



DEAR COLLEAGUES:

We are pleased to present the final program for the 19th Annual Meeting of ISMPP, **Medical Publications in a Data-Rich World: Enhancing Quality and Transparency**. Meeting sessions will highlight the increasing transparency being demanded by patients, investors and clinical colleagues, as well as how to ensure quality of data and reporting in all scientific communications in a fast-paced, multichannel environment.

The exciting program of the 12th Annual Meeting of ISMPP will enable attendees to:

- Discuss recent developments in several areas such as guidelines, regulations and data sharing
- · Learn from stakeholder perspectives including publication department heads, biostatisticians, and patients
- Continue sharing best practices and keep abreast of guidance updates to maximize the communication of medical information
- Anticipate upcoming trends and challenges in the field of medical publications

We have continued with a more interactive format for the Annual Meeting with roundtables now expanded across each day. This year's meeting content will be driven more than ever by member input with the inclusion of several different activities: a Favorite ISMPP U parallel session, Member Proposal parallel sessions, and an increased number of oral presentations. This year we are also introducing a Guided Poster Tour that aims to maximize attendee exposure to member research. A keynote speaker session will take place each day, and we are featuring a new workshop on Patient Lay Summaries. Each meeting day will continue to offer practical-based sessions and a host of networking opportunities.

On behalf of ISMPP's Board of Trustees, the 19th Annual Meeting Program Committee and the ISMPP staff, **Welcome!** Yours Sincerely,

Teresa L. Peña, PhD

feresa L Dina

Chair, ISMPP BOT (2015-2016)
Executive Director, Medical Publications
Bristol-Myers Squibb

Alice Choi, PhD, ISMPP CMPP™
Chair, ISMPP BOT (2014–2015)

Chair, ISMPP Annual Program Committee Global Head Complete Medical Communications Aruna Seth, PhD, ISMPP CMPP™

Co-Chair, ISMPP Annual Program Committee Scientific Strategy Lead Envision Pharma Group Juli Clark, PharmD

Co-Chair, ISMPP Annual Program Committee Executive Director, Global Medical Writing Scientific Affairs, Amgen, Inc.

PROGRAM AGENDA

SUNDAY EVENING, APRIL 10

6:30 PM -8:30 PM

7:30 AM -

Welcome Reception POSE Rooftop Lounge Gaylord National Resort & Convention Center

The Welcome Reception is generously sponsored by:





MONDAY MORNING, APRIL 11

8:30 AM Registration and Continental Breakfast			
8:30 AM - 10:00 AM	Pre-conference Workshops (schedule and descriptions on pages 28-39)		
10:00 AM - 10:30 AM	Morning Break and Visit Exhibits		
10:30 AM – Noon	Pre-conference Workshops (continued)		
Noon – 1:30 PM	Lunch for Workshop Attendees, Speakers, and Exhibitors only		

Desictantian and Continental Prophlact

MONDAY AFTERNOON, APRIL 11

1:30 PM -Welcome to the 12th Annual Meeting of ISMPP 1:40 PM **Opening Remarks** Teresa L. Peña, PhD, Chair, ISMPP Board of Trustees (2015 – 2016); Executive Director, Global Medical Publications, Bristol-Myers Squibb 1:40 PM -Keynote 2:10 PM Jennie Sykes, MD, Vice President, Global Medical Platforms, GlaxoSmithKline

MONDAY AFTERNOON, APRIL 11

2:10 PM -2:50 PM

Data-Sharing Expectations in an Age of Transparency: Spotlight on ICMJE Member Journal Proposal



Earlier this year, ICMJE member journals proposed new requirements for authors to include a data sharing plan, and access to related de-identified individual patient data supporting the clinical trial results, within 6 months of publication. As public demand for data transparency and the call for data generators to share and provide access to data is stronger than ever, our stakeholders have new expectations. This session will feature expert stakeholders and "consumers" of the scientific publications we help bring to our audiences. Selected panelists are professionals with expertise in trial design, data interpretation and dissemination, and represent viewpoints from within industry, academia and medical journals. This session is a "must see" for all publication professionals.

Christine Laine, MD, MPH, FACP, Editor-in-Chief, *Annals of Internal Medicine*; Senior Vice President, American College of Physicians

Karen Mittleman, PhD, Head, Publications, Office of the Group CMO, Sanofi

Grannum R Sant, MD, FRCS, FACS, Medical Affairs Consultant, Photocure ASA; Former Professor & Chairman, Department of Urology, Tufts University School of Medicine

Jennie Sykes, MD, Vice President, Global Medical Platforms, GlaxoSmithKline

Moderator: Al Weigel, MEd, ISMPP CMPP™, President & CEO, International Society for Medical Publication Professionals

2:50 PM -3:30 PM

Increasing Efficiency and Transparency Around Author Disclosures: Introduction to the CONVEY System

Academic medicine professionals report that administrative tasks infringe on time better devoted to teaching, research, and patient care. A new global disclosure system developed by the AAMC stands to reduce the amount of time physicians, researchers, and scientists spend filling out redundant disclosure forms intended to identify potential conflicts of interest (COI).

Known as Convey, the online system addresses an Institute of Medicine (IOM) recommendation to develop a centralized system for disclosing financial interests. This session will discuss key efficiency features and the potential impact on medical publication professionals and the overall peer-review journal manuscript submission process. Specifically, the Convey system will illustrate the COI submission process for a manuscript submitted to a peer-reviewed journal from the perspective of the author who must disclose potential COI.

Heather H. Pierce, JD, MPH, Senior Director, Science Policy Regulatory Counsel, Scientific Affairs Association of American Medical Colleges

Moderator: LaVerne Mooney, DrPH, Director & Team Leader, External Medical Communications Publications Management, Pfizer

Learning Objectives

By the end of the session, attendees will:

- Gain an understanding of what various stakeholders will expect from authors with respect to clinical trial publication, data sharing plans and providing access to supporting clinical trial data
- Learn what challenges the new ICMJE data sharing proposal presents to sponsors and researchers/authors as a condition for publication

Learning Objectives

By the end of the session, attendees will:

- Understand the impetus for and potential advantages of a global disclosure system
- Be knowledgeable of the ways in which a standardized system can impact the manuscript submission process

3:30 PM -4:00 PM

Afternoon Break and Visit Exhibits

MONDAY AFTERNOON, APRIL 11

4:00 PM -4:40 PM

Parallel Sessions

Your choice! Pick the topic of most interest to you, and engage in a 40-minute interactive exchange with faculty in a smaller group setting. Each parallel session is being held twice to provide attendees with more opportunity to take advantage of today's topics.



Real-life Authorship Challenges and How to Best Resolve Them

Have you been chasing an author for feedback on a manuscript draft or approval? Have all authors provided substantial feedback? What constitutes substantial feedback? Who qualifies as an author, and in what order should they be listed? What is an author's role according to GPP3? The aim of this interactive and engaging session is to discuss real-life author challenges faced by the ISMPP membership. If you are looking for guidance and solutions for authorship issues, this session is for you!



Lynne Gordon, MPH, ISMPP CMPP™, Director, Medical Affairs, Theravance

Kristen Mack, PharmD, ISMPP CMPPTM, Associate Director, Global Medical Publications, Biogen

Mina Patel, PhD, Senior Director, Global Scientific Communications Metabolics, Alexion Pharmaceuticals, Inc.

Michael Platt, MS, ISMPP CMPPTM, President, MedVal Scientific Information Services, LLC

Moderator: Aruna Seth, PhD, ISMPP CMPPTM, Scientific Strategy Lead, Envision Pharma Group

Learning Objectives

By the end of the session, attendees will:

- Identify the most common authorship issues faced by ISMPP colleagues
- Understand best practices and be able to address authorship issues



Unique Publication Plans: Focus on Oncology and Rare Diseases

The therapy area of oncology, including immuno-oncology, presents unique challenges, both in designing clinical trials and in presenting/ publishing trial results. In this rapidly evolving treatment landscape, quick dissemination of practice-informing data is paramount. This coupled with the acceleration of clinical development programs with novel designs requires a paradigm shift from the traditional publication planning and execution. Publication planning in rare disease areas presents different kinds of challenges (eg more focus on disease awareness or diagnosis, very few patients in clinical trials, data from patient registries, etc.). This session will highlight these unique features and educate attendees on how to successfully develop and execute these publication plans.

Diane Moniz Reed, PharmD, ISMPP CMPPTM, Head, Oncology Medical Publications, Bristol-Myers Squibb

Scott D. Newcomer, MS, ISMPP CMPP™, Consultant, Davenport Scientific Services

Moderator: Renu Juneja, PhD, Head, Medical Communications, MedImmune

Learning Objectives

By the end of this session attendees will:

- Understand the unique features of publication plans in rapidly evolving immuno-oncology and rare disease
- Identify key considerations when developing and executing these publication plans



Ins and Outs of Publication Steering Committees

Publication Steering Committees (PSCs) enhance transparency, and investigator engagement, and often optimize data output and publications from clinical trials by reaching the most appropriate audiences. This session will educate on the development and execution of successful PSCs via case studies and personal experience.

Jonathan Druhan, PhD, Director, Publications, US Medical Affairs, AstraZeneca

Grannum R Sant, MD, FRCS, FACS, Medical Affairs Consultant, Photocure ASA; Former Professor and Chairman, Department of Urology, Tufts University School of Medicine

Anita N. Schmid, PhD, Associate Director, Global Scientific Communications, Celgene

Moderator: Bhakti Kshatriya, PharmD, Director, Publication Excellence, Global Scientific Communications, GMA Novartis Pharmaceuticals Corporation

Learning Objectives

By the end of the session, attendees will:

- Be able to describe and understand key tactics for establishing and conducting successful PSCs
- Understand ways to overcome obstacles in assembling and driving PSC success

MONDAY AFTERNOON, APRIL 11

4:40 PM -4:50PM

Move to Next Session

Choose from one of our traditional parallel sessions, a guided poster tour or a roundtable session. Please note that the parallel sessions and guided poster tour are 40 minutes each, and the roundtable session is 55 minutes.

4:50 PM -5:30 PM

Parallel Sessions

Your choice! Pick the topic of most interest to you, and engage in a 40-minute interactive exchange with faculty in a smaller group setting.



Real-life Authorship Challenges and How to Best Resolve Them (see description on page 5)



Unique Publication Plans: Focus on Oncology and Rare Diseases (see description on page 5)



Ins and Outs of Publication Steering Committees (see description on page 5)

4:50 PM -5:30 PM

Guided Poster Tour - Theme: Quality & Transparency (NEW this year!)

Some of the richest Annual Meeting content is from member research. To further highlight these contributions to the medical publications space, we are offering a new opportunity for an in-depth discussion on select posters centered around themes determined by the focus of this year's member-submitted research. Taking place in the poster galley, the tour will be led by a member of the 12th Annual Meeting of ISMPP Abstract Committee, and poster authors will present and discuss their posters with tour participants. Tours will be limited in size in order to allow for a focused discussion and active participation.

4:50 PM -5:45 PM

Roundtable Session

Roundtables will be held each day of our program, with this Roundtable session being the longest. Many topics will have cases embedded in each discussion to ensure real-world applicability to your day-to-day work. Each discussion will be moderated by an area expert. Each attendee will have the opportunity to attend one Roundtable. Select topics will qualify for ISMPP CMPPTM credit.

- Challenges in Interpreting Publication Guidelines - ICMJE and Beyond
- Copyrights **NEW!**
- Digital and Enhanced Media Options

- Ethics/Compliance
- Industry-Agency Relationship Working as a True Team
- Patients and Publications Current Topics and Trends in an Age of Transparency NEW!

This session was made possible by an educational grant from:



Synchrony Medical Communications had no role in the development of the content or selection of the moderators.

MONDAY EVENING, APRIL 11

5:45 PM -6:45 PM



ISMPP Member Poster Presentation Assembly

Woodrow Wilson Ballroom Foyer

Please see pages 22-23 for a listing of this year's Poster Presentations.

The ISMPP Member Poster Presentation Assembly is generously sponsored by:



TUESDAY MORNING, APRIL 12

7:00 AM – 8:00 AM	Registration and Continental Breakfast
8:00 AM – 8:05 AM	Opening Remarks Alice Choi, PhD, ISMPP CMPPTM, Chair, ISMPP BOT (2014 – 2015); Chair, ISMPP Annual Program Committee; Global Head, Complete Medical Communications
8:05 AM – 8:45 AM	Keynote Richard Smith, former Editor, British Medical Journal
8:45 AM – 9:15 AM	Member Oral Presentations Four out of 37 abstracts were selected via blinded peer review for oral presentation. The two abstracts that will be presented today represent some of the top research submitted and reinforce the value served by medical publication professionals.



Who engages with patient-centered, peer-reviewed publications? Tweeting of JAMA Patient Pages

Karen Woolley, PhD, ISMPP CMPPTM, Division Lead, Envision; Director, Sunshine Coast Hospital & Health Service; Adjunct Professor, University of Queensland; Adjunct Professor, University of the Sunshine Coast

Patients and peer-reviewed publications: An analysis of journal websites and patient advocacy sites

Michael van der Veer, Associate Medical Publications Manager, Scientific Publication Planning, Excerpta Medica, Amsterdam, The Netherlands

Moderator: James Gurr, PhD, ISMPP CMPPTM, ISMPP Abstract Committee Chair; Publications Lead, Oncology, Scientific Publications, MedImmune

9:15 AM -9:45 AM

National Information Standards Organization (NISO): Focus on Altmetrics

NISO is a non-profit industry trade association is where content publishers, libraries, and software developers turn for information industry standards that allow them to work together. NISO has initiated a standardization program for altmetrics, known as the NISO Altmetric Initiative. This session will educate on these plans and offer opportunity for discussion.



Moderator: Kenneth Pomerantz, PhD, Director, Medical Publications, Boehringer Ingelheim Pharmaceuticals, Inc.

Learning Objectives

By the end of this session attendees will:

- Understand the mission and goals of NISO
- Be knowledgeable about the process and plans for the NISO Altmetric Initiative
- Gain insight into the implications for medical publication professionals of having standards around altmetrics

TUESDAY MORNING, APRIL 12

9:45 AM -10:15 AM

Morning Break and Visit Exhibits

10:15 AM -10:55 AM

Social Media and Publication Planning in 2016 and Beyond

CMPP RECEIPMENTERS GESTIS The advent of social media has changed the communication environment – what does this mean for publications and disseminating research? Organizational policies around social media vary and often lean to the conservative side, if allowed at all. Companies and the medical communication agencies that support them often struggle with effective ways to utilize such a powerful tool in a manner that is still within company compliance guidelines. This session will offer examples of social-media related activities at several industry companies. Different approaches will be illustrated as well as lessons learned.

Paul O'Grady, PhD, Senior Director, Medical Digital Strategy, Medical Science Liaisons & Medical Information, Oncology Global Development & Global Medical Affairs, Novartis

Kenneth Pomerantz, PhD, Director, Medical Publications, Boehringer Ingelheim Pharmaceuticals, Inc.

Catherine Skobe MPH, MT(ASCP), Director, Publications Management, Pfizer

Moderator: Sarah L. Feeny, BMedSc, Head of Scientific Direction, Complete Medical Communications

Learning Objectives

By the end of the session attendees will:

- Gain insight into the different opportunities in social media
- Understand the regulatory environment for social media
- Be knowledgeable about ways social media can be integrated into publication plans

10:55 AM -11:45 AM



Enhanced Content: Pros, Cons, Processes and Trends

As technology advances, mobile usage is becoming widespread and we are continuously pressed for time, there emerges the need for new ways to consume content. Recognizing this need, publishers and companies have started to offer enhanced content, including interactive articles, multimedia, and augmented reality posters. Enhanced content may also present the opportunity to target secondary audiences with layered content summaries. Great content is engaging, has compelling visuals, a clear story, and is tailored to the target audience. How can we make use of the advantages of enhanced content without losing scientific rigor and at the same time conform with best publication practices?

Neil Adams, ISMPP CMPP™, Publishing Manager, Nature Publishing Group

Grahame Conibear, BSc, Senior VP, Integrated Communications, Adelphi Communications

Catherine Skobe MPH, MT(ASCP), Director, Publications Management, Pfizer

Moderator: Terry Materese, Executive Publisher, Health & Medical Sciences, Elsevier

Learning Objectives

By the end of the session attendees will:

- Gain insights into why there is a need to create digital and enhanced content
- Learn about new trends in content development and be able to describe characteristics of a great digital/enhanced content product
- Be knowledgeable about key considerations as well as the publication process recommended for enhanced content

TUESDAY MORNING, APRIL 12

11:45 AM - 12:15 PM

ISMPP Business Meeting

12:15 PM -1:15 PM

Lunch

TUESDAY AFTERNOON, APRIL 12

1:15 PM -1:55 PM

Choose from one of our traditional parallel sessions or a guided poster tour (participation limited)

Parallel Sessions

Your choice! Pick the topic of most interest to you, and engage in a 40-minute interactive exchange with faculty in a smaller group setting.



Data Transparency - Domestic and Abroad

Requirements for transparency and data reporting have become more widespread, with potentially substantial consequences for those responsible for medical publication planning. Recently, the European Medicines Association (EMA) and European Federation of Pharmaceutical Industries and Associations (EFPIA) have implemented significant changes to existing rules and directives. Countries outside the EU are also considering similar transparency requirements. Stateside, the US government may soon require companies running clinical trials to post their informed consent forms publicly, under rules proposed by the Department of Health and Human Services (HHS). This session will feature a discussion of select current and proposed transparency initiatives, and examples of how one company is preparing to address processes affecting medical publications.

Brian P. Sharkey, JD, Vice President, Porzio Life Sciences, LLC

Susan Wieting, ISMPP CMPPTM, Director, Scientific Publications, Global Medical Affairs, Shire International GmbH Moderator: Juli Clark, PharmD, Executive Director, Global Medical Writing, Scientific Affairs, Amgen, Inc.

Learning Objectives

By the end of the session, attendees will:

- Understand current transparency initiatives that impact medical publications
- Be knowledgeable about planned transparency initiatives that may require public posting of additional documents (eg. Informed consent, subject lay summaries)



Nuts and Bolts of Biostatistics

Robust statistical practice is vital in medical research. Biostatisticians play an integral role in every step in the research process and effective collaboration within teams is essential. In an environment of accelerated trials and increasing emphasis on real-world studies, a thorough understanding of biostatistics is essential. This session will offer guidance from industry-based biostatisticians as well as from the medical journal perspective.

Janet Forrester, PhD, Associate Professor, Department of Public Health & Community Medicine Tufts University School of Medicine

Meg Franklin, PharmD, PhD, President, Franklin Pharmaceutical Consulting, LLC

Moderator: Nicholas J Combates, PhD, ISMPP CMPPTM Associate Director, Global Scientific Communications, Celgene

Learning Objectives

By the end of the session, attendees will:

- Understand the role of biostatisticians in industrysupported clinical research and how to partner successfully
- Be knowledgeable about the role of journal-based biostatisticians and what they look for in manuscript submissions

1:15 PM -1:55 PM

Understanding the Value of Your ISMPP Certified Medical Publication Professional™ (CMPP) Credential and the Importance of Continuing Education



Since the Certified Medical Publications Professional (CMPP) Program was initiated, it has not only reinforced ISMPP's ongoing commitment to the profession, it has also demonstrated to the public and the professional and lay media the industry's support of best practices aimed at ensuring scientific and professional integrity in medical publications. The CMPP Recertification program is designed to encourage ongoing professional development of certificants through active engagement in continuing education activities that enable them to stay abreast of evolving standards and maintain fluency in ethical publication practices.

Vincent Lima, Director, Computer-Based Testing, Professional Testing, Inc.

Suzann Schiller, ISMPP CMPPTM, Executive Vice President, Strategic Collaborations, Cello Health Communications | MedErgy and SciFluent

Jayme C. Trott, PharmD, MBA, ISMPP CMPPTM, Director, Global Medical Affairs Strategic Operations Janssen Global Services, LLC

Moderator: Sharon Willis, ISMPP CMPPTM, Director, Credentialing, ISMPP

Learning Objectives

By the end of the session, attendees will:

- Understand the value of the ISMPP CMPP™ credential
- Understand the importance of continuing education and the credit accrual process
- Be knowledgeable about recent developments and resources within the CMPP credential program

Guided Poster Tour - Theme: Metrics & Measurements (NEW this year!)

Some of the richest Annual Meeting content is from member research. To further highlight these contributions to the medical publications space, we are offering a new opportunity for an in-depth discussion of select posters centered around themes determined by the focus of this year's member-submitted research. Taking place in the poster galley, the tour will be led by a member of the 19th Annual Meeting of ISMPP Abstract Committee, and poster authors will present and discuss their posters with tour participants. Tours will be limited in size in order to allow for a focused discussion and active participation.

1:55 PM - 2:00 PM

Move to Next Session

2:00 PM -2:40 PM

Choose from one of our traditional parallel sessions or a guided poster tour (participation limited)

Parallel Sessions

Your choice! Pick the topic of most interest to you, and engage in a 40-minute interactive exchange with faculty in a smaller group setting.



Advancing Good Publication Practices in the Asia-Pacific Region: Good Practices for Recruiting, Training, and Retaining Publication Champions in Affiliates

Medical publications from the Asia-Pacific region are increasing . . . and coming under intense scrutiny. To meet some of the current challenges and advance good publication practices, ISMPP recently held its first-ever live medical publication meeting in this region. With input from the Asia-Pacific Advisory Committee (APAC), this session will draw upon experiences in the region to educate on how to achieve successful outcomes.

Gary Burd, PhD, ISMPP CMPP™, Global Medical Director, Caudex

Mieko Hamana, ISMPP CMPPTM, Associate Director, Medical Affairs, Astellas

Aya Takemoto Tokaji, ISMPP CMPPTM, Scientific Director, MDS-CMG Inc. McCann Complete Medical, Japan

Learning Objectives

By the end of the session, attendees will:

- Gain insights into some of the publication obstacles faced in the Asia-Pacific region
- Learn strategies to overcome challenges while working in the Asia-Pacific region



Nuts and Bolts of Biostatistics (see description on page 10)



Professional Literacy and Publications – Cutting through the Clutter

When we hear the term "health literacy," our minds go directly to the many patients who struggle to find, read, process and use health information. In this session, we "flip the script" and analyze the elements of publications that may impact literacy for healthcare providers. Key barriers such as time constraints, fatigue and overload can impact everyone's ability to process content offered through publications. The good news is that we can leverage the same best practice guidelines that drive clear communication for patients. Join this session and help us to analyze how these guidelines can cross over and improve clarity and engagement in publications.

Christopher G. Kelly, MEd, Associate Director, Medical Communications, Quintiles

Moderator: Sharon Suntag, MS, ISMPP CMPPTM, Medical Director, Quintiles

Learning Objectives

By the end of the session, attendees will:

- List 3 barriers that should be considered when developing publications
- Identify 5 best practices for clear communication in publications
- Describe 5 strategies that drive clear, engaging scientific presentations

Guided Poster Tour - Theme: Professional Issues & Industry Trends (NEW this year!)

Some of the richest Annual Meeting content is from member research. To further highlight these contributions to the medical publications space, we are offering a new opportunity for an in-depth discussion on select posters centered around themes determined by the focus of this year's member-submitted research. Taking place in the poster galley, the tour will be led by a member of the 12th Annual Meeting of ISMPP Abstract Committee, and poster authors will present and discuss their posters with tour participants. Tours will be limited in size in order to allow for a focused discussion and active participation.

2:40 PM -2:45 PM

Move to Next Session

2:45 PM -3:30 PM

Choose from one of our traditional parallel sessions or a roundtable

Parallel Sessions

Your choice! Pick the topic of most interest to you, and engage in a 40-minute interactive exchange with faculty in a smaller group setting.

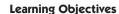


Biotech, Device and Diagnostic Publications

The biotech, device and diagnostics industry continues to be in the spotlight of regulators and enforcement agencies. In addition to differences in the regulatory process, other factors inherent to the product lifecycle of devices contribute to a publication planning process that is different from that for pharmaceuticals. This session will provide a framework for publication planning and best practices for biotech, device and/or diagnostics.



Seth J. Goldenberg, PhD, Director, Product Development Strategy, NAMSA



By the end of the session, attendees will:

- Understand the value and goals of publication planning for biotech, medical devices and/or diagnostics
- Identify best practices for executing a publication plan for biotech, medical devices and/or diagnostics
- Understand the regulatory landscape in this category



Health Economics and Outcomes Research (HEOR) 1.0: Roadmap of Top 10 Principles to Follow When Developing HEOR Publications

As a key part of the request for comparative effectiveness evidence, the increased use of HEOR data can be expected in future decision-making processes. In addition, a greater emphasis has recently been placed on positioning the patient at the center of healthcare decisions. Outcomes research plays an increasingly important role in this trend, because it can provide data on specific populations and treatment combinations that are used. This practical-based session will focus on the current trends driving HEOR and the different types of HEOR study designs and their relationship to product life cycle, with a focus on publication planning. HEOR 1.0 is a repeat of last year's top-rated HEOR session, providing key pointers for the development of HEOR publications.

Rina Mehta, PharmD, MBA, Senior Manager, I&I Publication Solutions, Celgene

 $\mbox{\bf Moderator/Faculty: Hester van Lier, PhD, ISMPP CMPP^{\mbox{\scriptsize TM}}, \mbox{\bf Program Director} \\ \mbox{\bf Excerpta Medica}$

Learning Objectives

By the end of the session, attendees will:

- Understand the different phases of HEOR
- Understand the implications of HEOR with respect to publication planning
- Gain ideas for how to continue to build credibility for these types of publications



2:45 PM -3:30 PM

Publication Planning for Biosimilars: Challenges and Opportunities

3



As more biosimilar products come to market in the US and around the world, publication professionals need to better understand the implications of biosimilars on their own company's product portfolio. In addition, companies developing biosimilar products will need publication professionals to develop related publication plans. During this session, experts will compare and contrast the unique challenges and opportunities of developing publication plans for biosimilar vs. innovator products. Publications must collectively establish the safety, efficacy, and cost effectiveness of the biosimilar, and must provide more detail about justifying extrapolation of indications and process development (complexity, comparability and biosimilarity).

Deborah Mayo, PharmD, VP, Global Scientific Communications, Teva Pharmaceuticals **Monica Ramchandani, PhD,** Sr. Manager, Medical Writing, Amgen

Moderator: Christine Gatchalian, PhD, Director, Medical Writing, Global Medical Writing, Amgen

Learning Objectives

By the end of the session, attendees will:

- Get an overview of the regulatory pathway to approval for biosimilars, including recent FDA guidance
- Learn about special considerations and components in biosimilar publication plans, including varied audiences and specialized topics on biosimilar policy, smaller, shorter clinical trials, and specific analytic models to demonstrate biosimilarity
- Be knowledgeable about potential impacts to innovator products when a company adds a biosimilar to the existing portfolio or enters the field as a competitor



Roundtable Session

Today's Roundtable sessions will provide a professional forum for attendees to exchange ideas, experiences, and information with their colleagues and peers around preselected topics identified by the ISMPP membership as key areas of interest to the medical publication community. Each attendee will have the opportunity to attend one Roundtable. Select topics will also qualify for ISMPP CMPPTM credit

- Accelerated Trials Challenges NEW!
- Best Practice Interacting with Authors
- Challenges in Interpreting Publication Guidelines- ICMJE and Beyond
- Doing More with Less Managing Resources and Budgets
- Future of Publishing New Models of Peer Review
- Social Media and Medical Publications
- Working with PAs/NPs as Authors NEW!

This session was made possible by an educational grant from:



Synchrony Medical Communications had no role in the development of the content or selection of the moderators.

3:30 PM -4:00 PM

Afternoon Break and Visit Exhibits

4:00 PM -4:45 PM

Choose from one of our traditional parallel sessions or a roundtable

Parallel Sessions

Your choice! Pick the topic of most interest to you, and engage in a 40-minute interactive exchange with faculty in a smaller group setting.



Biotech, Device and Diagnostic Publications (see description on page 12)



Health Economics and Outcomes Research (HEOR) 2.0: The Value of **HEOR Publication Planning**

Taught by the same faculty as the top-rated HEOR 1.0, HEOR 2.0 is an advanced session, providing insights into drug value and HEOR publication needs.



Rina Mehta, PharmD, MBA, Senior Manager, I&I Publication Solutions, Celgene

Moderator/Faculty: Hester van Lier, PhD, ISMPP CMPPTM, Program Director, Excerpta

Learning Objectives

By the end of the session, attendees will:

- Understand different perspectives on drug value
- Understand HEOR data needs to inform drug value decisions
- Gain ideas on adding value to publication plans with HEOR evidence



Publication Planning for Biosimilars: Challenges and Opportunities (see description on page 13)



Roundtable Session

Today's Roundtable sessions will provide a professional forum for attendees to exchange ideas, experiences, and information with their colleagues and peers around preselected topics identified by the ISMPP membership as key areas of interest to the medical publication community. Each attendee will have the opportunity to attend one Roundtable. Select topics will qualify for ISMPP CMPP™ credit.

- Approaches and Special Considerations for Publication Consultants
- Best Practice Interacting with Authors
- Challenges With Review Manuscripts and Supplements
- Digital and Enhanced Media Options
- EFPIA/Sunshine Act
- Ethics/Compliance
- Social Media and Medical Publications

This session was made possible by an educational grant from:



Synchrony Medical Communications had no role in the development of the content or selection of the moderators.

4:45 PM -4:55 PM

Move to Ballroom

4:55 PM -5:45 PM

Myth Busters: Separating Fact from Fiction in our Profession

We have seen many advances in our profession and there are a plethora of ongoing initiatives to raise awareness of best practice, including the ICMJE requirements and the recent publication of GPP3. However, at the same time, we still find ourselves exposed to misinformation in the public domain and a lack of understanding about the role of the medical publication professional. In this session, we will highlight 5 common and damaging "myths" covering a range of topics including "ghostwriting", the need (or not) for medical writing support and data disclosure. Each myth will be discussed by our expert panel and addressed through evidence-based discussion.

Jackie Marchington, PhD, ISMPP CMPPTM, Director of Operations, Scientific Services, Caudex

Santosh Mysore, PhD, Lead Publications Manager, Pneumococcal Vaccines, Vaccines Office of Medical Governance and Bioethics, GSK, Belgium

Richard Smith, PhD, former Editor, British Medical Journal

Karen Woolley, PhD, ISMPP CMPPTM, Division Lead, Envision; Director, Sunshine Coast Hospital & Health Service Adjunct Professor, University of Queensland; Adjunct Professor, University of the Sunshine Coast

Moderator: Alice Choi, PhD, ISMPP CMPPTM, Chair, ISMPP BOT (2014 – 2015); Chair, ISMPP Annual Program Committee; Global Head, Complete Medical Communications

This session was made possible with an educational grant from AlphaBioCom in honor of the late Mary Whitman.



Learning Objectives

By the end of the session, attendees will:

- Become familiar with a number of common misperceptions about our profession
- Understand how and why these myths can and should be countered and challenged
- Be knowledgeable about the evidence base to support the work we do
- Be able to proactively support and defend our profession with respect to common misperceptions

TUESDAY EVENING, APRIL 12

6:00 PM -8:00 PM **Annual Evening Networking Reception**

Join us at Rosa Mexicano, a short walk from the Gaylord, for an enjoyable evening with friends and colleagues.

WEDNESDAY MORNING, APRIL 13

7:00 AM -8:00 AM

Registration and Continental Breakfast

8:00 AM -8:05 AM **Opening Remarks**

Yvonne E. Yarker, PhD, ISMPP CMPPTM; Chair, ISMPP Board of Trustees (2016–2017); President, Medicite LLC

8:05 AM -8:45 AM

Predatory Journals: Protecting the Integrity of Scholarly Literature

The issue of predatory publishers is a growing problem in need of attention. Predatory journals and publishers are characterized by varying levels of deception, sometimes falsely asserting the existence of qualities such as a rigorous peer review process. This session will explore this important issue and discuss ways to educate authors and other key stakeholders.



Jocalyn Clark, PhD, Executive Editor, *The Lancet*; Former Executive Editor, icddr,b and Journal of Health, Population and Nutrition, Dhaka, Bangladesh; Former Senior Editor PLOS Medicine, Former Assistant Editor, *The BMJ*; Adjunct Assistant Professor of Medicine University of Toronto, Canada

Moderator: Yvonne E. Yarker, PhD, ISMPP CMPPTM, Chair, ISMPP Board of Trustees (2016–2017); President, Medicite LLC

8:45 AM -8:50 AM

Move to Next Session

Learning Objectives

By the end of this session attendees will:

- Understand the drivers for the predatory publisher market and the geographic regions most susceptible
- Appreciate how predatory journals affect the integrity of scientific literature
- Know how to recognize predatory journals/publishers

8:50 AM -9:30 AM

Choose from one of our traditional parallel sessions or a roundtable

Parallel Sessions

Your choice! Pick the topic of most interest to you, and engage in a 40-minute interactive exchange with faculty in a smaller group setting.



ISMPP Member Open Proposal - Academic Research Organization (ARO) Collaborations: A View from the Sponsor and the ARO

This session offers ISMPP members an opportunity to present a topic deemed to be timely and of interest to fellow colleagues. Publication planning and execution between a trial sponsor and an academic research organization is different than other collaborations including industrial joint ventures. Goals and expectations may differ greatly between the academics who led the study and write the publications and the sponsor. In the center of the collaboration are the ARO editor/publication manager and the sponsor publication manager. This session will discuss organization of study publication committees and managing publications arising from an ARO-led clinical trial. Critical areas are establishing a framework or charter, establishing robust mechanisms for scientific review and maintenance of corporate compliance requirements. The faculty are publications professionals who have managed ARO publication activities for an ARO and a sponsor.



Morgan deBlecourt, Editor & Publications Manager, Communications, Duke Clinical Research Institute

Moderator/Faculty: Charles Rosenblum, MS, PhD, ISMPP CMPP™, Director, Publication Management, Primary Care Lead, Merck & Co., Inc.

Learning Objectives

By the end of this session attendees will:

- Understand what an ARO-led trial is
- Understand the unique needs of the academics and the sponsor
- Obtain guidance on establishing best practices



Practical Navigation of Implementation and Use of GPP3 Guidance

Now that the GPP3 guidelines have been in effect for over six months and most publication managers have read and learned them, how are they being received and implemented in pharmaceutical companies and agencies? How have these guidelines helped the publication team and have there been challenges? Three faculty will present their experience and steps their companies have taken to implement the new guidelines. After their presentations, panel members will address questions from the audience.



Daniel Bridges, PhD, ISMPP CMPPTM, Regional Director, Europe & China, Nucleus Global

Nathan Rustay, PhD, Senior Manager, Medical Communications, Impax Laboratories

Stephen Valerio, MS, ISMPP CMPPTM, TA Director, Global Scientific Communications & Publications, Oncology and Immunoncology, Global Medical Affairs, AstraZeneca

Moderator: Barbara L. Rowe, MA, Global Publications Director, Global Medical Affairs, AstraZeneca

Learning Objectives

By the end of this session attendees will:

- Learn how companies have implemented the GPP3 guidelines and what changes they have made
- Gain practical insights into how others have leveraged and used the guidelines for support in day-to-day publication business issues
- Hear about challenges of working with the guidelines and how they can best be overcome

8:50 AM -9:30 AM

Scientific Platform Development



A scientific platform is a critical resource that provides a focal point and drives an integrated communications plan. Ideally developed early on in the lifecycle, it can help to identify information needs, structure key points and ensure that internal groups are communicating consistently and in the same language. This session will educate on the value of scientific platforms, provide practical guidance on their development and how to integrate with a medical publications plan.



Dheepa Chari, MS, ISMPP CMPPTM, Director, Scientific Communications, US Oncology, Novartis

Dustin Khiem, PhD, Director of Medical Communications, Kite Pharmaceuticals, Inc.

 $\label{thm:moderator/Faculty: Todd Parker, PhD, ISMPP CMPPTM,} Vice \ \ \text{President, Scientific Services Scientific Communications, MedThink SciCom}$

Learning Objectives

By the end of this session attendees will:

- Understand the value of and recognize when to best develop a scientific platform
- Understand the process for developing a scientific platform and how medical publication professionals can contribute
- Be knowledgeable about how to develop a lexicon within the scientific platform and how best to carry through to associated medical publications



Roundtable Session

Today's Roundtable sessions will provide a professional forum for attendees to exchange ideas, experiences, and information with their colleagues and peers around preselected topics identified by the ISMPP membership as key areas of interest to the medical publication community. Each attendee will have the opportunity to attend one Roundtable. Select topics will qualify for ISMPP CMPPTM credit.

- 3rd-to-Market (and beyond) Publications
- Emerging Markets: Challenges and Opportunities
- Patient Lay Summaries NEW!

- Pharmacoeconomics
- Publication Steering Committees the Basics
- Real World Evidence **NEW!**

This session was made possible by an educational grant from:



Synchrony Medical Communications had no role in the development of the content or selection of the moderators.

9:30 AM - 9:35 AM

Move to Next Session

9:35 AM -10:15 AM

Choose from one of our traditional parallel sessions or a roundtable

Parallel Sessions

Your choice! Pick the topic of most interest to you, and engage in a 40-minute interactive exchange with faculty in a smaller group setting.



Favorite ISMPP U Session: Real World Evidence

We asked and you voted! This session will feature the faculty from the top-rated ISMPP U session from 2015 - Real World Evidence. If you did not catch it the first time, or would like an opportunity to speak to the faculty face-to-face, attend this session for an "encore-esque" presentation of the winning session. Bring your questions!



Tim Koder, PhD, Account Director, Oxford PharmaGenesis

Moderator/Faculty: Richard White, MA, PhD, Commercial Director, Oxford PharmaGenesis

Learning Objectives

By the end of this session attendees will:

- Understand the specific issues associated with the publication and communication of RWE studies
- Understand how internal policies for publishing RWE studies can adopt the same level of rigor as those for RCTs



Practical Navigation of Implementation and Use of GPP3 Guidance (see description on page 17)



Scientific Platform Development (see description on page 18)

10:15 AM -10:45 AM

Morning Break and Visit Exhibits

10:45 AM -10:55 AM

Exhibitor Prize Drawing

10:55 AM -

Member Oral Presentations



Enhancing Transparency and Integrity in Clinical Manuscripts: A 12-year Trend Analysis of Conformance to Good Publication Practices-1, 2 and 3 Guidelines*

Ashwini Patil, Publication Writer, SIRO Clinpharm Pvt Ltd.

A Day in the Life of a Professional Medical Writer: An Online Survey-Based Study

Mittal Makhija, Scientific writer, Novartis Healthcare Pvt. Ltd., Hyderabad, India

Moderator: James Gurr, PhD, ISMPP CMPP™

11:25 AM -12:05 PM

Ask the Experts: Anticipating Industry Trends



The past few years have seen some major shifts in the world of medical publishing/communications – data sharing, open peer review models, increased transparency initiatives, and an increase integration of the patient voice – to name a few. This forward-looking session will feature seasoned Global Publication Heads from industry and tap into their knowledge of the current state of affairs and what everyone needs to be thinking about to operate successfully in the future.

Lorna Fay, Director/Team Leader, Publishing, Pfizer

Juli Clark, PharmD, Executive Director, Global Medical Writing, Scientific Affairs, Amgen, Inc.

Karen Mittleman, PhD, Head, Publications, Office of the Group CMO, Sanofi

Carolyn Hustad, PhD, ISMPP CMPP™, Executive Director, Global Scientific & Medical Publications, Merck

Moderator: Teresa L. Peña, PhD, Chair, ISMPP Board of Trustees (2015 – 2016)

Executive Director, Global Medical Publications, Bristol-Myers Squibb

12:05 PM -12:35 PM

Keynote

Andy Powrie-Smith, Director of Communications, European Federation of Pharmaceutical Industries and Associations (EFPIA)

12:35 PM

Closing Remarks: The Year Ahead for ISMPP

Al Weigel, MEd, ISMPP CMPPTM, President & CEO, International Society for Medical Publication Professionals

Learning Objectives

By the end of this session attendees will:

- Understand the current and anticipated changes in the medical publications environment
- Gain ideas on how individuals and/or organizations can best meet these changes

www.ismpp.org

WEDNESDAY AFTERNOON, APRIL 13

12:35 PM – 1:00 PM	Box lunch for Workshop participants
1:00 PM – 2:30 PM Post-conference Workshops (schedule and descriptions on pages 28-39)	
2:30 PM – 3:00 PM	Afternoon Break
3:00 PM – 4:30 PM	Post-conference Workshops (continued)
4:30 PM	Conference Adjourns

12TH ANNUAL MEETING OF ISMPP POSTER PRESENTATIONS

Analysis of publication timelines following clinical trial completion: Understanding industry trends

Amy Monpara, Jessica Hartung, Katherine S. Martinez, and Karen Craun

Assessing Industry-sponsored Medical Publications using Alternative Metrics
Catherine Skobe, LaVerne Mooney, Wendy Kopf, and Sara Rouhi

Attenuating the role of impact factor by including high-quality publications when reporting publication metrics

Miriam Gitler, Julliana Newman, Ian Hollingsworth, Nelson Olivier, and Elizabeth Youngdale-Myers

Avoiding high-risk authors: Should Corporate Integrity Agreements recommend searching the Retracted Publications database?

Luke C. Carey, Aruna Seth, Mark Woolley, and Karen L. Woolley

Can Centers for Medicare and Medicaid Services (CMS) reporting verify disclosures?

Melanie Blanchard, Gina Fusaro, Jill Sanford, Debbie Wolinsky, Dawn Martucci, John McGuire, and Suzanne Van de Water

Choose your target journal carefully: Quantification of delay to acceptance caused by each manuscript resubmission

Nicola Truss, Martina Fuchsberger, Ingeborg Streng-Ouwehand, Niina Nuottamo and Eva Polk

A comparison of publically available journal metrics and single-company experience

Jenilyn Virrey, James O'Kelly, Victoria Girard, Brian Wilburn, Mee Rhan Kim, Amy Foreman-Wykert, and Holly Tomlin

Criteria used for choosing a medical journal: A survey of authors, agencies, and sponsors

Colleen Hedge, Michael J. Stevinson, and Shawn J. Boyle

Do current guidelines identify characteristics of "predatory publishers"?

Kimberly J. Brooks, Kathryn C. Gersh, and Jason McDonough

Effect of congress presentations on internet search volume and Wikipedia page visits for PCSK9 inhibitors

Paul Lane

Forewarned is forearmed: Trends in industry-sponsored clinical trials relevant to publication professionals

Michelle F. Anderson, Masayo Hisayama, Jessica Deckman, Cassandra Haley, Russell Traynor, and Karen L. Woolley

Journal adoption of open research author guidelines to promote data transparency and reproducibility

Ira Mills, Sara Bowman, Ken Youngren, and Sheelah Smith

Journal choice: Which factors do you value when submitting a manuscript?*†

Noëlle L O'Regan, Andrew Desson, Catherine Hill, Antonia Panayi, Christopher Winchester, and Slavka Baronikova

Journal preferences and changing views about open access: Results from the 2015 Author Insights survey*

Neil Adams, Kathleen Lyons, Dan Penny, Katie Allin, and Alison Wrigley

Keeping your publication finances in order

Courtney Leo, Amy Di Tore, and George Samman

Key metrics for peer-reviewed publications: Time from submission to publication

Dikran Toroser, Janice Carlson, Micah Robinson, Julie Gegner, Victoria Girard, Lori Smette, Jon Nilsen, and James O'Kelly

Medical writer acknowledgment in industry-sponsored publications

Michelle Daniels, Robert Schupp, and Brian Szente

Blue font indicates 12th Annual Meeting of ISMPP Guided Poster Tour

*Encored poster

†Oral Presentation at the 2016 European Meeting of ISMPP

12TH ANNUAL MEETING OF ISMPP POSTER PRESENTATIONS

Needs assessment of patient education and information provision: A case study James O'Reilly, Keisha Peters, Niina Nuottamo and Anna Georgieva

Professional medical writing support increase the impact of articles reporting randomized controlled trials*†

William Gattrell, Paul Farrow, Elizabeth Costigan, Catherine Sheard, Richard White and Christopher Winchester

Public access to results: An analysis of publication availability across industrysponsored clinical trials

Cindy Busch, Doug Taylor, Nicole Coolbaugh, Nipa Patel, Megan Weigel, Monica Salvadore, Niki Emery, Gina Mushrock, and Philip Siostedt

Quantitative assessment of a pilot internal medical writing capability: Evaluation of strengths and weaknesses

Manon Boisclair, Susan Pacconi, Robert Matheis, Ruggero Galici, and Ann Loftus

Real world evidence publications: preliminary survey of experience, attitudes and understanding in ISMPP members

Richard White, Gary Male and Tim Koder

Role of medical publication professional in timely dissemination and transparent reporting of clinical data

Shruti Shah, Shalini Nair, Ashwini Patil, Sushant Naik, Vatsal Shah, and Susan Glasser

Survey of external authors to improve publication development processes Susan A. Nastasee, Jennifer Hughes, Sonia A. Schweers, Adelaida Sian, and Eric Y. Wong

Timeline implications of executive committee vs non-executive committee-led publications

Steven Sligh and Dan Sturm

Transparency and credibility of industry-sponsored clinical trial publications: A survey of journal editors

LaVerne A. Mooney, Lorna Fay, Barbara De Castro, Tatjana A. Zanki, Teresa Pena, and Bernadette Mansi

Turning obstacles into opportunities: Bringing GPP to scientific publications Julliana Newman

Understanding authors' attitude regarding the role of professional medical writers: an online survey-based study

Dinesh Makhija, Ananda Krishna Karanam, Siddharth Vishwakarma, Shiyani Mittra, and Julie Ford

Use of reporting standards for consistent reporting in medical publications* Matthew Booth, Natalie Dennis, Leigh Prevost, and Carol Richter

Use of supplementary materials in the era of data transparency* Denise Bonen, Lynda Chang, Glynis Davies, Tom Grant, and Lianne Young

Utility of a scientific communications tool kit to promote best practices Dheepa Chari, Anisha Bhagat, Torrey C. Volkman, Angie Miller, Jeffrey D. Stumpf, and David I. Wood

What are peer reviewers looking for? An analysis of positive feedback received on real-world/health-economic manuscripts

Keisha Peters, Marie Diamond, Niina Nuottamo, Pim Dekker, and Tessa E. Hartog

Blue font indicates 12th Annual Meeting of ISMPP Guided Poster Tour

*Encored poster

†Oral Presentation at the 2016 European Meeting of ISMPP



GET THE MOST OUT OF THE 12TH ANNUAL MEETING OF ISMPP!



ISMPP will be "tweeting" in real time from the meeting. Hear about exciting events as they happen! Follow ISMPP on Twitter (@ISMPP). Remember to use #ISMPP when tweeting and re-tweeting!

Media Partners













12TH ANNUAL MEETING EXHIBITORS & SPONSORS

ISMPP would like to thank the following organizations for their continued support of the society



ADELPHI COMMUNICATIONS













CACTUS





MedErgy | SciFluent







COMPLETE HEALTHVIZION



















inScienceCommunications



































WILEY





ISMPP CORPORATE SPONSORS





apothecom













CACTUS

CAUDEX

COMPLETE HEALTHVIZION



















































If you are interested in learning about the ISMPP Corporate Sponsorship programs that are currently available, please email sponsors@ismpp.org



Recertification Credit Information for ISMPP CMPPs™

Many of this year's presentations and workshops qualify for recertification credits. Look for the CMPP recertification credit icon throughout this brochure to identify qualifying sessions.

Speakers

Speakers and agenda are subject to change without notice. In the event of a speaker cancellation, every effort to find a suitable replacement will be made.

Disclaimer

The opinions of the faculty do not necessarily reflect those of the companies they represent or ISMPP.

Special Thanks

On behalf of ISMPP, we would like to express our sincere appreciation to the Program, Abstract, and Global Workshop Committees as well as those who provided meeting support, for an outstanding 12th Annual Meeting.

Program Committee Alice Choi (Chair) Courtney Leo		Abstract Committee	Global Workshop Committee
		James (Jim) Gurr (Chair)	Anca Serban (Chair)
Juli Clark (Co-Chair)	Harry Ma	Anna Georgieva	William Glass
Aruna Seth (Co-Chair)	Terry Materese	Courtney Leo	Chris Grantham
Paula Farmer	Ira Mills	Bhakti Kshatriya	Courtney Leo
Anna Georgieva	Todd Parker	Sharon Suntag	Thomas Rees
James (Jim) Gurr	Barbara Rowe		Charlotte Singh
Renu Juneja	Donna Simcoe		
Meera Kodukulla	Erin Sternberg		
Bhakti Kshatriya	Sharon Suntag		

ISMPP would like to thank its dedicated staff for their contributions to the 12th Annual Meeting of ISMPP and also acknowledge the contributions from the Creative Department at MedErgy HealthGroup for graphic support and project coordination of all design pieces associated with the meeting.

WORKSHOP OFFERINGS



Advanced Publication Planning: A Research-based Approach to Bringing your Publication Plan to the Next Level (Monday and Wednesday)

Prerequisite: This workshop is appropriate for those with an awareness of publication planning and/or at least 2 years of experience in the field of publication planning and implementation.

This workshop will be predominantly interactive, with participants sharing their techniques to assist other publication professionals in developing and executing a comprehensive publication plan that ensures balanced, evidence-based, timely, and targeted communication of data to key audiences. Participants will discuss useful tools to refine, manage, and document their plan, and examine important contemporary challenges faced by medical publication professionals. Throughout the workshop, attendees will be asked to share their own experiences and insights as publication planners. They will also be encouraged to benchmark their practices against those of others in the group.

Learning Objectives

At the end of this workshop, attendees will:

- Be able to develop a current and desired state map
- Develop and test scientific communication points
- Understand how to examine and forecast competitor publications
- Analyze and develop potential authors
- Identify options for publishing when faced with limited clinical trial data
- Distinguish between planning for full therapeutic area vs a single product
- Understand useful metrics for feeding back into the publication plan and sharing with management. Altmetric

Faculty (Mon.)

Namit Ghildyal, PhD

Associate Director, Medical Writing Janssen Research & Development

Shula Pollard, PhD, ISMPP CMPPTM Publications Specialist, Allergan

Faculty (Wed.)

Kim Gersten, ISMPP CMPP™

Medical Publications Consultant

Keith Goldman, MA

Manager, Global Medical Publications, Allergan

12TH ANNUAL MEETING OF ISMPP www.ismpp.org 28





Altmetrics for Medical Publication Professionals (Wednesday)

Prerequisite: Completion of the "Metrics" global workshop or a basic understanding of altmetrics and how they are measured

This workshop will provide participants with an understanding of altmetrics in theory and practice and an awareness of implications for planning publications. The session will cover the range of different altmetrics, what they measure, practical issues in their measurement (and implications for interpretation), and measurement tools. Participants will learn how different altmetrics relate to each other as well as to conventional publication metrics and how to better gauge publication impact in different audiences and at different timescales. A group activity will provide attendees with the opportunity to work with altmetrics data. Sample topics include: (1) definition of different metrics and their sources (how they are measured; for example, mendeley counts vary according to tool used to measure them); (2) how they can be categorized and weighted; (3) how they inter-relate, and how they relate to conventional metrics; (4) which metrics are best for different purposes; (5) which should be included for assessing publication impact; (6) pros and cons of different assessment tools/techniques/dashboards; (7) issues in measuring and interpretation; and (8) gaming, spoofing, noise. The session will conclude with an exploration of what other publication professionals are doing with altmetrics and information on how to incorporate altmetrics into a publication plan.

Learning Objectives

At the end of this workshop, attendees will:

- Understand the relationship between different altmetrics
- Have a solid grasp of practical issues in measuring and interpreting altmetrics
- Recognize how publications professionals can monitor and interpret altmetrics to gain a broad understanding of publication impact in different spheres and audiences

Faculty

Ira Mills, PhD

Senior Scientific Specialist, PAREXEL

Sara Rouhi, MS

Product Specialist, Altmetric



Ethics in Publications Practice: Real-World Case Studies in Determining Authorship (Monday)

Prerequisite: This workshop is appropriate for publication professionals with at least 2 years of experience in publication development, although professionals at all levels are welcome.

The important issues of authorship, data transparency, and other topics become especially challenging in instances where current publication guidelines (ICMJE, GPP3, etc.) do not provide specific guidance. This interactive workshop will enable participants to explore these and related issues that sometimes fall into gray areas in depth, going beyond the letter of the guidelines, and employing real-world case studies to examine ethics, potential solutions, consequences, and best practices. Participants will also be asked to provide their own case studies and experiences for exploration by the entire group. Enrollees in last year's workshop appreciated the "thought-provoking" discussions and the appropriateness of examples for professionals of different experience levels.

Learning Objectives

At the end of this workshop, attendees will:

- Identify solutions for resolving ethical dilemmas that arise using case studies from the real world
- Learn new ways to think about ethical considerations that constitute "gray areas" and practical options available in these situations
- Discuss potential solutions to ethical challenges and what resources are needed to achieve them
- Discuss stakeholder roles in achieving consensus and implementing solutions to ambiguous ethical situations

Faculty

Mukund Nori, PhD, MBA, ISMPP CMPP™

Senior Medical Writer, Scientific Solutions, Envision Pharma Group

Charlotte Singh, MD, ISMPP CMPP™

Vice President, Group Medical Director, The Lockwood Group



Global Publication Planning: Issues and Challenges (Monday)

Prerequisite: This workshop is appropriate for experienced publication planning professionals with an interest in or responsibility for publication planning and tactical execution at a global level.

Delivery of publication outputs while ensuring compliance with good publication practice can be fraught with challenges. These challenges intensify when working with multiple regions, sometimes with partner companies, where different perspectives on timing of publications or on addressing different regulatory situations apply. Factors such as differences in launch timings, specific indications, audiences, and even time zones can play a role in making the publication, authorship, planner's decision-making process even more complicated. The transparency landscape continues to evolve globally, with growing expectation for data disclosure and inclusion of patient-level trial results. Consumption of medical information is also changing, with advances in social media, open access, and the emergence of predatory publishers. Facilitated by publication leaders with experience in industry and medical communications agencies, this interactive workshop provides an overview of important considerations in global publication planning and delivery, as well as the opportunity to work in small groups to formulate solutions to a series of real-life scenarios.

Learning Objectives

At the end of this workshop, attendees will:

- Know the guidelines and considerations affecting publications in major world markets
- Understand the current and potential impact of new trends on global publication planning
- Be conversant in the issues affecting global publication planning and tactical execution
- Be knowledgeable of best practices for planning globally with a partner biopharmaceutical company
- Acquire tips for negotiating the challenges of working with multiple regions and in different regulatory environments

Faculty

Antonia Panayi, PhD, ISMPP CMPP™

Publications Lead, Neuroscience, Shire International GmbH





HEOR: What Constitutes a Good Health Outcomes Manuscript? (Wednesday)

Prerequisite: This workshop is appropriate for individuals with 3 years of publication planning and/or writing experience, including at least 1 year of working with HEOR publications or completion of another HEOR workshop.

Last year's attendees described this workshop as "an excellent overview with tangible examples that can be applied in day-to-day work, and claimed they left with a "better understanding of HEOR terms and requirements for publication." This highly interactive workshop is targeted toward non-HEOR experts who are otherwise proficient in medical publication planning. Attendees will learn about the specific aspects involved in creating high-quality HEOR manuscripts, and provide insight into the effective interpretation and communication of HEOR data. An explanation of basic vocabulary and the elements of a good HEOR publication will be featured. The CHEERs (Consolidated Health Economics Reporting Standard; 2013) checklist, will also be briefly discussed. Later, participants will break into groups to evaluate examples of HEOR publications, focusing on the presence or absence of essential elements. and then present their findings to the entire group.

Learning Objectives

At the end of this workshop, attendees will:

- Identify the components of a high-quality HEOR manuscript
- Identify health outcomes trends and their implications for the discipline of publication planning

Be able to knowledgeably explain the differences between a superior HEOR publication and an inferior one

Faculty

Chris Carswell, MSc

Editor-in-Chief, Pharmacoeconomics, Springer Science and Business Media, LLC

Keith Evans, PhD

Director, Global Health Outcomes, inScience Communications



How to Integrate Digital Advances into Your Publication Strategy: Planning, Rollout, and Metrics (Monday and Wednesday)

Prerequisite: This workshop is appropriate for individuals in pharma/biotech/device companies, publication agencies, and publishers who have at least 2 years of experience in the field of publication planning and implementation.

This interactive workshop will explore emerging efforts by leading journals to utilize multimedia and social media as a method of enhancing the educational value of scientific publications. Participants will review the latest innovations from prominent medical publishers and assess obstacles and practicalities that have limited the adoption of such new media opportunities thus far. Real-life case studies from the perspectives of publishers, pharma and agencies will be presented. Cost-effective approaches to optimizing scientific value by promoting interactivity and enabling a greater depth of content, while maintaining the scientific and ethical integrity of the peer review process will be examined. The trend toward increased online dialogue associated with scientific articles and how this is revolutionizing the ways we gauge interest in and value of peer reviewed publications will be reviewed. Participants will be encouraged to share experiences from their own organizations, helping all attendees identify new approaches to optimizing scientific value of publications.

Learning Objectives

At the end of this workshop, attendees will:

- Understand the range of enhanced digital content opportunities available
- Be equipped with cost-effective approaches to the development of enhanced content
- Understand what happens when journals share and promote discussion of key data and publications via social media, and how we can learn from it
- Appreciate the value and application of alternative metrics, and how these can supplement traditional measures of publication effectiveness
- Be able to include and budget for the use of new media within their own publication plans

Faculty

Hilary Carson, MBS

Director of Business Development, Omnicon/Adelphi Communications

Dheepa Chari, MS, ISMPP CMPP™

Director, US Oncology Scientific Communications, Novartis Pharmaceuticals Corporation

Rhiannon Meaden, PhD

Head of Commercial Development, Complete HealthVizion

Brian Jenkins

Executive Multimedia Editor, Multimedia Publishing, Elsevier





Integrating Comparative Effectiveness Research, Health Economics and Outcomes Research into Your Publication Plan (Monday)

Prerequisite: This workshop is appropriate for publication professionals with at least 2 years of experience in publication planning, 2 years of experience working with CER/HEOR concepts, and experience developing publication plans/policies/processes across these two disciplines.

A 2015 participant found that this workshop added new ways of thinking "I wasn't aware of," while another claimed it "provided me with valuable insights to take back to my teams" and "encouraged me to ask better questions to stimulate discussion." Comparative effectiveness research (CER, which focuses on real-world evidence vs. randomized controlled trial findings,) is becoming an increasingly important consideration for medical publication professionals as they develop their publication plans. The goal of CER is to help increase quality and decrease costs of healthcare by providing stakeholders with evidence on the relative value of interventions in broad and diverse populations, and in routine settings of care – in brief, to identify what works best for which patients, under which circumstances. CER encompasses health economics and outcomes research (HEOR) and diverse study designs and methods.

Communicating CER results via a manuscript targeted for a peer-reviewed journal can be challenging, which is why adherence to standard publication practices can ensure transparency and quality. By integrating CER/HEOR into an overall publication plan, publication professionals can complement core scientific and clinical publications and strengthen a product's evidence base for medical decision-makers. This interactive workshop will provide an overview of CER/HEOR and a discussion of their roles in publication planning. After breaking into groups, attendees will participate in publication planning exercises, followed by presentations to the entire class.

Learning Objectives

At the end of this workshop, attendees will:

- Understand the terms encompassed by CER
- Understand trends driving CER/HEOR
- Be familiar with different types of CER/HEOR studies and study designs and their relationship to product life cycle
- Identify stakeholders and the target audiences/venues for CER/HEOR publications
- Understand the benefits a publications department can offer to an internal HEOR group

Faculty

Chris Carswell, MSc

Editor-in-Chief, Pharmacoeconomics, Springer Science and Business Media, LLC

Charles (Chuck) Stevens, JD, MB

Vice President and General Manager, Reimbursement and Market Access, PAREXEL





Introductory Publication Planning: The Best of the Basics for New Publication Planning Professionals (Formerly Publication Planning 101) (Monday)

Prerequisite: This workshop is appropriate for newer professionals in the field of publication planning and implementation who have 1 year or less of experience.

This workshop provides an interactive and instructional introduction to the process of publication planning, with didactic presentations targeted toward newer professionals with publication responsibilities in the pharmaceutical, biotech and/or device industries, communication and publication agency personnel, publication support staff, writers, editors, and allied members of the publication planning team. Beginning with a look at the history of publication planning as a profession and an exploration of good publication practices, especially with reference to the newly published GPP3, the workshop covers components of a publication plan, including authorship, formation of publication steering committees, journal selection, and more. Key principles will be examined using a combination of case studies and discussion.

Learning Objectives

At the end of this workshop, attendees will:

- Understand the value and goals of effective publication planning
- Identify the major components of a tactical publication plan
- Be familiar with publication planning terminology and good publication practices
- Appreciate the importance and benefits of a collaborative team environment

Faculty

Gregory Bezkorovainy, MA ISMPP CMPP™

Vice President, Scientific Services, Adelphi Communications

Kim Pepitone, ISMPP CMPP™

Scientific Director, Cactus Communications

Carol Sanes-Miller, MS, ISMPP CMPP™

Sr. Manager, Medical Communications, Baxalta US Inc.

Craig Smith

Manager & Senior Editor, Multimedia Publishing, Elsevier



NEW THIS YEAR!

Patient Lay Summaries: Communicating Scientific Research to Patients and the Public (Wednesday)

Prerequisite: This workshop is appropriate for publication professionals with at least 2 years of experience in publication planning.

Under the 2013 Joint Principles for Responsible Clinical Trial Data Sharing, a dual initiative of PhRMA and EFPIA, member companies commit to share a factual, plain English summary of the results of clinical trials with the patients who participate in them, primarily via posting on publicly accessible, online databases. In this workshop, participants will gain a solid understanding of what lay summaries are, how they are used, and why they are important to medical research. Associated issues and challenges involved with provision of lay summaries, including the importance of safeguarding patient privacy and preserving scientific rigor will be explored. Operational insights into coordinating these communications and specific experiences and guidance related to lay patient summaries will be shared. Participants will explore how summaries can best be communicated to ensure that they are reaching intended audiences and maximizing their usefulness.

Learning Objectives

At the end of this workshop, attendees will:

- Appreciate the role that lay patient summaries play in transparency of scientific communications
- Understand the commitment for the release of lay patient summaries within the framework of the Joint Principles
- Coordinate and maintain consistency in external scientific communications with patient stakeholders

Faculty

Barbara E. Bierer, MD

Faculty Co-Director, Multi-Regional Clinical Trials (MCRT) Center at Harvard, Harvard University

Zach Hallinan

Director, Patient Communication & Engagement Programs, Center for Information & Study on Clinical Research Participation (CISCRP)

Mark Springer

Project Lead, Clinical Open Innovation, Eli Lilly





Publication Planning in the Asia-Pacific Region (Monday)

Prerequisite: This workshop is appropriate for individuals who currently or expect to manage publication activities in the Asia-Pacific (APAC) region or who interact with authors from this area.

The growing demand for publication management in this increasingly significant region calls for the involvement and support of publication professionals worldwide. Managing publications in this diverse area is not an easy task. ISMPP leaders with extensive experience in the region will share their real-world experiences and insights in developing a team of publication managers and working with authors to improve publication planning in the region.

In this interactive workshop, participants will be encouraged to share their experiences of working with individuals in the APAC region and suggest innovative ways to best achieve collaboration. Group exercises, with completion of hypothetical publication "missions" will be featured.

Learning Objectives:

At the end of this workshop, attendees will:

- Understand the characteristics of publication practice in the APAC region
- Know how to form teams with local authors and managers, and support the local champions in publication practice
- Be able to apply updated publication management skills and principles to an APAC regional team

Faculty

Tim Collinson, ISMPP CMPP™

Business Unit Head, West Coast, Fishawack Communications

Andrew Sakko, PhD, ISMPP CMPP™

Inventiv Health Clinical



Publication Planning for Medical Devices and Diagnostics (Monday)

Prerequisite: This introductory workshop is appropriate for those medical publication professionals with responsibility for the planning of publications for medical devices and diagnostics.

Although medical devices can be anything from a tongue depressor to a surgical device, one thing is certain; they are uniquely regulated. In the US, medical devices are classified by the FDA into Class I, II, and III, with regulatory control increasing from Class I to Class III. Historically, regulatory approval was considered sufficient for convincing payers and hospitals of the efficacy of devices and diagnostics, and trial results often went unpublished. With the advent of transparency initiatives and greater regulatory demand for more substantial evidence, publications are increasingly important. In addition to differences in the regulatory process, other factors inherent to the product lifecycle of devices contribute to a publication planning process that is different from that for pharmaceuticals.

This interactive workshop will establish the essential role of medical publications in underscoring the scientific evidence to support FDA regulatory decisions critical to bringing new devices and diagnostics to patients. A framework for publication planning and best practices for the devices and diagnostics will be explored through didactic presentations and group discussion.

Learning Objectives

At the end of this workshop, attendees will:

- Recognize the essential role of medical publications in the medical device and diagnostics category for both new and existing products
- Understand the value and goals of publication planning for medical devices and diagnostics
- Have learned about a framework for publication planning and best practices for devices and diagnostics
- · Identify best practices for delivering a good publication plan for medical devices and diagnostics
- Understand the need to remain current with the evolving regulatory landscape

Faculty

LeeMing Boo, PharmD

Program Director, Medical Affairs, Biosense Webster Inc.

Lorena Telofski, ISMPP CMPP™

North America Scientific Engagement Leader, Baby Skincare, R&D, Johnson & Johnson Consumer Companies, Inc.



Successful Publications Steering Committees: Practice Pearls from Biopharmaceutical, Medical Device and Agency Perspectives (Monday)

Prerequisite: This workshop is appropriate for individuals working for pharmaceutical/ biotechnology device companies, agencies, and publishers, who have 2 or more years of experience in the field of medical publications.

Publication Steering committees (PSCs) typically consist of sponsor contributors and external investigators who may have contributed to clinical protocol design or trial development, and serve a leadership role in the conception, development, and execution of a publication plan. PSCs help foster increased transparency, engagement from investigators, and consistency regarding data sharing and disclosure. PSCs also serve to optimize data output and publications from clinical trials and to increase the impact of these data on the academic and health care communities by reaching the most appropriate audiences.

Surveys of the ISMPP membership reveal that the use of PSCs remains limited. This workshop will provide publication planning professionals with an opportunity to learn and discuss the essentials of successful PSC conception, formation, development, and execution. The workshop will focus on the perspectives of biopharmaceutical companies and medical publication agencies in the development and execution of successful PSCs. Different PSC concepts will be reviewed; case studies and experiences will be discussed to provide good practices that may help achieve more frequent, productive, and successful use of PSCs. For the interactive sessions, attendees are encouraged to come prepared with specific questions on PSCs and/or to discuss challenges they have faced with PSC development and execution.

Learning Objectives

At the end of this workshop, attendees will:

- Understand the purpose, benefit, and role of a PSC in publication planning and execution from sponsor and agency perspectives
- Describe and understand key tactics for establishing and conducting successful PSCs
- Understand ways to overcome obstacles in assembling and driving PSC success
- Have participated in the identification and initial codification of factors critical to the success of a PSC

Faculty

Michael Mandola, PhD, ISMPP CMPP™

Senior Vice President, Articulate Science

Ken Pomerantz, PhD, Director

Medical Publications, Boehringer Ingelheim Pharmaceuticals, Inc.

Brian Scheckner, PharmD, BCPP, ISMPP CMPP™

Director, Medical Communications, Jazz Pharmaceuticals



WE LOOK FORWARD TO SEEING YOU NEXT YEAR!

13TH ANNUAL MEETING OF ISMPP MAY 1-3, 2017 NATIONAL HARBOR, MD, USA



Presentations from the 12th Annual Meeting of ISMPP will be available to view online shortly after the meeting closes.

Members may log in to www.ismpp.org.

Artwork and design provided by

