in translating strategy into actionable field-medical tactics, emerging approaches in using technology and tools, and improving OL management with an aim of sharing practical tips.

Learning Objective:

- Identify and prioritize KOLs and design engagement activities that align with strategic objectives and product lifecycle stages, ensuring interactions are focused, relevant, and impactful
- Discuss best practices in aligning field medical teams to understand and translate strategy into meaningful opinion leader engagement using advanced technology and tools
- Identify how field medical feedback can inform and influence subsequent field medical strategy

Track: Field Medical

Session Chair(s)



a senior fellow in Medical Genetics at the University of Washington.

Richard Swank is the former head of US Field Medical and Global Field Medical Excellence at Amgen and Founder of Scientific Engagement LLC. He has spent most of his career building medical capabilities in Medical Affairs, including building and managing MSL teams, managing medical information call centers, and improving how medical teams execute and measure field medical performance. He holds a PhD in Biochemistry and Molecular Biology and prior to joining industry completed an NIH Postdoctoral Fellowship and was

Speaker(s)



Speaker

Joanna Gonsalves, PhD

Executive Director, Field Medical Excellence
Amgen, United States

Joanna Gonsalves has 18+years of experience in the bio-pharmaceutical industry. Joanna joined Amgen in April 2010. During her tenure at Amgen Joanna has held a variety of different medical roles in different therapeutic areas. She currently serves as the Head of Field Medical Excellence, where she partners with global field medical teams to empower them with tools, competencies, and culture to be best-in-class today and tomorrow.



Speaker

Vanessa A. Johnson, MS

Executive Director, Head of Global Medical Excellence Gilead Sciences, United States

Vanessa is the Executive Director and Head of Global Medical Excellence at Gilead Sciences. Vanessa has been active in the industry for over 21 years, elevating teams across Medical Affairs, Marketing and Sales functions.



Speaker

Sunil Mehta, PharmD

Senior Vice President, Medical Affairs Annexon Biosciences, United States

11:35 AM - 12:20 PM

Session 11: Closing Plenary: Charting New Courses: Reshaping Opportunities and Breaking the Expert Mold in Career Development

With the rise in pharma and biotech acquisitions, retaining and developing talent in cutting-edge fields is essential for maintaining a competitive edge. However, technical experts often lack opportunities for broader experience, limiting career growth and creating retention challenges. Companies also struggle to cultivate leaders with diverse skills to navigate a complex and evolving business environment. A comprehensive approach is needed to support succession planning and build a sustainable leadership pipeline, particularly in areas that drive competitive advantage. We addressed this challenge by creating opportunities to enhance the career journey of technical experts, moving them beyond their functional roles while developing global career pathways aligned with the organization's growth strategy. Our goal was to develop leaders with the necessary knowledge, skills, and exposure to navigate a complex business ecosystem.

Learning Objective:

- Describe strategies for breaking the "expert trap" and enhancing career growth for technical talent
- Recognize how to align talent development with organizational growth through strategic initiatives
- Identify methods to cultivate a diverse leadership pipeline in life sciences

Track: General Session

Session Chair(s)



Representative Invited FDA, United States

Speaker(s)



Speaker
Sajida Roberson, MBA, MPH
Business Transformation
Independent Consultant, United States

Meet Sajida Roberson, a dynamic consultant blending strategic leadership with hands-on expertise to drive impactful business transformations. With a proven track record in global pharmaceutical companies, Sajida seamlessly transitioned from corporate strategy roles to independent consulting, delivering both visionary solutions and actionable results. Sajida excels in solving complex challenges, streamlining operations, and achieving sustainable outcomes. She brings a broad range of experience in financial optimization, organizational change, and project management, ensuring practical and impactful solutions for her clients. Sajida's approach leverages Agile principles and Lean Six Sigma practices to transition organizations to adaptiv

12:20 PM — 12:30 PM Grand Ballroom CDE

Closing Remarks

Speaker(s)



Speaker

Maria Paula Bautista Acelas, MSc

Senior Scientific Project Manager

DIA, United States

Maria Paula offers expert scientific content guidance and project management support for DIA's global consortium initiatives and specialty meetings. She is dedicated to ensuring the development and delivery of impactful, patient-centric scientific content that generates evidence to facilitate the integration of innovation in medical product development. She brings experience in public health, patient engagement, and research management. She holds a Master of Science in Health Care Management from Marymount University and a Bachelor of Science in Microbiology and Bioanalysis from Universidad Industrial de Santander, Colombia.

12:30 PM - 12:30 PM

Forum Adjourns