Disney's Coronado Springs Resort

Mar 06, 2024 7:00 AM - Mar 08, 2024 12:30 PM

1001 West Buena Vista Drive, Lake Buena Vista, FL 32830, USA

Medical Affairs and Scientific Communications Forum

3 Tracks (Medical Communication, Medical Writing, and Field Medical) + 1 Location = A cross-functional experience for knowledge sharing, integrated thought leadership, and proactive networking.

Print Agenda

Day 1 Mar 06, 2024

7:30 AM — 8:00 AM — Veracruz North Registration

Short Course and Executive Forum Registration

8:00 AM — 12:00 PM

Medical Affairs Executive Forum

8:00 AM — 12:00 PM

Short Course: Advertising and Promotional Content Review: The Role of Medical Information

Speaker(s)

Instructor

Colleen Tholen, PharmD, RPh

Director, Global Medical Information
Intercept Pharmaceuticals, Inc., United States

Colleen Tholen is Director, Global Medical Information at Intercept Pharmaceuticals where she oversees all aspects of Medical Information as well as medical review of promotional and medical materials. Colleen has served as medical reviewer both at Intercept and her previous company and enjoys the dynamic nature of the role, working collaboratively in a cross-functional environment, and staying up-to-date with the data and science. She is eager to share her experiences and best practices as a Medical Information professional within advertising and promotional content review.

Instructors

Dena Gayle Sonnenberg, PhD

Executive Medical Reviewer
Takeda, United States

Dena Sonnenberg is an Executive Medical Reviewer, US Medical Information and Review for Takeda. She supports both promotional and medical strategies for the neuroscience and vaccine portfolios. Dena has been with Takeda since 2014. Prior to that, she worked at Eli Lilly as a Neuroscience Medical Liaison in Medical Affairs, and in R&D and Demand Realization Finance; she has also worked in biotech venture capital. Dena has enjoyed adding to both the depth and breadth of her experience at Takeda.

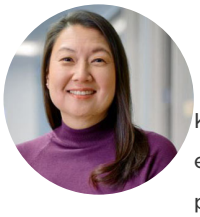
8:00 AM — 12:00 PM

Short Course: Medical Communications: Compliance in 2024

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 brand-legal 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.

10:30 AM — 5:10 PM Veracruz North Registration

Forum Registration

12:00 PM — 1:00 PM Veracruz C

Opening Luncheon in the Exhibit Hall

1:00 PM — 1:30 PM Fiesta Ballroom 6-10

Welcoming Remarks and Presentation of Excellence in Service Awards

Session Chair(s)

Tamei Elliott, MS

Associate Director, Scientific Programs
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)

Congratulations to our 2024 Excellence in Service Awardees!

Alicia Alexander Cadogan, PharmD, RPh

Director, Oncology Medical Information
Pfizer Inc, United States

Alicia is Director and Team Lead for North America Oncology Medical Information at Pfizer Inc. Alicia has participated in the DIA Core Curriculum both as faculty and Chairperson, and in 2010 served as Chairperson for the DIA Annual March Med Comm Meeting. She has led the Fellow program for the DIA Med Comm Meeting from 2012 thru 2021. Alicia received her BS in Pharmacy from St. John's University, and her PharmD from Albany College of Pharmacy. She spent 4 years at The University of Pittsburgh School of Pharmacy as a Nephrology Fellow and then as Assistant Professor of Pharmacy and Therapeutics. Alicia also worked in Medical Communications at Wyeth Pharmaceuticals and as Medical Director at CoMed Communications.

Congratulations to our 2024 Excellence in Service Awardees!

Andrea Tuttle Meyers

Senior Vice President, Clinical Operations
Syneos Health, United States

Ms. Meyers is a Senior Vice President at Syneos Health. She has led clinical operations and medical writing teams for more than two decades in both CRO and sponsor organizations. Ms. Meyers has authored documents across all phases of clinical development for pharmaceutical products as well medical devices, including regulatory dossiers and submissions. In addition, she has also led regulatory and clinical development, leading two oncology products to NDA submission and subsequent approval. Prior to her career in clinical research, Ms. Meyers practiced neuropsychology. In 2020, Ms. Meyers was honored to be named a Healthcare Businesswomen's Association Luminary in recognition of her 25+ years of service in Clinical Research.

1:30 PM — 2:15 PM Fiesta Ballroom 6-10

Session 1: Opening Keynote Address - Design Thinking for Healthcare Revolution: Crafting Patient-Centric Medical Solutions

Karen is responsible for the first-of-its-kind design thinking lab in healthcare, education, pro-sports, and government sectors. She co-developed the nation's inaugural undergraduate program in Innovation and Social Entrepreneurship at Rollins College. Karen also co-created two innovative leadership programs – The Revolutionaries, as well as the Orchard Model of Innovation. A two-time TEDx speaker with an extensive speaking portfolio, Karen and her team have successfully completed 610+ Design Thinking projects, earning three innovation awards.

This presentation will delve into specific case studies where design thinking has significantly improved patient experiences and outcomes in healthcare, illustrating the power of human-centered design in a medical context.

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

- Describe the fundamental principles of design thinking, particularly its pivotal role in fostering innovation and patient-centric approaches
- Examine practical case studies showcasing the advantages of design thinking in healthcare and discuss methods for integrating these principles into medical affairs and scientific communication roles

Track: General Session

Session Chair(s)

Karen Tilstra

Published Author, Founder and President
Creativity Effect, United States

Dr. Karen Tilstra is a driving force in the innovation sector. She's responsible for the first-of-its-kind design thinking lab in healthcare, education, pro-sports, and government sectors. A two-time TEDx speaker with an extensive speaking portfolio, Karen and her team have successfully completed 610+ Design Thinking projects, earning three innovation awards. In addition to her innovation pursuits, she's a licensed Educational Psychologist with a Ph.D. in Creative Leadership. As an author, she's penned 'The Deathline: Stopping the #1 All Time Killer of Human Potential' (2022) and '101 Ways to Ignite Collaboration, Boost Creativity & Fuel Innovation' (2023).

2:15 PM — 3:00 PM Veracruz C

Networking Break in the Exhibit Hall

2:20 PM — 2:50 PM Fiesta Ballroom 3&4

Hosted Session/Non-CE: Case Study Spotlight hosted by Within3: Amplifying the Value of Medical Affairs Insights with Effective AI-powered Reporting

In this presentation, Within3 CEO Lance Hill will walk the audience through a real-world example of how one pharma company applied AI-powered insights analysis to turn data into actionable next steps with more frequent, less biased reporting.

The discussion will include an overview of the business case, the solution, and how pharma companies are moving from highly manual, first-generation insights management to modern insights management maturity.

Featured Topics:

- Medical affairs insights analysis and reporting
- Increasing strategic impact of medical affairs
- Effective applications of AI

Track: Hosted Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Lance Hill

CEO
Within3, United States

3:00 PM — 4:00 PM Fiesta Ballroom 6-10

Session 2 Track 1: Navigating the Changing Medical Communications Landscape: Evolving to Meet the Needs

of the Future

As the Medical Communications landscape continues to rapidly evolve, the current strategies and “ways of working” as Medical Communications professionals must also evolve. In this session we will hear from industry leaders who will provide an overview of some of the key drivers and factors that are contributing to the evolving landscape. We will also gain some insight into new technologies and strategies that are being implemented across the industry. This session will provide an overview and set the stage for specific detailed discussions in subsequent sessions.

Learning Objective :

- Identify factors that contribute to the evolving Medical Communications landscape
- Evaluate new technologies and models that are being employed
- Discuss strategies on how to prepare for evolution in your area of support

Track: Medical Communications

Session Chair(s)

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.

Speaker(s)

Speaker

Jenny Reid-Young

Vice President, Global Medical Information
Inizio Engage, United Kingdom

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

Leena Jindia, PharmD, MS

Senior Director, Medical Information
Johnson & Johnson, United States

Leena is Director, Medical Information at Janssen Pharmaceutical Companies of Johnson & Johnson. She has been with J&J since 2000. In her current role, Leena is responsible for leading global content and Innovation for Janssen's Medical Information community. In the past Leena has managed Medical Information teams across various TAs including Metabolism, Infectious Disease, Pain, Women's Health, Urology products. Leena is responsible for defining processes, developing strategies, integrating technology to create innovative customer response solutions and executing projects. Leena earned her Doctor of Pharmacy degree from Rutgers College of Pharmacy, New Jersey, in 2000.

3:00 PM — 4:00 PM Fiesta Ballroom 5

Session 2 Track 2: Hot Topics and Trends in Medical Writing Today

The field of medical writing is always evolving, bringing both opportunities and challenges which directly impact our daily activities and strategic outlook. In this session, we will explore hot topics and trends in the industry today, many of which will be covered in more depth throughout the forum. One hot topic that continues to challenge the medical writing industry, especially as the industry strives to bring new therapies to the public faster, is accelerated timelines. One of the main pain points that authoring teams struggle with when faced with reduced cycle times, is the document review process. Developing and finalizing the documents required for clinical research and especially those required for regulatory marketing authorization can be a long and, sometimes, tortuous process owing to arduous rounds of review and revision that are not efficient or well-coordinated.

This session will focus on how to achieve good review practices and aims to give participants tools they can apply in their companies to improve their own review processes. It will look first at why we are getting the process wrong, and the main problems associated with document review and then address how to get it right. By presenting tools and techniques that can be employed to make these processes more effective, the presentation will make practical suggestions and propose educational ideas that participants can use to change the mindset of their teams.

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

- Identify key opportunities and challenges facing medical writers today
- Explain the purpose of a document review and recognize what a good review practice looks like
- Discuss the basic principles of document review processes
- Identify tools and techniques that can make review processes more efficient and effective

Track: Medical Writing

Session Chair(s)

Elizabeth Brown, MS, PMP

Senior Director, Medical Writing
Merck & Co., Inc., United States

Elizabeth Brown is a Senior Director and TA Lead of Oncology Medical Writing at Merck & Co, Inc. near Philadelphia, PA. She has led regulatory projects and initiatives in the pharmaceutical industry for 20+ years. First as a laboratory scientist, then as a clinical researcher, and currently as a medical writer. Elizabeth brings a project and people management focus to her role as a regulatory medical writer and department leader. With this focus, she has developed a passion for developing people, advising teams and providing strategic guidance how to deliver efficient, effective, and high-quality documents.

Speaker(s)

The Power of Good Document Review Practice

Julia Forjanic-Klapproth, PhD

Senior Partner/President
Trilogy Writing & Consulting, Germany

After receiving her PhD in Developmental Neurobiology, Julia became a medical writer in 1997. In 2002, she co-founded Trilogy Writing & Consulting, a company specialized in medical writing of regulatory documentation. As a Senior Partner she continues to bring her enthusiasm and experience to client projects. 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.

3:00 PM — 4:00 PM Yucatan

Session 2 Track 3: Adapting Horizons: Insights from the Pandemic to Shape the Future of Field Medical

The Covid-19 pandemic wreaked havoc across the pharmaceutical industry but it especially impacted the activities of field medical team members. Teams quickly pivoted to virtual interactions, both internally and externally. This session will focus primarily on key learnings from these pivots and how Field Medical can be better prepared for the future.

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

- Analyze the changes to Field Medical during and beyond the pandemic, primarily focusing on 2021 and beyond
- Identify best practices initiated during the pandemic which will be carried forward into future activities
- Discuss how teams have moved forward following the pandemic

Track: Field Medical

Session Chair(s)

J. Lynn Bass, PharmD, RPh

Senior Director, Medical Science Liaisons
BridgeBio, 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)

Implementation of a COVID-19 Slide Deck for the Community by a MSL Team: Community Outreach to Combat Misinformation

Rodney H Taylor, PharmD

Senior Director, Medical Sciences
Gilead Sciences Inc, United States

Field Medical Training The Impact of a Pandemic

Craig Klinger, RPh

Director - Global MSL Trainer, The Office of Medical Professional Development
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.

Speaker

Ann Westra, MD

Senior Medical Knowledge Expert
McKinsey & Company, United States

Ann is a Senior Knowledge Expert in McKinsey & Company's Minneapolis Office. In her 10+ years at the Firm, she has served clients across the pharmaceutical industry, focused on medical topics including Chief Medical Officers, Medical Affairs, and real-world evidence. Ann leads McKinsey's medical service line and related internal knowledge efforts in Medical Affairs, Real World Evidence and other related topics. Prior to joining McKinsey & Company, Ann

earned her M.D. from Johns Hopkins University School of Medicine and completed her residency in pediatrics at New York Hospital / Weill Cornell Medicine.

4:10 PM — 5:10 PM Fiesta Ballroom 6-10

Session 3 Track 1 : Strategies for Generating and Sharing Medical Information Insights

The goal of this session is to discuss strategies for generating medical information insights and sharing them effectively across Medical Affairs and other internal teams. Practical case examples of learnings and challenges will be provided.

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

- Discuss innovative approaches and techniques for identifying insights
- Develop strategies for sharing insights and examine the integration of insights across Medical Affairs functions
- Discuss how to effectively demonstrate the value of actionable insights and their impact on other internal teams

Track: Medical Communications

Session Chair(s)

Elizabeth Froom, PharmD, RPh

Senior Director, Medical Writing and Healthcare Communications
Evidera, United States

Elizabeth C. Froom, PharmD, is a Senior Director in the Medical Writing and Healthcare Communications team at Evidera. 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)

Generating Medical Information Insights

Denise Staley, PharmD

Director, Operations
PPD, United States

Denise has over 25 years of experience in the pharmaceutical contact center industry at PPD. Currently serving as a Director of Operations, she manages global teams providing medical information, pharmacovigilance, and product complaint processing for pharmaceutical and biotechnology clients. Prior to her current role, she dedicated her time

to roles focused on ensuring quality and compliance. Denise received her Doctor of Pharmacy degree from Campbell University in North Carolina.

Medical Affairs and the Insights Gold Mine

Natalie Gearhart, PharmD

Associate Director, External Engagement Strategy, Medical Affairs
Johnson and Johnson, United States

Natalie Gearhart is an employee of Johnson and Johnson. Her 23-year history with the company includes leadership of multiple product launches, inspections, change management initiatives, and reorganizations, as well as roles in multiple functions and therapeutic areas. She is currently serving as an Associate Director, External Engagement Strategy in Medical Affairs. Her current focus includes fostering an insights-driven medical organization and developing innovative strategies for stakeholder interactions in a rare disease therapeutic area. Prior roles have been in the areas of Pharmacovigilance, Medical Information, and Medical Call Center. She received her Doctor of Pharmacy degree from the University of Pittsburgh.

4:10 PM — 5:10 PM Fiesta Ballroom 5

Session 3 Track 2: Exploring the Interplay of Regulatory and Publication Writing

Medical writers work in many different settings, including regulatory documentation, publications, and medical communication. While each of these areas has guidelines and may be impacted by regulations, understanding the relationships between these areas may be difficult, limiting opportunities for effective teambuilding or career progression. In some cases, an awareness of medical writing requirements in some areas, such as publications, might also help improve document development in other settings, such as protocols or data analysis plans. The connection between regulatory guiedlines like ICH E3, ICH E6 and publication recommendations like the CONSORT/SPIRIT guideline will be discussed, as will experiences of writers who work in various areas.

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

- Describe the range of medical writing roles
- Identify guidelines for publications and their relationship to common regulatory guidelines
- Discuss opportunities for interdisciplinary cooperation and learning

Track: Medical Writing

Session Chair(s)

Lisa DeTora, PhD, MS

Associate Professor, Director of STEM Writing
Hofstra University, United States

Lisa is an assistant professor of Writing Studies at Hofstra University, where she teaches a wide range of courses including scientific writing, health communication, medical humanities, and narrative medicine. Her research interests include vaccination policy, medical humanities, publication ethics, regulatory writing, and theories of the body. Lisa is the lead author of Good Publication Practice Guidelines for Company-Sponsored Biomedical Research: 2022 Update and the editor of Regulatory Writing an Overview.

Speaker(s)

Panelists

Jenny Boyar, PhD

Principal Medical Writer
Abbvie, United States

Jenny Boyar is a Principal Medical Writer at AbbVie, with nearly a decade of experience in medical and scientific writing. She has contributed to publications with professional organizations like the Regulatory Affairs Professionals Society, and her academic work has appeared in multiple scholarly journals. A Fulbright recipient, she holds a PhD in English from the University of Rochester. With extensive experience across a variety of clinical and regulatory documents, she is invested in working collaboratively and cross-functionally to produce impactful writing.

Panelists

Jennie G Jacobson, PhD

President
Jacobson Medical Writing, Inc., United States

Jennie G. Jacobson is President of Jacobson Medical Writing. She earned her BA from Swarthmore College, and PhD from Harvard University. Jennie was a post-doc at Upjohn Laboratories and the University of Michigan before realizing being a medical writer would allow her all the fun of interpreting data without having to generate it. She rounded out her education with two AMWA certificates, a certificate in Medical Writing from U Chicago, and CMPP certification. In her 24 years as a medical writer, Jennie has written publications in a wide array of therapeutic areas including oncology, neurology, health outcomes research, gene therapy, endocrinology, respiratory disease, autoimmune disease, ophthalmology, and gastrointestinal disease.

4:10 PM — 5:10 PM Yucatan

Session 3 Track 3: Roundtable Discussion

This roundtable discussion will provide the opportunity for our MSL Program Committee members and fellow attendees to dive deeper into the the topics their industry is currently facing. Our attendees will be able to raise the tough questions they've been facing in their everyday roles, share their experiences, and walk away with key learnings to share amongst their company or organization.

Track: Field Medical

Session Chair(s)

J. Lynn Bass, PharmD, RPh

Senior Director, Medical Science Liaisons
BridgeBio, 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.

Dustin Cavida, PharmD

Associate Medical Director
Amgen, United States

I started in the industry as a Medical Affairs fellow in 2015 then became a Medical Science Liaison supporting products in the immunology and ophthalmology space. I later transitioned into Medical Communications before taking on my current role at Amgen as the Associate Medical Director supporting the rare disease team focused on neuroimmunology

5:10 PM — 6:30 PM Veracruz C

35th Anniversary Welcome Reception

Day 2 Mar 07, 2024

7:45 AM — 8:30 AM Veracruz C

Networking Breakfast in the Exhibit Hall

7:45 AM — 5:00 PM Veracruz North Registration

Registration

8:30 AM — 8:50 AM

Fiesta Ballroom 6-10

Welcome, DIA Community Update, and Fellow Poster Program Overview

Welcome, DIA Community Update, and Fellow Poster Program Overview

Track: General Session

Session Chair(s)

Stacey Soares, PharmD

Executive Director, Medical Information
Amgen, United States

Stacey leads MedInfo at Amgen and her 19 year career journey is marked by a series of contributions to MedInfo and patient care. With her background as a pharmacist and a MedInfo professional, Stacey possesses a profound understanding of the challenges and opportunities within the field. At Amgen, Stacey leads a global team of dedicated professionals, driving forward the integration of cutting-edge technologies and AI to enhance MedInfo services and redefine industry standards. Stacey is passionate about the potential of AI to transform MedInfo, believing that the next evolution of MedInfo lies in leveraging technology to provide more personalized, accessible, and timely support, creating a more informed, empowered, and healthier world.

Nimita Limaye, PhD

Research Vice President, Life Sciences R&D Strategy and Technology
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.

8:50 AM — 9:50 AM

Fiesta Ballroom 6-10

Session 4: Plenary Session: Leveraging AI Responsibly and Ethically in Life Sciences R&D

Session 4: Plenary Session – Leveraging AI Responsibly and Ethically in Life Sciences R&D

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

- Discuss insights on the influence of AI on life sciences R&D
- Recognize the importance of the responsible utilization of AI
- Explore the principles guiding responsible AI usage and ethical decision-making in the industry
- Analyze practical strategies and approaches for effectively integrating AI into current life sciences R&D practices

Track: General Session

Session Chair(s)

Tamei Elliott, MS

Associate Director, Scientific Programs
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)

Speakers

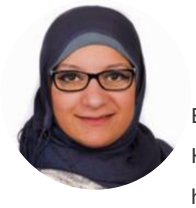
Stephen Pyke, MSc

Chief Clinical Data and Digital Officer
Parexel, United Kingdom

Stephen is responsible for leading and directing Parexel's enterprise patient data strategy. He is also leading the development of Parexel's AI strategy. Stephen trained as a statistician, and began his career in academia (London), where he held various research and teaching positions. He subsequently joined the pharmaceutical industry where he was fortunate to have the chance to take on a number of global leadership roles, at Pfizer and GSK. Stephen has also been honoured to serve on the Boards of a number of professional and not-for-profit organisations, including among others: PSI Board Chair, RSS Vice President, CDISC Board Chair. Stephen Studied Mathematics and Statistics at University of York and Imperial College, London.

Speakers

Sherrine Eid, MPH



Global Head, RWE, Epidemiology and Observational Research
SAS Institute Inc., United States

Eid has more than 20 years of experience in real-world evidence, epidemiology and biostatistics. Her passion for better public health led her to work for USAID, CDC and other donors in global health development with a focus on reproductive health and family planning and infectious diseases. Her current focus is supporting regulatory, safety, late-phase and post-marketing activities across therapeutic areas using clinical and real-world data to glean real-world insight.

10:00 AM — 11:15 AM

Fiesta Ballroom 6-10

Session 5 Track 1: Next-Gen MedInfo: Empowering Scientific Communications Through AI and Voice Technology

Embark on a journey through the landscape of Artificial Intelligence (AI) as it revolutionizes medical information and scientific communications. This session will provide an in-depth analysis of how AI technologies like NLP, machine learning, and voice recognition are innovating the field with practical applications ranging from writing standard response documents (SRDs) to deploying chatbots and intelligent voice assistants. Discover how tools like ChatGPT enhance efficiency and accuracy; in particular, delve into the specifics of how two MedInfo contact centers have harnessed ChatGPT for efficiency and voice AI for enhanced call steering and inquiry response, setting new benchmarks in scientific communications.

Learning Objective :

- Identify AI technologies currently applied in scientific communications, supported by a clear understanding of their functional impact as evidenced by real-world use cases
- Evaluate the effectiveness of AI applications in their operations, aiming to formulate at least two measurable improvement metrics
- Outline a strategic roadmap for integrating AI into their MedInfo processes

Track: Medical Communications

Session Chair(s)

Marie-Ange Noue, PhD

Senior Director, Head of Scientific Communications
EMD Serono, Canada

Marie-Ange Noue is a PhD chemist trained at Curie University in Paris and at the University of Houston. She started her career working as a research scientist in petrochemicals. She later found her niche upon joining EMD Serono in 2008, where she's held a number of positions of increasing responsibility. In her current role as Senior Director, Head of US Scientific Communications, she provides strategic leadership and oversight for activities related to Medical Information, Medical Communication, Medical Training, and Medical

Education for the US. Marie-Ange chairs the Board of Directors of the Canadian Medical information network, and serves as Vice President on the Executive Board of PhactMI.

Speaker(s)

Medical Response Authoring Assistance using Artificial Intelligence

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.

Voice Recognition AI: A MedInfo Contact Center Adopts Virtual Agent for Call Steering and Inquiry Response

Anthony Villanova, PharmD

Director, Medical Information
Amgen, United States

Tony is a biopharmaceutical professional with in-depth experience in clinical development operations and medical affairs. He oversees Amgen's US MedInfo function, leading teams to optimize performance and efficiency by adopting new technology and strengthening cross-functional partnerships. Other areas of focus, current or previous, include expanded access, product launches, clinical trial site selection and activation, and field medical effectiveness. Prior to joining industry in California, he ran clinical trial recruitment at several of Boston's top academic medical centers. Tony is passionately driven by organizational efficiency and finding elegant and pragmatic solutions to confront challenges to serve patients on a global scale.

Use of an Intelligent Voice Assistant in Medical Information

Benedicte Perreault, MSc

Medical Information Scientist
Pfizer, Canada

I completed my bachelor's degree in pharmacology at the University of Sherbrooke in 2012 and received my master's degree in clinical pharmacology from the University of Montreal in 2014. I then started working for Pharmascience

Inc. as a Medical Information Associate before becoming a Specialist in Scientific Communication. For the past 4 years, I have been working as a Medical Information Scientist at Pfizer Inc. where I'm responsible for managing medical information content and activities related to the COVID-19 vaccine.

10:00 AM — 11:15 AM Fiesta Ballroom 5

Session 5 Track 2: Direct Use of AI in Clinical Regulatory Document Development: Real-World Use

Recent advancements of AI tools have leveraged machine learning algorithms and natural language processing (NLP) techniques to enable AI models to learn from large datasets and generate more sophisticated and coherent written content; this can greatly assist medical writers by automating routine tasks such as data analysis and summarization, freeing up time for more complex and creative work, as well as ensuring consistency and accuracy in medical writing, particularly when generating reports or other documents that require strict adherence to specific formatting and style guidelines. This session presents real-world examples of AI utilization throughout the creation of clinical regulatory documents, demonstrating the potential benefits of integrating AI technology into the medical writing process. Such examples will include both positive and negative issues observed in live document writing cases of CSRs, Module 2 submission documents, and medical device writing. This informative session will explore the current use cases of AI tools and future development direction of several AI tools.

Learning Objective :

- Evaluate the capabilities of an AI GPT-style chat tool to support clinical regulatory document development
- Describe the abilities of an AI tool to facilitate the speed, accuracy and consistency of the creation of clinical regulatory documents of various types, including CSRs and Module 2 submission documents
- Differentiate between different types of AI writing tools and their best use for regulatory document creation, base on real world use cases

Track: Medical Writing

Level: Intermediate

Session Chair(s)

Diane Cleverley, PhD

Senior Regulatory Writer
Certara, United States

Dr. Cleverley has more than 20 years experience in the medical publication field, which she entered shortly after earning her PhD in Microbiology and Molecular Genetics as a joint degree from Rutgers and UMDNJ. During that time, she proposed the "glycine hinge" theory. She has contributed editorial support for publications for prestigious higher tier journals such as NEJM and JCO. Dr. Cleverley has also written award-winning patient literature, clinical trial materials, and healthcare provider education. She currently is lending her writing talents to the regulatory field. She developed a patient advocacy tool for making diagnosis more effective. Dr. Cleverley has been an active team member of AMWA, ISMPP, and MAPS, and holds a CMPP.

Speaker(s)

Speaker

David Meats

Director, Regulatory Services Management
Certara, United States

David Meats is a Director of Regulatory Services and Medical Affairs at Certara. He has been a medical writer and manager for 23 years working in oncology, immuno-oncology, endocrinology, musculoskeletal, cardiac, hepatic, renal, and infectious disease therapeutic areas on nearly every available clinical document type. He specializes in leading and writing FDA and EMA regulatory submissions and an expert in technology development in regulatory services. David is also a co-chair for the Medical Writing track of the DIA 2024 conference, and has been a member of DIA for 8 years.

10:00 AM — 11:15 AM Yucatan

Session 5 Track 3: AI – A Deep Dive for Field Medical

This session provides a comprehensive overview of AI's impact on Medical Affairs, specifically for Field Medical. Industry leaders will share their experiences in evaluating and implementing AI solutions as well as the fundamentals of machine learning (ML) and natural language processing (NLP). A dynamic panel discussion will offer insights into real-life applications and challenges with current AI solutions while engaging exercises highlight current AI capabilities and limitations, fostering a clear understanding of implementable solutions. Participants leave equipped with the knowledge to evaluate AI opportunities and make informed decisions in their own organizations.

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

- Explain how AI is reshaping Field Medical capabilities
- Recognize good opportunities and know whom to connect with in their organizations
- Evaluate what types of opportunities exist for their organization

Track: Field Medical

Session Chair(s)

Sarah Jarvis, MBA

Global Medical Affairs Lead
ZS, United States

Sarah Jarvis leads our Global Medical Affairs 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.

Richard Swank, PhD

Founder
Scientific Engagement LLC, United States

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 has a PhD in Biochemistry and Molecular Biology and prior to joining industry completed an NIH Postdoctoral Fellowship and was a senior fellow in Medical Genetics at the University of Washington.

Speaker(s)

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.

Speaker

Donna A. Holder, PharmD

Daiichi Sankyo, Inc.
Executive Director, Head of Digital Strategy and Innovation, 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

Rishi Ohri

Senior Director, Digital Excellence, Medical Affairs
Astellas, United States

Leveraging my extensive technical and business management background, I am a high-performing medical affairs and informatics professional with a passion for innovation and results. I have been in Pharma for the past 20 years with a deep focus in Medical Affairs Digital Transformation and Omnichannel.

11:15 AM — 11:50 AM Veracruz C

Networking Break in the Exhibit Hall

11:20 AM — 11:50 AM Fiesta Ballroom 3&4

Hosted Session/Non-CE: Case Study Spotlight hosted by Digital Science: Driving Innovation & Collaboration Across Boehringer Ingelheim: A Case Study in Innovation, User Engagement, and Positive Change

As a leading global pharmaceutical company, innovation is second nature to Boehringer Ingelheim (BI). Innovation isn't just about drug design but is in everything BI does, from process optimization to improving the tools used every day. This culture is reflected in all of its teams, especially the Scientific Information Center (SIC).

The core task of the SIC is to provide global access to external information and knowledge from thousands of renowned journals and publishers via enterprise subscriptions and document delivery services. In this case study, Dr. Karlheinz Spenny and his team at the SIC share in their own words what triggered their internal innovation campaign to move from their legacy literature management solution to ReadCube and their experiences along the way.

For more information click here

Featured Topics

- Improving workflow efficiency
- Global access to knowledge via enterprise subscriptions
- Document Delivery
- Evaluating the 'cost of change'
- Research management improvements

Track: Hosted Session

Session Chair(s)

EXHIBITOR

Sponsored Sessions

United States

Speaker(s)

Instructor

Ryan Clark

Vice President - Corporate Markets, Americas
Digital Science, United States

As the Vice President of Corporate Sales at Digital Science, Ryan lead's the strategy and execution of sales initiatives across the Americas region, with a focus on expanding the reach and impact of Digital Science's innovative research solutions. Ryan has over 15 years of experience in sales, business development, and digital services, working with diverse and global clients in the sector. Ryan is passionate about making research more accessible and connected, which aligns with the mission and vision of Digital Science. Ryan is an active member of DIA and has attended several DIA meetings over the past decade.

11:50 AM — 12:50 PM

Fiesta Ballroom 6-10

Session 6 Track 1: Cross-Functional Collaboration: Optimizing Medical Information and Communications for Patient-Centric Impact

This session will discuss opportunities and best practices for Medical Information/Medical Communications when collaborating with internal functions or teams to achieve objectives that positively impact patient care.

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

- Identify functions within their own companies for potential collaborations
- Examine internal collaborations that positively impact deliverables for omnichannel communication of scientific content
- Discuss MI collaborations and activities to adapt to shifting strategic focus of MI

Track: Medical Communications

Session Chair(s)

Ivy Chang, PharmD

Principal Therapeutic Area Lead, Medical Information

Genentech, A Member of the Roche Group, United States

Ivy has 20+ years of experience in the pharmaceutical industry. She is a Principal Medical Information Lead at Genentech with experience across diverse therapeutic areas including Oncology, Rheumatology, Respiratory, Ophthalmology, Endocrinology, Neurology, Cardiovascular Disease, and various clinical conditions with an immunologic basis in pathophysiology. Prior to joining Genentech, she was a Clinical Pharmacist in General Surgery, Surgical Subspecialties, and Solid Organ Transplant at the University of California San Francisco (UCSF) Medical Center, and an Assistant Clinical Professor with the UCSF School of Pharmacy. Ivy received her PharmD from University of Tennessee Health Science Center.

Speaker(s)

Speaker

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.

Collaboration with Field Medical to Accelerate Opportunities for Patient Access

Ayesha Ahmed

Senior Therapeutic Area Lead, Medical Information
Genentech, A Member of the Roche Group, United States

Complex Network of Internal Collaborations Supporting a Single Inquiry Topic

Stacey Soares, PharmD

Executive Director, Medical Information
Amgen, United States

Stacey leads MedInfo at Amgen and her 19 year career journey is marked by a series of contributions to MedInfo and patient care. With her background as a pharmacist and a MedInfo professional, Stacey possesses a profound understanding of the challenges and opportunities within the field. At Amgen, Stacey leads a global team of dedicated professionals, driving forward the integration of cutting-edge technologies and AI to enhance MedInfo services and redefine industry standards. Stacey is passionate about the potential of AI to transform MedInfo, believing that the next evolution of MedInfo lies in leveraging technology to provide more personalized, accessible, and timely support, creating a more informed, empowered, and healthier world.

11:50 AM — 12:50 PM Fiesta Ballroom 5

Session 6 Track 2: Building the Bench: Leveraging and Developing Early Talent in Regulatory Medical Writing

Across the industry, there is a shortage of experienced regulatory medical writers. At the same time, many individuals are looking to break into medical writing roles. This is an exciting opportunity for organizations to build their own bench by providing programs to develop emerging and early talent to fill this gap. Come hear insights from developers of early talent regulatory medical writing programs and team members who have completed those programs. Attendees looking to develop early talent programs within their own organizations will take away best practices and lessons learned. Those who are already managing or recruiting early talent will better understand how they can leverage employee skillsets and best position early talent for initial and sustained success as regulatory medical writers.

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

- Identify different types of programs for developing new regulatory medical writers
- Apply feedback from developers of early talent medical writing programs and team members who have recently completed those programs
- Develop best practices for supporting, developing, and retaining team members who are new to regulatory medical writing

Track: Medical Writing

Level: Intermediate

Session Chair(s)

Elizabeth Brown, MS, PMP

Senior Director, Medical Writing
Merck & Co., Inc., United States

Elizabeth Brown is a Senior Director and TA Lead of Oncology Medical Writing at Merck & Co, Inc. near Philadelphia, PA. She has led regulatory projects and initiatives in the pharmaceutical industry for 20+ years. First as a laboratory scientist, then as a clinical researcher, and currently as a medical writer. Elizabeth brings a project and people management focus to her role as a regulatory medical writer and department leader. With this focus, she has developed a passion for developing people, advising teams and providing strategic guidance how to deliver efficient, effective, and high-quality documents.

Speaker(s)

Speaker

Kim Jochman, PhD

Senior Director, Medical Writing
Merck & Co., Inc., United States

Kim Jochman is a Senior Director, Medical Writing at Merck. She has a Ph.D in biological psychology and has been a regulatory medical writer since 2007, with experience across a broad range of document types, development phases, and therapeutic areas. Kim is passionate about training, mentoring, and process optimization. In her current role, she leads a variety of training, technical, and strategic initiatives to maximize the quality and efficiency of the authoring process. These include developing & leading training programs for early career Medical Writers, conducting industry trainings on lean authoring & data interpretation, and supporting technology initiatives at Merck.

Speaker

Shengjie Xu, PhD

Regulatory Medical Writer
Merck & Co. Inc, United States

Shengjie Xu is currently a Senior Medical Writer at Merck working on clinical documents to support global regulatory approval for various vaccine programs. Prior to joining Merck, she was trained as a bench scientist and specialized in immunology, most notably in host-microbial interactions. Shengjie has published original research works in multiple peer-reviewed journals and has been an invited speaker at several international conferences. She also served as an IRB member for two years, where she reviewed clinical research conducted at Duke University Health System. Shengjie received her PhD in immunology from Duke University in North Carolina and her BS in biology from Purdue University.

Speaker

Jacqueline Cytacki, PharmD

Senior Principal Medical Writer
Parexel International, United States

Jackie Cytacki has more than 23 years of experience in the pharmaceutical industry. Currently, she is a Senior Principal Medical Writer at Parexel International, where she serves as a client-partnership liaison and as a lead writer/submission coordinator. Jackie also mentors junior writers and supports their professional growth. Before joining Parexel, Jackie worked as a Medical Writing Consultant at Comprehensive Clinical Development, and prior to that, she held various positions at Kos Pharmaceuticals, including Associate Director of Drug Information Services, Manager of Medical Writing, and Drug Information Specialist. Jackie holds a BA in Chemistry from Florida Atlantic University and a PharmD from Nova Southeastern University.

Speaker

Joanna L Gore, PhD

Senior Medical Writer
Parexel International, Canada

I received a BSc in Biology/Neuroscience from McMaster University, and a PhD in Physiology/Medicine from Queen's University. I began my career as a junior Medical Writer at ApoPharma Inc. before becoming a primary Medical Writer at Appili therapeutics Inc. and then a Clinical Research Scientist. For the past 4 years, I have been working as a Senior Medical Writer at Parexel International. I work primarily on a Strategic Partnership, supporting that client's established product portfolio. My medical writing focuses on preparing documents for regional Health Authorities including responses to Health Authority Queries and Clinical Overviews to support changes to product labeling.

11:50 AM — 12:50 PM Yucatan

Session 6 Track 3: Navigating Field Medical Challenges in Shifting Priorities, Digital Initiatives, and Stakeholder Management

The Leadership Challenges panel discussion will focus on current field medical leadership challenges including those identified by the audience. With a lens specifically intended for field medical, the discussion topics will include navigating shifting priorites, learnings from digital initiatives, how reallocation of resources are typically considered, and how managing internal stakeholders has shifted and where these and other areas are expected to shift in future. Industry leaders will share their experiences in these areas and the dynamic panel discussion will offer insights into real-life examples. Participants will leave the session with a deeper understanding of leadership challenges in field medical, and with key insights into handling the management of large dispersed teams while simultaneously managing internal stakeholder relationships.

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

- Discuss the top 3 field medical leadership challenges in running dispersed teams
- Identify successful as well as failed examples of managing field medical initiatives in digital strategy
- Apply new perspectives in understanding challenges within their own organizations

Track: Field Medical

Session Chair(s)

Richard Swank, PhD

Founder
Scientific Engagement LLC, United States

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 has a PhD in Biochemistry and Molecular Biology and prior to joining industry completed an NIH Postdoctoral Fellowship and was a senior fellow in Medical Genetics at the University of Washington.

Speaker(s)

Speaker

Christian DiMaano, PhD, MPH

Vice President, Medical Affairs

Lassen Therapeutics, United States

Christian has over 15 years of industry experience in R&D and medical affairs encompassing translational research, medical affairs, HEOR, patient advocacy, and public health. Christian is currently Vice President, Medical Affairs at Lassen Therapeutics where he is responsible for building out and leading medical communications, external engagement, patient advocacy, and driving clinical trial enrollment. Over his career, Christian has held roles of increasing responsibility at Myriad Genetics, Bristol Myers Squibb, Gilead Sciences, Astellas, Mirati Therapeutics, and Kinnate, facilitating early asset development as well as leading the medical affairs launch of several FDA approved products.

Speaker

Jim Wilkinson, PhD

Vice President, Global Medical Affairs
Amgen (former), United States

Jim Wilkinson, PhD is an executive leader in global and US Medical Affairs, with over 22 years in the biopharma industry. 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, omnichannel communications, and promotional review. Jim received his B.S. from UW-Madison and his Ph.D. from UM-Minneapolis.

12:50 PM — 1:50 PM Veracruz C

Networking Luncheon in the Exhibit Hall

12:50 PM — 1:50 PM Fiesta Ballroom 1&2

Resident and Fellow Professional Development Luncheon – Engaging in Volunteering: A Pathway to Professional Growth and Social Impact

Resident and Fellow Professional Development Luncheon – Engaging in Volunteering: A Pathway to Professional Growth and Social Impact

Track: General Session

Session Chair(s)

Evelyn R. Hermes-DeSantis, PharmD

Director, Research and Publications
phactMI, United States

Evelyn R. Hermes-DeSantis, PharmD, BCPS, is the Director for Research and Publications for phactMI and Professor Emerita at the Ernest Mario School of Pharmacy at Rutgers, the State University of New Jersey. She is dedicated to advancing and elevating the practice of medical information. She received both a BS in Pharmacy and a PharmD from Rutgers and completed a Drug Information specialty residency at the Medical College of Virginia Hospital in Richmond, Virginia prior to working at the University of Utah Hospital Drug Information Service. For 25 years she was the Director of Drug Information Services at Robert Wood Johnson University Hospital and a Clinical Professor at the Ernest Mario School of Pharmacy at Rutgers.

1:50 PM — 3:05 PM

Fiesta Ballroom 6-10

Session 7 Track 1: Effective Customer Engagement Strategies for Patients & HCPs

This session aims to explore various principles in effective customer engagement, whether engaging with patients or HCPs, including: Tools, Strategies, and Innovation.

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

- Identify innovative tools and technology that enable a better customer engagement experience
- Discuss principles that lead to effective engagement of patients and HCPs
- Evaluate tools that enhance the delivery of MI to patients and HCPs

Track: Medical Communications

Session Chair(s)

Hanady Elhadidy, PharmD

Senior Director, Global Customer Engagement
Bristol Myers Squibb, United States

Hanady has 15 years of experience in Medical Affairs and Medical Information. She currently leads the Global Customer Engagement team at Bristol Myers Squibb. Hanady is an executive board member of the phactMI Board of Directors. Prior to BMS, Hanady worked with large and mid-size pharmaceutical companies in a variety of roles, always with a focus on simplification, standardization, and innovation.

Speaker(s)

Medical Omnichannel: Elevating HCP-centricity, Engagement, and Connected Experiences

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

Speaker

Rebecca Burns, PharmD, PhD, RPh

Head of US Medical Affairs, Epilepsy and Rare Syndromes
UBC, Inc., United States

Rebecca is a seasoned professional with a rich background in both academia and the pharmaceutical industry. Beginning her career at Mercer University School of Pharmacy, she spearheaded a successful research program, collaborating with prestigious institutions. Transitioning from academia to Arbor Pharmaceuticals, Rebecca took on progressively higher responsibilities in Medical Affairs. Seeking fresh challenges, she joined UCB in 2019 where she currently is the Head of US Medical for Epilepsy and Rare Syndromes, leading all functions of US Medical Affairs across the Epilepsy and Rare Syndromes portfolio. In this role, she strives to create an environment and vision for the team that inspires innovation and patient centricity.

Speaker

Sheryl Johnson, PharmD

Senior Director of NA Operations
Alphanumeric, United States

Throughout my two-decade tenure in pharmacy, I've dedicated myself to pharmaceutical contact centers. Beginning as a phone agent, I progressed to spearheading Medical Information Contact Centers. Joining Alphanumeric in 2016 as a Team Lead, I steadily advanced into senior leadership positions. By 2021, I held the esteemed role of Global Director for a Covid-19 Global Medical Information Contact Center within one of the world's leading pharmaceutical companies. Presently, I oversee two Medical Information Contact Centers, one based in the US and the other in Canada.

1:50 PM — 3:05 PM

Fiesta Ballroom 5

Session 7 Track 2: Patient-Centric Protocols: Bridging Understanding and Impactful Communication in Clinical Study Design

A protocol is the foundation for a clinical study, and the first opportunity for a medical writer to interact with a clinical study team. Ideally, a medical writer would understand the full clinical impact of the clinical trial protocol's design and assessment schedule on the patient. This interactive session will explore what it truly means to be a patient, particularly one with a disability, a rare disease, chronic pain, or other unique characteristics, and how that deep understanding might be well translated by a medical writer during the interactions with a clinical team at protocol drafting.

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

- Describe the importance of medical writers' impact in clinical protocol design
- Demonstrate the impact of patient disease state on ability to participate in clinical trials
- Compare various protocols and differentiate how trial design would impact patients

Track: Medical Writing

Session Chair(s)

Lisa DeTora, PhD, MS

Associate Professor, Director of STEM Writing
Hofstra University, United States

Lisa is an assistant professor of Writing Studies at Hofstra University, where she teaches a wide range of courses including scientific writing, health communication, medical humanities, and narrative medicine. Her research interests include vaccination policy, medical humanities, publication ethics, regulatory writing, and theories of the body. Lisa is the lead author of Good Publication Practice Guidelines for Company-Sponsored Biomedical Research: 2022 Update and the editor of Regulatory Writing an Overview.

Speaker(s)

Speaker

Blake Scott, PhD

Professor
University of Central Florida, United States

Blake Scott is Professor of Writing & Rhetoric at the University of Central Florida, where he teaches graduate and undergraduate courses related to health and medical writing/communication. He is the founding co-editor of the journal Rhetoric of Health and Medicine and now co-edits a digital column for the journal called "Graphic RHM" (which explores the intersection of comics, rhetoric, and medicine). Dr. Scott has published fives books and edited collections, most recently Methodologies for the Rhetoric of Health and Medicine (with Lisa Meloncon). He co-leads a multidisciplinary research team exploring the uses of comics to combat HIV stigma and to support nurses well-being.

Speaker

Gunasekaran Singaravelu, PhD, MSc

Manager, Medical Writing
Daiichi Sankyo, inc., United States

Gunasekaran Singaravelu, Ph.D., earned his doctorate in Life Science from Gwangju Institute of Science and Technology. He brings over a decade of experience to his work. Dr. Singaravelu specializes in medical writing, focusing on oncology, immunology, specialty medicine, geriatrics, and ophthalmology. As Medical Writing Manager at Daiichi Sankyo Inc., he oversees regulatory document preparation and provides leadership in writing strategies. Previously, at Alcon and T.A. Sciences Inc., he contributed to regulatory and scientific documentation. Dr. Singaravelu's research includes primary publications and reviews in respected journals.

1:50 PM — 3:05 PM Yucatan

Session 7 Track 3: Data-Driven Resource Planning for Field Medical

Our workshop addresses the need for innovation in Field Medical resource allocation as more traditional methods based on geographical alignment and KOL tiering face limitations. Through interactive case studies and expert discussions, participants will scrutinize challenges in current methods and explore the potential of data analytics to customize resource allocation and engagement planning. The workshop format includes panel discussions, breakout activities with case studies, and knowledge-sharing segments on best practices. Participants will leave empowered to implement data-driven resource planning and tailored engagement strategies for improved outcomes.

Learning Objective :

- Recognize challenges with historical and current resourcing methods and where we can make improvements
- Identify how data and analytics can be leveraged to more strategically deploy field resources in a targeted manner
- Discuss the impact regional and local engagement strategies for meeting needs of clinicians and other stakeholder groups

Track: Field Medical

Level: Intermediate

Session Chair(s)

Sarah Jarvis, MBA

Global Medical Affairs Lead
ZS, United States

Sarah Jarvis leads our Global Medical Affairs 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(s)

Speaker

Jon Gonzales, PhD

Field Medical Capabilities Lead
ZS Associates, United States

Jon is an Associate Principal for ZS and lead of the Field Medical capabilities for the Medical Affairs practice. In this role, Jon leads the development, oversight, and innovation of Medical Affairs projects that impact strategy through execution for field medical teams. During his 9.5 years at ZS, Jon's focus has been within the Medical Affairs practice at ZS. He's supported Medical teams across the industry across the different stages of the product lifecycle. He has helped clients by bringing data-driven and customer-oriented solutions for medical strategy and field medical execution. Jon holds a Ph.D. in Biomedical Sciences from the University of California, San Diego and a BS in Biochemistry from Colorado State University

Speaker

Rick Jarecke, PharmD

Executive Director, Medical Affairs Field, Women's Health & Urology
Sumitovant, United States

Industry veteran of nearly 30 years with experience in and passion for field medical affairs.

Speaker

Sahar Javaherian, PhD, MSc

National Director, US Medical Affairs Oncology
Jazz Pharma, United States

3:05 PM — 3:45 PM Veracruz C

Networking Break in the Exhibit Hall

3:45 PM — 5:00 PM Fiesta Ballroom 6-10

Session 8 Track 1: Spotlight on Scientific Communication: Strategies for Demonstrating Value to Leadership

This session will delve into the evolving role of medical affairs (MA) professionals, transitioning from traditional operators to strategic conductors. It will highlight the significance of MA in supporting patient outcomes and the overall impact on healthcare strategies. Key discussions will include embracing digital innovations, the necessity for MA professionals to comply with eveolving guidances, regulations and law, and the necessity for MA strategic communication. Special emphasis will be placed on how to effectively demonstrate their department's value to senior leadership and the organization.

Learning Objective :

- Recognize how medical affairs (MA) professionals are transitioning from data handlers to strategic influencer
- Identify MA strategies to support patient-focused care
- Describe the compliance elements necessary to enhancing MA effectiveness
- Discuss the value of MA within organizations

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.

Speaker(s)

Speaker

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.

Speaker

Randy Levitt, PhD

Director, Pharmacovigilance and Medical Affairs
Paladin Labs Inc., Canada

Randy Levitt is the Director of Pharmacovigilance and Medical Affairs at Paladin. He is also the local compliance champion and works closely with the legal and compliance teams at Endo, the parent company of Paladin. He joined Paladin in 2011 as Manager, Scientific Communications and Publications after Paladin's acquisition of Labopharm, where he had worked in the medical department since 2008. Randy completed his undergraduate and graduate degrees at McGill University, graduating with his PhD in Experimental Medicine in 2006.

Sonia Sandhu, PharmD

Senior Director, Medical Information
Gilead Sciences, Inc., United States

Currently serving as the Senior Director of Global Medical Information at Gilead Sciences, she specializes in Virology. In her role, she actively shapes the industry's knowledge advancement through her authorship of articles on medical affairs and medical information. Dr. Sandhu contributes to the medical community with a focus on HIV, COVID-19 and Liver diseases. As a leader, she develops strategy, engages in cross-functional work, and impacts medical narrative. With academic credentials including a Bachelor of Science in Biological Sciences from UC Davis and a Doctor of Pharmacy from Midwestern University, Dr. Sandhu is dedicated to advancing healthcare.

3:45 PM — 5:00 PM

Fiesta Ballroom 5

Session 8 Track 2: Overview of Recent Changes in Clinical Trial Guidelines and How to Enhance Medical Writing Impact

This session will highlight recent changes to regulatory guidelines that will modernize how clinical trials are conducted and reported. Key changes that will impact the functions of medical writers relating to safety reporting, informed consent, maximizing patient engagement, decentralized trials, digital health technologies, and data disclosure will be discussed. Presentations will cover proposed updates in the ICH E6(R3) Good Clinical Practice guideline and clinical trial data disclosure requirements in the Clinical Trials Information System (CTIS).

Learning Objective :

- Discuss the changes to guidance and explore the impacts to clinical trial development and conduct, meaningful patient engagement, and content creation
- Identify opportunities in which medical writers can drive innovative trial design, improve patient engagement, and ensure data integrity and quality outcomes
- Recognize anticipated changes to disclosure of clinical data and interpret the impacts of these requirements on medical writing activities

Track: Medical Writing

Session Chair(s)

Blake Schouest, PhD

Scientific Medical Writer
Aroga Biosciences, United States

Blake is a Scientific Medical Writer at Aroga Biosciences, Inc. with experience authoring documents for regulatory submissions, including INDs, IBs, DSURs, protocols, and CSRs. Blake also serves as Vice President of Member Relations and Secretary of the San Diego Regulatory Affairs Network (SDRAN) and holds the RAC-Drugs designation from RAPS. Prior to joining Aroga, Blake worked as a research scientist at Inovio Pharmaceuticals, Inc., serving as lead scientist on multiple nonclinical research programs. Blake conducted his postdoctoral training at La Jolla Institute for Immunology and holds a PhD in Biomedical Sciences from Tulane University School of Medicine.

Speaker(s)

Modernizing Trials: Digitizing Design and Delivery

Jane Elizabeth Myles, MSc

Program Director
Decentralized Trials and Research Alliance (DTRA), United States

Jane has over 25 years of experience improving clinical trials and patient experiences. She has focused on driving innovation in trial design and execution to accelerate getting medicines to patients. Jane transitioned from molecule focus to portfolio focus about 14 years ago, first concentrating on patient recruitment, then patient experience and input, followed by adoption of patient-facing technology. In her current role as Program Director for the Decentralized Trials and Research Alliance (DTRA), she merges these focus areas. Additionally, she is a member of the Board of Directors of The Myositis Association, adding her experience to their mission. She has held roles across pharmaceutical, biotech, CRO and tech start up organizations

Adapting to ICH E6(R3): Regulatory Medical Writing in an Evolving Clinical Landscape

Andrea Clark, PhD, MSc

Senior Regulatory Medical Writer
Aroga Biosciences, United States

Andrea is a Senior Regulatory Medical Writer at Aroga Biosciences, Inc. with experience authoring protocols, IBs, DSURs, briefing packages, CSRs, and manuscripts. Prior to joining Aroga, Andrea worked as a Senior Drug Regulatory Specialist at Registrar Corp. Andrea serves as the Southern Virginia Regional Event Coordinator for the American Medical Writers Association Mid-Atlantic Chapter. She received her BS degree in biology from Salisbury University and MS and PhD degrees in chemistry from Old Dominion University.

3:45 PM — 5:00 PM Yucatan

Session 8 Track 3: Pre-Approval Information Exchange (PIE) – What Medical Affairs Should Know and Consider

This session will review the provisions of the PIE Act, and discuss why payers need and how payers use this information. In a panel format, speakers will solicit audience responses and discuss hot topics in PIE to provide guidance and considerations for Medical Affairs professionals in the development and implementation of PIE communications.

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

- List the types of unapproved product information that can be communicated to payers
- Identify two ways that manufacturers can communicate PIE information
- Describe why payers need product information before FDA approval

Track: Field Medical

Session Chair(s)

Iris Tam, PharmD

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

Iris Tam, PharmD, FAMCP, is Senior Vice President & Head of Medical Affairs and HEOR at COEUS Consulting with over 30 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 for the last 3 years.

Speaker(s)

Speaker

Jeff Lee, PharmD

Vice President, Value Demonstration
Lumanity, United States

Jeff is a senior HEOR leader, with a focus on generating and communicating value evidence for payor audiences. Jeff led the Global Health Outcomes and Payer MSL teams at Allergan after several years as International Director of Pharmacoeconomics at Glaxo. Jeff is an ACCP Fellow, led development of ACCP's pharmacoeconomics fellowship training programs, and was Chair of the AMCP Format Executive Committee, where he led development of the AMCP Format 4.0. He also actively supported AMCP's advocacy efforts around preapproval information exchange in Congress. At Lumanity, Jeff is the US Region Lead within the Value Demonstration Practice, advising clients across the spectrum of value evidence generation and communication activities.

Speaker

Sonja Wesley Hokett, PharmD, MS, MSc

Executive Director/Head of Medical Managed Care
BioXcel Therapeutics, United States

Residing in Branson, Missouri, Sonja holds PharmD degree from the University of Louisiana Monroe, Master of Science degree in Hospital Pharmacy Administration from the University of Houston, and Executive Master's degree Health Economics, Policy & Management from the London School of Economics. During her 19 years in the pharma industry, Sonja has held both Field and Headquarter pharma Medical Affairs positions at BioXcel Therapeutics, Jazz, Intercept, and Genentech. She currently manages a Medical Managed Care field team and oversees HEOR for BioXcel Therapeutics.

5:00 PM — 6:00 PM | Veracruz C

Poster Reception in the Exhibit Hall – View Resident and Fellow Posters!

Day 3 Mar 08, 2024

7:30 AM — 12:30 PM | Veracruz North Registration

Registration

7:30 AM — 8:15 AM | Veracruz C

Registration and Networking Breakfast in the Exhibit Hall

8:15 AM — 9:30 AM | Fiesta Ballroom 6-10

Session 9 Track 1: Podium Pearls

Session 9 Track 1: Podium Pearls

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

- Discuss and share best practices, experiences, and innovative processes for medical communications topics related to insights, contact center best practices, application of AI, and NLP searches

Track: Medical Communications

Session Chair(s)

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.

Speaker(s)

Considerations for the Development of Interactive/Innovative Medical Information Content– Insights From a Service Provider

Mary Mehrabian, PharmD

Associate Director of Global Medical Content Development
Eversana, United States

Mary Mehrabian is the Associate Director, Global Head of Content Development and Medical Review at EVERSANA, leading teams of medical writers, medical fact checkers, medical reviewers, and MLR coordinators in the United States, Europe, and India. She is a dual board-certified PharmD, who received her degree from the University of Illinois at Chicago and possesses over 20 years of experience in various therapeutic areas. Mary serves on two PhactMI committees and is passionate about leveraging technology to create fair and balanced medical information deliverables in a digestible and easy-to-use format for her biotech and pharma clients.

Medical Information Contact Center Best Practices

David Bowers, PharmD

Senior Director, Operations
PPD, United States

David Bowers has 20+ years of experience managing pharmaceutical contact center programs at PPD. As Senior Director of Operations, David supports global medical information for pharmaceutical, biotechnology and medical device clients. He has a background in pharmacy, with a Doctorate of Pharmacy from the University of North Carolina in the United States. During his time at PPD, David has worked with over 30 client contact center programs providing medical information, pharmacovigilance and product complaint processing, patient adherence programs, REMS support and other services. David's recent experience includes implementing contact center operations in the US, Europe, Latin America and Asia.

Applications of AI to Medical Communications Beyond Document Writing

Kevin Chen

Consultant, Medical Writing
Synterex, United States

Kevin?Chen is a freelance medical writer in the pharmaceutical industry, providing clinical and regulatory writing and business development services. Previously, he held full-time medical writing positions at small- and mid-size companies, emerging within less than a decade as a strategic leader with a passion for managing chaos, optimizing process, and nurturing talent. He lives in the San Francisco Bay Area with his wife and son, enjoying a life of food, sports, music, family, and friends.

Impact on Tier 2 Escalations in a Global Contact Center After Introducing an NLP-based Search

Sandrina Clemente, PharmD, MSc

Global Director, Operations & Conversational AI Architect for Life Sciences
Alphanumeric, Portugal

With 17 years of immersion in the Life Sciences sector and credentials including a PharmD and MSc in Clinical Analysis, Sandrina Clemente operates from Portugal, dedicated to enhancing global well-being through streamlined processes and top-notch customer service. Her passion lies in pioneering innovative solutions and tackling challenges with creativity. Sandrina's expertise spans leveraging cutting-edge technologies and artificial intelligence to ensure secure and efficient service delivery. Continuously forward-thinking, she delves into the evolving interplay between processes, human resources, and technology, anticipating future synergies.

8:15 AM — 9:30 AM

Fiesta Ballroom 5

Session 9 Track 2: Transforming Clinical Trial Protocol Development: A Modern Approach

This session will dive into topics that present challenges and opportunities in clinical trial protocol development. Speakers will present, how decentralized trials affect approaches to writing effective protocols, and how patient input can help engage patients and enhance protocol design and the role of generative AI and it's potential in revolutionizing protocol creation.

Learning Objective :

- Discuss decentralized clinical trial methodologies during the protocol planning process and identify protocol sections impacted by the addition of decentralized clinical trial methodologies
- Examine the critical role of patient perspectives in shaping clinical protocols, identifying how patient input can enhance protocol design, improve engagement and shorten timelines
- Evaluate applications of generative AI in medical content creation

Track: Medical Writing

Session Chair(s)

Elizabeth Olbrich, MS, RN

Associate Director
Evidera | PPD, United States

Speaker(s)

Impact of Decentralized Clinical Trial Methodologies on Protocol Planning and Development

Katie Kelm, PhD

Associate Director, Global Medical Writing
PPD, Part of Thermo Fisher Scientific, United States

Katie Kelm has more than 14 years of clinical research experience in academic and contract research organization settings. She provides oversight for medical writing projects and programs, including the client relationship, quality, timelines, resourcing, and finances. She has led revisions to standard operating procedures and has developed process guides and tools for describing decentralized clinical trial methodologies in protocols, risk mitigation, medical writing project management roles and responsibilities, audit preparation, financial systems, and electronic document management systems.

Voices that Matter: Capturing Patient Input for Clinical Protocol Development

Leanne Woehlke, MA

Director, Life Sciences Solutions
TransPerfect, United States

Leanne Woehlke, is a Director of Life Sciences Solutions at TransPerfect where she helps clients create transformational impact with language, technology and business consulting. She is also a Trainer for Tony Robbins, Professional Certified Coach and Host of the Clinical Research Coach podcast. Her career began as a CRA then she worked her way up to Director before consulting in patient recruitment, training and process optimization. Following an entrepreneurial decade, she returned to the corporate world integrating her knowledge of clinical research, patient recruitment and digital marketing. She is passionate about impacting the industry in meaningful ways and brining life changing treatments to patients who need them.

Unleashing the Power of Generative AI in transforming Study Protocol Design and Medical Writing Process

Susant Mallick, MBA

Founder and CEO, Life Sciences Practice Leader
Cloudhub BV, Netherlands

Susant Mallick comes up with 23+yrs of Pharma and IT background on building disruptive solutions/products in Clinical and Regulatory space. He is technology evangelist on cutting edge technology like (Artificial Intelligence, Machine Learning, IoT, Cloud etc) and an industry leading speakers across geographies. He has been working with various customers and partners in pharma and healthcare to drive digital transformation in clinical and regulatory landscape. He was instrumental in implementing/building many Regulatory solutions using advanced technology. Innovation and Digital Transformation in Healthcare and Life Sciences are two key focus areas.

8:15 AM — 9:30 AM Yucatan

Session 9 Track 3: Evolving Role of Medical Science Liaisons

Panel discussion on current MSL practices and opportunities for career growth.

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

- Discuss the current expectations of MSLs as a cross functional partner
- Outline the impact of MSLs on Medical Affairs strategic and tactical planning
- Identify areas of growth for the MSL profession

Track: Field Medical

Session Chair(s)

Dustin Cavida, PharmD

Associate Medical Director
Amgen, United States

I started in the industry as a Medical Affairs fellow in 2015 then became a Medical Science Liaison supporting products in the immunology and ophthalmology space. I later transitioned into Medical Communications before taking on my current role at Amgen as the Associate Medical Director supporting the rare disease team focused on neuroimmunology

Speaker(s)

Speakers

April Johnson, PharmD

Regional Director, Medical Science Liaisons
Novartis, United States

April graduated from the University of Florida College of Pharmacy in 2002 and completed an Ambulatory Care Residency in 2003. She then spent three years in academia at the FSU College of Medicine before transferring to the payer space, where she spent seven years at a nationally recognized HMO, both as a Clinical Pharmacist and a Pharmacy Director. This was followed by three years at a Pharmacy Benefit Management company, where she served as both a Clinical Advisor and an Executive Advisor for Product Innovation and Management. April made the transition to industry in 2015, working initially as an Evidence and Outcomes Liaison for Eli Lilly, and most recently, serving as a Regional Director for Medical Science Liaisons at Novartis.

Speaker

J. Lynn Bass, PharmD, RPh

Senior Director, Medical Science Liaisons
BridgeBio, 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

Iris Tam, PharmD

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

Iris Tam, PharmD, FAMCP, is Senior Vice President & Head of Medical Affairs and HEOR at COEUS Consulting with over 30 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 for the last 3 years.

9:30 AM — 10:15 AM Veracruz C

Networking Break in the Exhibit Hall – View Professional Posters!

10:15 AM — 11:15 AM Fiesta Ballroom 6-10

Session 10 Track 1: Navigating the Multichannel Frontier in Medical Communications

This session will explore the strategic use of multichannel approaches within the pharmaceutical industry, particularly from the perspective of Medical Information landscape. Attendees will gain insights into three case studies where multichannel strategies have significantly impacted customer engagement. The speakers will share valuable learnings, addressing best practices and challenges encountered in implementing multichannel communications strategies within Medical Information.

Learning Objective :

- Discuss the strategic utilization of multichannel approaches for Medical Information
- Examine three case studies illustrating the impact of multichannel strategies on enhancing customer engagement
- Evaluate best practices and challenges associated with implementing multichannel communication strategies within Medical Information

Track: Medical Communications

Session Chair(s)

Truc Dinh, PharmD

Associate Director, Global Medical Information
Gilead Sciences, Inc., United States

Truc Dinh is an Associate Director in Global and US Medical Information at Gilead Sciences focused on Virology and COVID-19. She brings over 5 years of experience in Medical Information launch

excellence, medical and promotional review, insights generation and cross-functional collaboration. She received a Bachelors degree in Public Health and Public Policy from the University of California, Berkeley and a Doctor of Pharmacy degree from the University of California, San Francisco with an emphasis on the Health Sciences and Policy Management pathway. She completed her postdoctoral fellowship in Medical Information with Gilead Sciences and the University of Southern California.

Speaker(s)

The Multichannel Journey

Robert Hunter, PharmD

Director, North America Medical Information
EMD Serono, United States

With over 20 years in the pharmaceutical industry within both clinical and scientific affairs, Robert now serves as the North America Medical Information Director for EMD Serono. In this role, Robert oversees and is responsible for all activities related to the handling of unsolicited medical information inquiries from healthcare providers, and is also responsible for overseeing the development and implementation of various digital initiatives on the medical resources website.

Beyond the Self-service Portal

Rebecca Falcone, PharmD

Global Medical Information Systems, Insights and Omnichannel Lead
Sanofi, United States

Rebecca Falcone, PharmD has over 20 years of pharmaceutical industry experience and is currently the Global Medical Information Systems, Insights & Omnichannel Lead at Sanofi. Rebecca is responsible for the implementation and management of a global medical information system for inquiry and content management utilized in more than 175 countries, along with managing medical information insight generation and data analytics, and supporting innovative medical information digital projects. Rebecca has been a speaker at both the DIA Annual and MASC meetings and participated as a past MASC program committee member.

From Search to Clinical Decisions: Empowering HCPs with Med Info through SEO

Joy Yee, PharmD

Associate Director, Global Medical Information
Gilead Sciences, Inc., United States

Joy is the Business Innovations Lead on the Global Strategic Capabilities team supporting Global Medical Information at Gilead Sciences, Inc. In her current role, Joy leads initiatives focused on new ways of working and innovative solutions to connect customers and patients with Medical Information. Joy also spent several years supporting numerous products/therapeutic areas as a Medical Information Specialist. Prior to joining Gilead in 2014, she practiced clinical pharmacy at the California Pacific Medical Center in San Francisco, California. Joy has a Doctor of Pharmacy degree from the University of the Pacific Thomas J. Long School of Pharmacy in Stockton, California.

10:15 AM — 11:15 AM Fiesta Ballroom 5

Session 10 Track 2: Time Well Spent – Strolling Session

This session is designed to be an interactive, discussion on the value of time, how to determine if something is worth doing, and evaluate the utility of various tools for time keeping, saving, and management in the world of the medical writer. Join us as we get out of the traditional meeting room and have these conversations with peers as we stroll around the venue.

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

- Discuss the value of time in our work, and our lives
- Analyze how we set priorities as medical writers
- Evaluate and share different tools for time keeping, saving and management as medical writers

Track: Medical Writing

Session Chair(s)

Diane Cleverley, PhD

Senior Regulatory Writer
Certara, United States

Dr. Cleverley has more than 20 years experience in the medical publication field, which she entered shortly after earning her PhD in Microbiology and Molecular Genetics as a joint degree from Rutgers and UMDNJ. During that time, she proposed the “glycine hinge” theory. She has contributed editorial support for publications for prestigious higher tier journals such as NEJM and JCO. Dr. Cleverley has also written award-winning patient literature, clinical trial materials, and healthcare provider education. She currently is lending her writing talents to the regulatory field. She developed a patient advocacy tool for making diagnosis more effective. Dr. Cleverley has been an active team member of AMWA, ISMPP, and MAPS, and holds a CMPP.

10:15 AM — 11:15 AM Yucatan

Session 10 Track 3: Access Tools for HEOR Field Teams

This session will review field medical tools targeted to answer access questions. With a blend of dedicated field HEOR teams with cross training of therapeutic MSL Teams, some clarity on common clinical and economic tools will be discussed. Focus will be on standard tools expected by payers and decision makers. Specifically, this session will cover the AMCP Dossier and economic tools such as the Budget Impact Model with cost offsets.

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

- Review the AMCP dossier format with clinical and economic information included
- Discuss the features of a standard budget impact models with examples of cost offsets
- Describe standard HEOR field tools needed for medical and economic discussions

Track: Field Medical

Session Chair(s)

Sonja Wesley Hokett, PharmD, MS, MSc

Executive Director/Head of Medical Managed Care
BioXcel Therapeutics, United States

Residing in Branson, Missouri, Sonja holds PharmD degree from the University of Louisiana Monroe, Master of Science degree in Hospital Pharmacy Administration from the University of Houston, and Executive Master's degree Health Economics, Policy & Management from the London School of Economics. During her 19 years in the pharma industry, Sonja has held both Field and Headquarter pharma Medical Affairs positions at BioXcel Therapeutics, Jazz, Intercept, and Genentech. She currently manages a Medical Managed Care field team and oversees HEOR for BioXcel Therapeutics.

Speaker(s)

"Everything you Want to Know" - AMCP Dossiers

Iris Tam, PharmD

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

Iris Tam, PharmD, FAMCP, is Senior Vice President & Head of Medical Affairs and HEOR at COEUS Consulting with over 30 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 for the last 3 years.

The Price is Right, or Is It? Budget Impact Models & Cost Offsets

Jeff Lee, PharmD

Vice President, Value Demonstration
Lumanity, United States

Jeff is a senior HEOR leader, with a focus on generating and communicating value evidence for payor audiences. Jeff led the Global Health Outcomes and Payer MSL teams at Allergan after several years as International Director of Pharmacoeconomics at Glaxo. Jeff is an ACCP Fellow, led development of ACCP's pharmacoeconomics fellowship training programs, and was Chair of the AMCP Format Executive Committee, where he led development of the AMCP

Format 4.0. He also actively supported AMCP's advocacy efforts around preapproval information exchange in Congress. At Lumanity, Jeff is the US Region Lead within the Value Demonstration Practice, advising clients across the spectrum of value evidence generation and communication activities.

11:20 AM — 12:20 PM Fiesta Ballroom 6-10

Session 11: Closing Plenary: Designing for Forgetting – Adapting Scientific Communication to a New Picture of Scientific Knowledge

What if the primary imperative for advancing scientific communication is not simply to disseminate data to support optimal care decisions, but rather to design communications better calibrated to how and what people forget, what they choose to ignore, and how selective they are in absorbing and putting into practice the evidence? What if, as in the recent case of the complete reversal of thinking as to how elementary school reading is taught in the US—based on revisiting evidence from cognitive psychology, neuroscience and other branches of research— we too have had it all wrong? Advances in cognitive neuroscience—specifically recent findings that have led to some reevaluation of the interplay between memory, knowledge, and decision-making— now merit our consideration. These advances chart paths for innovation in medical affairs and scientific communication practice. In some respects, they call for reconsideration and change.

In this closing talk, we will consider adaptations to form and content; discuss best practices and lessons learned; and dip into the key ideas from those pushing the science forward. Specifically, looking beyond the suppositions of pure rationality or even "ecological rationality," we will discuss the cardinal problems of:

- Persistently suboptimal evidence-based medical decisions
- Apparently intractable misconstruals of scientific evidence, in the face of new or better evidence, up to and including those based in misinformation

We will lay out some contributing factors, in the form of individual/group differences in the automatic appraisals of scientific information; individual differences in memory encoding-retrieval; and, of course, how much (even) experts forget. We will do so with an eye for practical solutions, end users, and end goals of supporting optimal health outcomes.

Learning Objective :

- Employ cognitive neuroscience insights in refining scientific communication strategies, emphasizing considerations of individual memory processes and information absorption to improve patient health outcomes
- Examine enhanced medical affairs and scientific communication practices, specifically targeting challenges related to the suboptimal evidence-based medical decisions and misinterpretations of scientific evidence

Track: General Session

Session Chair(s)

Representative Invited

Session Chair, United Kingdom

Speaker(s)

Speaker

Brian Dunn, MS, MSc

Associate Principal
ZS, United States

Brian leads ZS's Health Decision Science research practice. He serves as a consulting subject matter expert for primary research and design in questions of clinical judgment and decision making in medicine. Brian draws from over 15 years of experience in the fields of cognitive neuroscience, experimental psychology, and psychiatry research. He is a coauthor of publications in the areas of molecular psychiatry, neuroeconomics, and human affective neuroscience. His primary area of academic research was the functional neurocircuitry of human emotion and judgment, specifically the interface of somatic signals, emotion and cognition, as mapped using functional magnetic resonance imaging (fMRI).

12:20 PM — 12:30 PM

Fiesta Ballroom 6-10

Closing Remarks

12:20 PM — 12:30 PM

Forum Adjourns