THE 8TH ANNUAL MEETING OF ISMPP

PRACTICAL SOLUTIONS FOR A COMPLEX MEDICAL PUBLICATIONS WORLD

APRIL 23-25, 2012
HYATT REGENCY BALTIMORE
BALTIMORE, MARYLAND, USA



Dear Colleagues:

Welcome to the 8^{TH} Annual Meeting of ISMPP, *Practical Solutions for a Complex Medical Publications World*. This year, we introduce a new format to help us navigate through many of our key challenges—more guidelines, increased restrictions, enhanced requirements, and less resource, among others—using a practical, integrated approach.

Day 1: The Environment

 Here the faculty will focus on the legal and compliance challenges we face in today's environment—compliance/interpretation of corporate integrity agreements, operating in a new era of budget restrictions, the Physician Payment Sunshine Act, global markets, and pressure to publish earlier in the drug lifecycle.

Day 2: The Stakeholders

Next, the faculty will move beyond the 'usual suspects' involved in the creation of
publications to provide perspectives on the trends in healthcare decision-making
and in meeting the needs of various stakeholders who utilize publications in this
evolving healthcare environment. Through this session, the expanded cast of
stakeholders will be identified and their needs will be explored.

Day 3: New Challenges, Emerging Technologies

Finally, the faculty will hone in on doing more with less, to help us better understand how to balance budget constraints with 'getting the job done.' They will also address the trends in 'new media' to take us beyond print, covering topics ranging from the new media themselves to the technologies and devices available to our end users to access the published information.

At the end of each of the three days, you will find yourself better equipped to manage many of our day-to-day challenges identified in each of these topics areas. You'll note this year we've provided you with a new tool—a template for your personal action plan. We both challenge and encourage you to create your personal action plan, so that you can immediately apply your key learnings from the meeting.

True to form, in addition to the general session presentations, this year's Annual Meeting provides the following activities, designed to enrich your Annual Meeting experience.

- Premier of ISMPP's new annual research project.
- Member oral and poster presentations based on research-focused abstracts that will have been reviewed and approved by a committee of your peers
- Roundtable discussions that will allow for in-depth exploration of many of the topics covered during the general sessions
- An opportunity to 'meet the experts'—many of the general session faculty will be hosting several of the roundtable discussions

Over each of the three days, you'll have extensive opportunities to ask questions, interact electronically through ISMPP's meeting app, and, as always, network with your peers.

Many of this year's meeting presentations and workshops qualify for CMPP continuing education credits. Be sure to check the program contained herein, and the ISMPP meeting app, for the full constellation of qualified presentations, denoted with the CMPP recertification credit icon ().

Exhibits will open bright and early on Monday morning, and will stay open throughout the course of the meeting. Thus you will have ample time to visit the exhibits and attend all educational sessions. New this year: there's an Exhibitors Passport in your meeting materials. Visit each booth, get your passport validated, and enjoy an opportunity to win an Amazon Gift Card

In keeping with our tradition, networking opportunities abound, beginning with our Welcome Reception on Sunday evening, at 7:00 PM, at Pisces, which is located on the 15th floor of the Hyatt Regency—a lovely venue overlooking the harbor. And of course, it wouldn't be an ISMPP Annual Meeting without our Tuesday Evening Networking Reception, this year at The Rusty Scupper, located directly on the Baltimore Inner Harbor on Tuesday, April 24th at 5:45 PM.

All in all, we anticipate an exciting, educational experience at the meeting. Again, on behalf of the ISMPP Board of Trustees and staff, welcome!

Rob Matheis. PhD

ISMPP President, 2011-2012

Kollet J. Catherin

ISMPP CMPP™

Senior Director, Medical Communications

Evidence Based Medicine

Sanofi

Russell Traynor, MSc

ISMPP President Elect, 2011-2012

ISMPP CMPP™

Director, Business Solutions

UBC-Envision Group

Program Agenda

Sunday, April 22

	7:00 PM-9:00 PM	Welcome Reception
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Monday, April 23

*Pre- and Post-Conference Workshops: Please refer to the workshop schedule and descriptions that follow. **Workshop descriptions that contain the CMPP credit logo qualify for CMPP continuing education credit hours.

MORNING	
7:30 AM-8:30 AM	Registration and Continental Breakfast
8:30 AM-10:00 AM	Pre-Conference Workshops*,**
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
AFTERNOON	

Day 1: **General Session**

The Environment

Understanding the external environment is the first step in determining and evaluating internal processes. Staying abreast of the ever-evolving regulations is not always easy. In 2012, we're faced with even more challenges and constraints than before. It's critical not only to understand these factors but also to hear how our counterparts have successfully navigated the external environment to formulate policies and procedures. On Day 1 of the Annual Meeting, speakers will focus on the legal and compliance challenges we face in today's environment government mandates and guidelines, impact of operating in an era of budget restrictions, the Physician Payment Sunshine Act. global markets, and the pressure to publish earlier in the drug lifecycle.

1:30 PM-1:45 PM

Welcome to ISMPP 2012

Kim Goldin, Senior Director of Operations and General Manager. **ISMPP**

Robert J. Matheis, PhD, Senior Director, Medical Communications. Evidence Based Medicine. Sanofi: President. ISMPP (2011-2012): ISMPP Certified Medical Publication Professional

Monday, April 23 (continued)

1.45 PM-2.45 PM

Keynote Panel:

Communicating in the Real World

In this interactive discussion session, a multidisciplinary panel will share their experiences with the legal and compliance challenges we face in today's environment. In particular, the panel members will reveal the issues that concern them the most and discuss and debate their respective interpretations of the current regulations and potential geographic differences. The panel will also address how we can achieve appropriate ethical outcomes and full disclosure, whilst appropriately dealing with commercial sensitivities: is it ever too early to communicate?

William Hoffman, Partner and Co-Chairman of the Food and Drug Practice Group, Kaye Scholer LLP

Mariam Koohdary, Senior Counsel, AstraZeneca

Learning Objectives

By the end of this session, attendees will:

- Gain insight into the types of compliance issues that may arise and understand what has already been achieved by individuals and companies who have faced these issues
- Have practical ideas of what they could do as individuals and within their organizations to further improve their communication practices to ensure full compliance

Monday, April 23 (continued)

2:45 PM-5:15 PM	Best Practices in Medical Publications There are a plethora of guidelines available to us: which are helpful and which hinder? In this session, we explore, discuss,
	and challenge these guidelines. Our speakers will share their own experiences and perspectives in dealing with daily, sometimes complex issues: the FDA and publications, interaction with healthcare professionals, and authorship, to name but a few. In particular, the panel will share real-life cases and help to identify practical solutions for some of the communication dilemmas we all face.
	Learning Objectives By the end of this session, attendees will: Gain a broad view of the experiences of different individuals and companies, their evaluation of guidelines, and how they have tackled problematic issues Have some practical solutions and best practices that can be easily adapted and applied to their own settings
2:45 PM-3:15 PM	Walking the Compliance Line: A Regulatory Lawyer's Perspective Alan G. Minsk, Partner and Leader, Food and Drug Practice Team, Arnall Golden Gregory LLP
3:15 PM-3:45 PM	Afternoon Break and Visit Exhibits
3:45 PM-4:15 PM	Authorship and Algorithms: Assessing Contributions at Lilly Jeffrey Clemens, PhD, Consultant and Medical Lead for Communications, Eli Lilly
4:15 PM-4:45 PM	Industry Support for Publications: Interactions with Physicians Peter O. Safir, Partner, Partner, Covington & Burling LLP
4:45 PM-5:15 PM	Issues in Authorship: An update from the Committee on Publication Ethics (COPE) Liz Wager, PhD, Publications Consultant, Sideview; COPE Chair (2009-2012)

Monday, April 23 (continued)

5:15 PM-5:30 PM	ISMPP in the Asia Pacific: A Journey of a 1000+ Miles Begins
	with a Single Step
	Karen Woolley, PhD, CEO, Proscribe; Professor, University of
	Queensland and University of the Sunshine Coast; ISMPP Director
	and Chair, Asia-Pacific Advisory Committee;
	Honorary Fellow, American Medical Writers Association;
	ISMPP Certified Medical Publication Professional™
5:30 PM-5:35 PM	Closing Remarks
	Rob Matheis
EVENING	
5:35 PM-6:30 PM	ISMPP Member Poster Presentation Assembly
	See pages 15–17 for a listing of 8 TH Annual Meeting of ISMPP
	Poster Presentations

ISMPP thanks the following exhibitors for their support of the Member Poster Presentation Assembly:



















Rapid Publications





Tuesday, April 24

MORNING	
7:00 AM-8:00 AM	Registration and Continental Breakfast
Day 2: General Session	Stakeholders Day Publications serve the important function of disseminating scientific information and communicating clinical best practices and novel approaches to patient care. Those involved in scientific publications strive to maintain accuracy, transparency, and trust through a rigorous process. Readers then utilize the published information in various decision-making capacities. Day 2 of the Annual Meeting will move beyond the 'usual suspects' involved in medical publications, providing perspectives on the trends in healthcare, decision-making, and meeting the needs of various stakeholders who utilize publications in this evolving healthcare environment.
	Learning Objectives By the end of this session, attendees will: Be aware of the activities of collaborative groups impacting publication activities Be able to evaluate whether such collaborations may be appropriate for their (or their organization's) involvement
8:00 AM-8:15 AM	Opening Remarks Rob Matheis
8:15 AM-9:15 AM	Keynote Presentation: Understanding Stakeholders: Beyond the Usual Suspects
	J. Russell Teagarden, PhD, Vice President, Scientific Affairs, Advanced Clinical Science & Research, Express Scripts
	Learning Objectives By the end of this session attendees will: Understand the ways in which publications are accessed and utilized by healthcare decision-makers Consider strategies to incorporate the needs of an expanded base of stakeholders into publication planning activities
	This session has been funded, in part, by an educational grant from
	Abbott A Promise for Life

iucsuay, April 24 (C	,untillueu)
9:15 AM-10:00 AM	End-User Perspectives on Publications Scientific publications are a source for evidence that impact clinical decision-making. This panel session will provide perspective on how to address the needs of healthcare decision makers so that they may best utilize the published data. This panel will explore issues at all levels of clinical decision-making, including patients, practitioners, and payors.
	Learning Objectives By the end of this session attendees will: • Understand the informational needs of the various groups involved in making healthcare decisions • Generate ideas about how to make publications more relevant to these various stakeholders
	Patient Perspectives on Uses of Medical Publications Donna Cryer, CEO, CryerHealth LLC
	Publications: A Managed Care Perspective Victoria Zarotsky, PharmD, Director, Market Access and Value Strategy, OptumInsight
	End-User Perspectives: A Medical Librarian's Point of View Victoria Goode, MLIS, Clinical Informationist, William H. Welch wwMedical Library, School of Medicine, Johns Hopkins University
	Chris Carswell, PharmD, <i>Editor,</i> PharmacoEconomics – <i>Adis, Springer Healthcare</i>
	J. Russell Teagarden, PhD, Vice President, Scientific Affairs, Advanced Clinical Science & Research, Express Scripts.
	Session Moderator: Tom Gesell, PharmD , Development Director, Medical Affairs, UBC-Envision Group; Member, ISMPP Board of Trustees
10:00 AM-10:30 AM	Morning Break and Visit Exhibits
10:30 AM-11:30 AM	End-User Perspectives on Publications (continued)
11:30 AM-Noon	ISMPP's Annual Business Meeting
Noon-1:00 PM	Lunch for all Attendees, Faculty, and Exhibitors

AFTERNOON	
1:00 PM-2:30 PM	Member Oral Presentations and Poster Awards Five out of 32 abstracts were selected, via a blinded peer-review process, for oral presentation. These five abstracts represent the best of the best—in terms of high-quality and innovative research, with results that continue to reinforce the value served by medical publication professionals. The annual poster awards follow immediately after the oral presentations.
1:00 PM-1:05 PM	Opening Remarks/Introductions Session Moderator: Faith DiBiasi, M(ASCP), MBA, Associate Director, Knowledge Management, Medical Affairs at Human Genome Sciences; ISMPP Certified Medical Publication Professional™
1:05 PM-1:20 PM	Benchmarking Twitter Usage Among Scientific Journals Todd Parker, Managing Director, Scientific Services, MedThink SciCom; ISMPP Certified Medical Publication Professional™
1:20 PM-1:35 PM	Utilization and Attitudes on Technological Advances in Medical Publications Carol Hudson, SVP, Group Director, SCI Scientific Communications & Information; ISMPP Certified Medical Publication Professional
1:35 PM-1:50 PM	Corporate Integrity Agreements 2007-2011 Thomas Babcock, Associate Director Scientific Publications, Shire Development; ISMPP Certified Medical Publication Professional™
1:50 PM-2:05 PM	Development and Implications of Redacted Clinical Trial Protocol for Posting Online with the Published Manuscript Namit Ghildyal, Associate Director, Sci & Med Publication, Janssen Research & Development, LLC
2:05 PM-2:20 PM	Evaluating Factors Influencing Timelines for Publication Submission After Implementation of GPP2 Guidelines— Raising the Bar to Shorten Timelines Kanaka Sridharan, Associate Director, US Publications, US Medical Services, Novartis Pharmaceuticals Corporation
2:20 PM-2:30 PM	Poster Awards Faith DiBiasi

2:30 PM-5:30 PM	Collaborations in the Medical Publications Arena Collaborations with publications departments and various external stakeholders are not only beneficial but also increasingly critical to success. In this afternoon's sessions we will hear from
	speakers who have built alliances that maximize the success of publications departments and communications to the healthcare community. Included are such organizations as ISMPP, MPIP, and COPE. In addition, this session includes a snapshot of some realworld experience in the form of a case study sharing details on the collaboration between the Pfizer publications group and two publishers, Elsevier and Nature.
	Learning Objectives By the end of this session attendees will: Be familiar with the organizational collaborations that exist in the medical publication space Know how some of the ongoing collaborations are impacting our profession
2:30 PM-3:00 PM	Case Study on Collaborations: One Company's Alliances with the Publishing World
	Jodie Gillon, Director, Publications Management Team, Pfizer
	Martin Delahunty, Associate Director, Academic Journals & Pharma Solutions, Nature Publishing Group
	Leighton Chipperfield, Publishing Director, Elsevier Ltd.
	Session Chair: Julia Ralston, President and CEO, MedErgy HealthGroup; ISMPP Immediate Past President; ISMPP Certified Medical Publication Professional™
3:00 PM-3:30 PM	Afternoon Break and Visit Exhibits
3:30 PM-3:50 PM	Collaborations (continued)
	ISMPP I&A Committee Update Greg Thompson, MD, Senior Vice President and Medical Director, KnowledgePoint360; ISMPP Certified Medical Publication Professiona ™

3:50 PM-4:10 PM	An Update from MPIP Mary-Margaret Lannon, MS, Director, Medical & Scientific Publications, Takeda Pharmaceuticals North America, Inc.
4:10 PM-4:30 PM	An Update from the Committee on Publication Ethics (COPE) Liz Wager, PhD, Publications Consultant, Sideview; COPE Chair (2009-2012)
4:30 PM-5:30 PM	Roundtables/Meet the Experts One important component of ISMPP annual meetings is the opportunity for practical and intellectual discussion among attendees. The Roundtable sessions at the 8 TH Annual Meeting of ISMPP will provide a professional forum for attendees to gather and exchange ideas around preselected topics. The roundtables provide a hub for moderator-led discussions, attendee inquiry, and an open exchange of information about core topics that are evolving in the medical publications community.
	Each meeting attendee will have the opportunity to attend two roundtable discussions.
	Session Moderator: Gayle Scott, PharmD , <i>Principal Medical Writer, UBC-Envision Group; ISMPP Certified Medical Publication Professional™</i>
5:45 PM-7:45 PM	Annual Evening Networking Reception
	ISMPP thanks UBC-Envision Group for their support of the Annual Evening Networking Reception
	UBC envision group

Roundtable Topics at the 8TH Annual Meeting of ISMPP

Table Number	Topic
1	Advocacy: Responding to negative criticism of our industry
2	Best practices in interacting with authors
3	Challenges surrounding review manuscript development and submission
4	Differences between medical device and drug publications
5	Expanding awareness of our profession to ensure an influx of new talent
6	ISMPP in the Asia-Pacific
7	Issues surrounding medical writing outsourcing and/or off shoring
8	Trends in medical publication planning
9	New opportunities in publications
10	Professional development: Necessary skills/competencies, career paths, and other considerations
11	The Sunshine Act: What do we know?
12	Transparency in information release
13	Working as a true team: Making the industry/agency relationship more collaborative
14	Why become CMPP certified?: The value of certification

Wednesday, April 25

Wednesday, April 2	
MORNING	
7:00 AM-8:00 AM	Registration and Continental Breakfast
Day 3:	Medical Publications: Capturing the Change
General Session	In today's environment, two of the moving targets that we need to keep up with are decreased budgets and increased technologies—both of which impact our professional practices. Day 3 of the Annual Meeting will focus on the challenges associated with these changes, and provide hands-on solutions to help us manage change.
8:00 AM-8:15 AM	Opening Remarks
	Russell Traynor, MSc, Director, Business Solutions, UBC-Envision Group; President Elect ISMPP (2012-2013); ISMPP Certified Medical Publication Professional™
8:15 AM-8:45 AM	Special Presentation: ISMPP Annual Research Initiative
	Julia Ralston , <i>President and CEO</i> , <i>MedErgy HealthGroup; ISMPP Immediate Past President; ISMPP Certified Medical Publication Professional™</i>
	Viv Adshead, BSc , Executive Vice President, Knowledgepoint360 Group; Group Managing Director, Healthcare Communications Network
	James Mercante, MBA, Senior Vice President, Innovation, TGaS Advisors
8:45 AM-9:45 AM	The Challenge of Doing More with Less
	Publication teams are increasingly required to develop and execute publication plans that fulfill commitments to publish results of all trials in a timely manner in an environment of diminishing budgets, constrained resources, and increased internal and external scrutiny. This panel session focuses on the theme of 'doing more with less' and discusses practical approaches to meeting this challenge.
	Learning Objectives By the end of this session attendees will: Gain insight into how new compliance activities affect publication professionals' day-to-day activities Understand how budget constraints and increased scrutiny affect the publication process Be familiar with approaches to publishing more trial results with reduced resources

Wednesday, April 25 (continued)

The Challenge of Doing More with Less

Marc Eisenberg, PhD, Associate Director, Publication Operations-Immunology, Global Medical Publications Center of Excellence, Bristol-Myers Squibb

Streamlining Processes to Increase Efficiencies: An Agency Perspective

Suzann Schiller, Vice President, Client Services, ApotheCom; ISMPP Certified Medical Publication Professional

The Impact of Decreased Budgets on Publications
Angela Sykes, Director, Publication Specialist, Pfizer

Session Moderator: Alice Choi, PhD, Global Head, Complete Medical Communications; ISMPP Certified Medical Publication Professional™

9:45 AM-10:15 AM

Morning Break and Visit Exhibits

Note: Wednesday's program continues on the next page

Wednesday, April 25 (continued)

10-15 AM-Noon

Emerging Technologies: New Opportunities Post-Publication

The advent of social media, digital media, and other innovative technologies has presented new opportunities for publishing, consuming, sharing, and evaluating medical content. Publication professionals must now take into consideration these new technologies when selecting a publication medium for their data. This session will explore trends in the ways in which healthcare professionals access publications, regulations that affect the use of social and digital media, new options for tracking article readership, and practical applications of technology to attract and enhance readership.

Learning Objectives

By the end of this session attendees will:

- Become familiar with publishing models beyond the printed page
- Be aware of new web-based data-sharing models
- Understand the complexity associated with building an app

Traditional Publishing Meets Modern Technology Rebecca Lawrence, PhD, Publisher, F1000 Research, Faculty of 1000

Best Practices for Mobile Engagement

Trevor Roald, Mobile Technology Evangelist, QuickMobile

New Techniques Beyond Print from the Perspective of a Medical Publisher

Alison Brown, PhD, Publishing Director, Springer Healthcare

Delivering Messages from the Beach

Session Moderator and Presenter: Scott Virkler, MBA, Senior Vice President, e-Products of Global Medical Research, Health Sciences, Elsevier Ltd.

Noon-12:25 PM	ISMPP Evolution: Where We Are and Where We Plan to Be Rob Matheis
12:25 PM-12:30 PM	Closing Remarks Russell Traynor
12:30 PM-1:00 PM	Box Lunch for Workshop Participants
1:00 PM-2:30 PM	Post-Conference Workshops
2:30 PM-3:00 PM	Afternoon Break
3:00 PM-4:30 PM	Post-Conference Workshops (continued)
4:30 PM	Conference Adjourns

Poster Presentations at the 8TH Annual Meeting of ISMPP

Poster Number	Title and First Author
1	Systematic review on the prevalence of ghostwriting: Misleading, misguided, and mistaken 'evidence' Serina Stretton, Proscribe Medical Communications; ISMPP Certified Medical Publication Professional
2	Plagiarism in Medical Publications: Practical solutions for maintaining integrity in the industry Doug Taylor, The Medicine Group
3	Corporate Integrity Agreements: What they say about publications, publication planning, transparency, and ICMJE Frank J. Rodino, Churchill Communications; ISMPP Certified Medical Publication Professional
4	Can free online tools help publication professionals identify therapeutic area experts and target journals? Karen Woolley, ProScribe Medical Communications; University of Queensland; University of the Sunshine Coast; ISMPP Certified Medical Publication Professional*
5	Innovative, evidence-based, practical primer tools for publica- tion professionals working with authors in the Asia-Pacific region Rebecca Lew, <i>ProScribe Medical Communications</i>
6	Use of stakeholder survey feedback for improvement of the publication review and approval process Jean Barilla, MedImmune
7	Publication steering committee development at a pharmaceutical company: Experience one-year post-departmental guidance document development Brian Scheckner, Global Publications Group, Shire Specialty Pharma; ISMPP Certified Medical Publication Professional
8	Publication planning at one pharmaceutical company: A guid- ance document creation to ensure compliance with industry best practices and laws Gina D'Angelo, Global Publications Group, Shire Specialty Pharma
9	"Ripe" for change: Introducing a new index of publication efficiency Stephen W. Gutkin, Rete Biomedical Communications Corp

Poster Presentations (continued)

Poster Number	Title and First Author
10	Case reports: Expanding clinical knowledge John Fallows, <i>BioMed Central</i>
11	Structuring publication teams to meet global needs — where are we now? Diane Moniz Reed, Bristol-Myers Squibb; ISMPP Certified Medical Publication Professional
12	Streamlining and improving the global publication development process to align with best publication practices Susan Nastasee, Bristol-Myers Squibb; ISMPP Certified Medical Publication Professional
13	Making the grade: analysis of performance on the ISMPP CMPP examination Robert Matheis, Sanofi; ISMPP Certified Medical Publication Professional™
14	A survey of medical publication professionals on the role of copy editors Russell A. Gazzara, ReSearch Pharmaceutical Services, Inc
15	Industry-sponsored clinical trials: Time to publication Marla Mathias, Complete Healthcare Communications, Inc.
16	Accesses Versus Citations: Why you need to measure both to assess publication impact Tom Rees, PAREXEL International
17	An analysis of industry-funded studies published in the New England Journal of Medicine Sarah Feeny, Complete Medical Communications Inc.; ISMPP Certified Medical Publication Professional™
18	Positive and negative trial data: Are there publication differences? John Besemer, PAREXEL International
19	Monitoring the external publications environment: Identifying and communicating significant developments to key stakeholders in a corporate setting Geoff Smith, <i>Amgen Inc.</i>

Poster Presentations (continued)

Poster Number	Title and First Author
20	A survey of global publication practices for authors of commercially-sponsored original research and review articles Bryce McMurray, inScience Communications, Springer Healthcare
21	Perceived challenges to open peer review and opportunities for education Kristen Clark, Quintiles Medical Communications; ISMPP Certified Medical Publication Professional™
22	Authorship criteria in medical journals: A review of guidance Jackie Marchington, Caudex Medical; ISMPP Certified Medical Publication Professional™
23	Journal impact factors benefit from the content of pharma-affiliated authors Leighton Chipperfield, Elsevier Ltd.
24	Social Media Usage by Medical Journals: Implications for publication planning Ira Mills, PAREXEL International
25	Benchmarking Twitter hashtag usage at medical conferences Ginny Boland, MedThink SciCom
26	Acceptance and utilization of digital congress poster presentations: A survey of medical publication professionals Melissa S. McGrath, Boehringer-Ingelheim; ISMPP Certified Medical Publication Professional
27	Novel approaches to conveying scientific communication outputs Sheryl Selvey, <i>Genzyme, a Sanofi Company</i>
28	Publication of past and future clinical trial data: Perspectives and opinions from a survey of 607 medical publication professionals* Ryan Woodrow, Woodrow Medical Communications, Ltd. *Poster Award Winner, Best in Original Research; 2011 European Meeting of ISMPP, November 15-16, Alderly Park, Chesire, UK

Workshop Offerings

Pub Planning 101: The Best of the Basics for New Publication Planning Professionals (Monday only)

Prerequisite: This workshop is appropriate for new entrants with less than 1 year in the field of strategic publication planning and implementation.

The Pub Planning 101 workshop provides an interactive and instructive introduction to strategic publication planning. It includes didactic presentations tailored toward newly appointed planners in the pharmaceutical, biotech, and/or device industry, communication and publication agencies, publication support staff, publication writers and editors, and allied members of the publication planning team.

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 strategic publication plan
- Be familiar with publication planning terminology and good publication practices
- Appreciate the importance and benefits of a collaborative team environment

Workshop Faculty

Kristvn Basile

Client Solutions, UBC Scientific Solutions Gregory Bezkorovainy, MA

Vice President, Scientific Services,
AdelphiEden Health Communications; ISMPP
Certified Medical Publication Professional™
Carol Sanes-Miller

Global Publications Manager, AstraZeneca ISMPP Certified Medical Publication Professional™

Johnathan C. Maher, PhD

Manager, BioTherapeutics, Global Medical Affairs, Baxter BioScience

Craig Smith

Senior Editor and Manager, Multimedia Publishing, Elsevier Ltd.

Pub Planning 201: Ethical and Regulatory Challenges: Optimizing Your Publication Process in the Age of Transparency (Wednesday only)

Prerequisite: This workshop is appropriate for those with a basic awareness of publication planning (topics covered in Pub Planning 101) and/or at least 1 year of experience in the field of publication planning and implementation.

This workshop will consist of didactic and interactive sessions discussing the need for transparency in order to develop credible publications based on industry-sponsored clinical trials. The US and European laws governing registration and posting of results of clinical studies and their implications for publications will be explored. Best practices for presenting data in a balanced manner as well as guidance on authorship, the Physician Payment Sunshine Act, and corporate integrity agreements will be discussed. In addition, this workshop will help frame current FDA guidelines that regulate the discussion of publications with healthcare professionals. These practices assure consistency with recognized publication policies and guidelines; adherence to these standards can promote greater efficiency in achieving ethical publication goals.

Learning Objectives

At the end of this workshop, attendees will:

- Be able to identify best ethical practices in achieving publication goals according to relevant laws and guidelines
- Know the key steps in working with authors and journals to ensure that Good Publication Practice 2 (GPP2) is followed
- Understand the need to keep up with constantly evolving laws and guidelines

Workshop Faculty

Wendy P. Battisti, PhD

Director, Scientific & Medical Publications,
Janssen Research & Development, LLC
(Johnson & Johnson); ISMPP Certified Medical
Publication Professional™

Jeffrey Fletcher, PhD

Senior Clinical Publications Lead,
AstraZeneca Pharmaceuticals LP; ISMPP
Certified Medical Publication Professional™
Sheelah Smith. PhD

Vice President, Scientific & Editorial Services, PAREXEL Int.



Pub Planning 301: Building a Strategy to Guide Your Plan (Monday only)

Prerequisite: This workshop is appropriate for those with at least 3 years of experience in publication planning.

This workshop is designed to help publication professionals better understand how to develop a publication strategy to ensure evidence-based, timely, and targeted publication of data to all key audiences. Many publication professionals find themselves focusing on tactics without a clearly defined strategy. However, with a carefully considered strategy as your foundation, you are in a better position to manage the publication plan, allowing it to evolve as needed based on the emerging clinical results of your product. Throughout the workshop, attendees will be participating by sharing their ideas and experiences as publication professionals and will be asked to benchmark their practices against those of others in the group.

Learning Objectives

At the end of this workshop, attendees will:

- Understand the role of strategy in publication planning
- Understand key building blocks and components of a publication strategy
- Recognize the differences between the strategic and tactical plans
- Differentiate between a good strategy and a weak one
- Build in checks and balances to evaluate when changes in the environment might require changes to the overall strategy and/or tactical plan

Workshop Faculty

Rick Lamb
President,
Complete Publication Solutions, LLC
Jorge J. Moreno-Cantu, MSc, PhD
Senior Publications Manager,
Merck & Co., Inc.



Ethics in Publications Practice: Publishing Data from "Negative" and Terminated Trials

(Wednesday only)

Prerequisite: This workshop is appropriate for seasoned veterans with at least 3 years of experience in publication planning.

This workshop will provide an interactive and instructive environment for seasoned veterans in publication practice to discuss the issues involved in accurate, contextual, and ethical reporting of data from trials that have either failed to achieve their goals or that have been terminated

Learning Objectives

At the end of this workshop, attendees will:

- Know the definition of "negative" data
- Understand the issues involved in publishing negative data
- Be familiar with the concerns and perspectives of the stakeholders
- Be aware of potential barriers to publication Professional™ and be able to identify positive solutions

Workshop Faculty

Joe Bennett

Publishing Manager, Pharma Solutions,

Nature Publishing Group

Mukund Nori, PhD. MBA

Senior Medical Writer, UBC-Envision Group: ISMPP Certified Medical Publication

Geoff Smith, PhD

Medical Writing Senior Manager, Amgen Inc.

NEW THIS YEAR!

Evolution of Publications from Print to New Media (Monday only)

Prerequisite: This workshop is appropriate for individuals in pharma/biotech/medical device companies and publishers who have at least 3 years of experience in the field of publication planning and implementation.

This interactive workshop is designed to explore the types of new media that are available to enhance publications and to identify the best practices for implementation. Attendees will discuss measures to ensure that enhanced media maintain the scientific integrity of the publications. Processes will be shared to show how to merge the utilization of new media with publications and how partnering with publishers to create a solution can meet the needs of all parties. Participants will be encouraged to share their experiences and help define a better process.

Learning objectives

At the end of this workshop, attendees will:

- Know the various types of new media available to accompany/enhance publications
- Understand the measures used to ensure scientific integrity and appropriate presentation of content
- Be able to apply learnings to identify media to use with their publications

Workshop Faculty

LaVerne Mooney, DrPH
Director Publications, Pfizer
Kurt Polesky

Business Development Manager, Medical & Health Sciences Journal, Wiley-Blackwell Catherine Skobe

Director, Publications Management, Pfizer Angela Sykes

Director, Publication Specialist, Pfizer



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.

Delivering publication outputs and ensuring compliance with good publication practice are fraught with everyday challenges. These challenges are increased when working with multiple regions, sometimes with partner companies, or with different requirements regarding the timing of publications, or the need to address different regulatory situations. In addition, national activities and the need for global-to-local coordination efforts make the publication planner's decision-making even more complex. Facilitated by representatives from industry and medical communications agencies, this interactive workshop provides an overview of considerations in global publication planning and delivery, as well as the opportunity to work in small groups to discuss how to handle a series of real-life scenarios. Attendees will also be able to obtain advice on issues they are currently facing through an anonymous submission process that will allow their cases to be discussed without disclosing confidential information.

Learning Objectives

At the end of this workshop, attendees will:

- Know the guidelines and considerations affecting publications in major world markets
- Understand who the stakeholders are of global publication plans
- Be conversant in the issues affecting global publication planning and tactical execution
- Be knowledgeable in the best practices for planning globally with a partner biopharmaceutical company
- Be able to negotiate the challenges of working with multiple regions and different regulatory situations

Workshop Faculty

Sarah Feeny, BSc
Head of Scientific Direction,
Complete Medical Communications;
ISMPP Certified Medical
Publication Professional™
Terry Peña

Director Clinical Publications, AstraZeneca

NEW THIS YEAR!



Comparative Effectiveness Research, Health Economics, and Outcomes Research: Their Growing Importance and Implications for Publication Professionals (Monday only)

Prerequisites: This workshop is appropriate for publication professionals with at least 2 years of experience in publication planning and those developing publication plans/policies/processes across these disciplines

Comparative effectiveness research (CER) is becoming an increasingly important component of medical publication strategy. 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. By integrating CER/HEOR into an overall publication strategy, publication professionals can complement core scientific and clinical publications and strengthen a product's evidence base for medical decision makers

Learning Objectives

At the end of this workshop, attendees will:

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

Workshop Faculty

Jamie Banks, PhD

Senior Medical Director, Complete Publication Solutions, a CHC Group company

Kirtida Pandva, BPharm, PharmD

Associate Director, Medical Communication Leader, Novartis Pharmaceuticals Corporation; ISMPP Certified Medical Publication Professional™



Prerequisite: This workshop is appropriate for individuals with 3 years of publication planning and/or writing experience, including 1 year of working with HEOR publications or having attended a HEOR workshop.

This highly interactive workshop is designed to educate on more specific aspects of creating high-quality HEOR manuscripts, and to provide insight into the effective interpretation and communication of HEOR data. An initial didactic presentation will elaborate on the basic vocabulary and define the elements of a good HEOR publication, which will be followed by breakout groups evaluating examples of well- and poorly-written HEOR publications, especially pointing out the presence or absence of essential elements. The breakout groups then will present to the whole group in the final discussion period.

Learning Objectives

At the end of this workshop, attendees will:

- Know the components of a high-quality HEOR manuscript
- Be familiar with health outcomes trends
- Understand the implications of HEOR with respect to publication planning

Workshop Faculty

Chris Carswell, PharmD

Editor, PharmacoEconomics —

Adis, Springer Healthcare

Keith Evans, PhD

Director, Global Health Outcomes —
inScience Communications,

Springer Healthcare

The Joy of Gap Analysis (Monday only)

Prerequisite: This workshop is appropriate for individuals with all levels of strategic publication planning and implementation experience who are interested in conducting a gap analysis.

Using an interactive format, workshop leaders will guide participants through the process of conducting a gap analysis, including considerations of appropriate source material, assessment of the findings, and discussions on how to apply the results effectively to build a strategic publication plan. The workshop leaders will demonstrate how to gain the most value for a publication plan through analysis of the literature and other informational sources.

Learning Objectives

At the end of this workshop, attendees will:

- Define what a gap analysis is and the purpose of conducting one
- Understand how to conduct a gap analysis that will provide meaningful results
- Learn the potential ways that a gap analysis can go astray
- Describe how to use the information learned from the gap analysis

Workshop Faculty

Thomas Gegeny, MS, ELS

Team Lead and Senior Medical Writer, Envision Scientific Solutions, Inc; ISMPP Certified Medical Publication Professional™ Paul O'Grady, PhD

Sr Director, Scientific Communications, Novartis Oncology



The Mechanisms Behind a Systematic Review: Applying the PRISMA Statement (Monday only)

Prerequisites: This workshop is appropriate for individuals in pharma/biotech/medical device companies or in communications agencies who have a basic awareness of publication planning (topics covered in Pub Planning 101 and 201) and at least 2 years of experience in the field of publication planning and implementation

Designed for publication planners, medical writers, medical editors, and journal editors with an interest in or responsibility for preparing or evaluating a systematic review, this workshop provides an in-depth review of the PRISMA guidelines, with a step-by-step presentation guiding participants through the preparation of a systematic review. From the first steps of selecting a topic and conducting literature searches through applying study selection criteria and presenting results, this workshop explores each step of the writing process and how to interpret PRISMA guidelines throughout the review. Workshop leaders will also conduct an interactive discussion using sample systematic reviews to determine which papers best adhere to the PRISMA guidelines, which fall short, and which have the best chance of surviving a journal's peer-review process.

Learning Objectives

At the end of this workshop, attendees will:

- Define the differences between traditional and systematic reviews
- Understand the PRISMA guidelines and how to apply them to a systematic review
- Be able to write, edit, or evaluate a systematic review, ensuring that it adheres to the PRISMA guidelines

Workshop Faculty

Chris Carswell, PharmD
Editor, PharmacoEconomics —
Adis, Springer Healthcare
Teri O'Neill
Executive Managing Editor,
Peloton Advantage

Metrics: Practical Application and Experiences (Monday only)

Prerequisite: This workshop is appropriate for those with a basic understanding of publication planning, including the manuscript development process, review and approval processes, and prioritizing publication activities and resources. Participants should have one—two years of experience in a publication planning role.

The goal of this interactive workshop is to provide a foundation for identifying appropriate metrics of success consistent with publication plan objectives, stage of drug development, data availability, and resources. This year's workshop offers an open forum format in which participants will come prepared with one major question or challenge to be addressed during the session. The goal is to learn from one another and obtain relevant input. Metrics vary, and this session is designed to explore them and to provide participants with options, as there is no one universal metric that applies to all situations.

Learning Objectives

At the end of this workshop, attendees will:

- Understand the process of developing publication plan metrics
- Review and discuss various types of publication metrics
- Participate in an open forum discussion designed to address the needs of each participant
- Identify potential resources to help achieve publication plan objectives

Workshop Faculty

Christine Gatchalian, PhD
Director, Medical Writing, Amgen Inc.
Renu Juneja, PhD
Senior Director, Novo Nordisk, Inc.

Partnerships Between Pharma and Medical Communication Companies (Monday only)

Prerequisite: This workshop is open to all medical publication professionals.

Optimizing the relationship between pharmaceutical clients and medical communication companies is challenging. This interactive workshop will be presented by publication professionals who have worked for both medical communication and pharmaceutical companies as medical writers and managers of large strategic publication plans and will provide in-depth information on how to understand the challenges of both groups and share insights on how work together to meet scientific and business goals.

Learning Objectives

At the end of this workshop, attendees will:

- Understand who the 'clients' are and what challenges and expectations they have
- Know the roles and responsibilities that each member of the partnership is expected to assume
- Develop an optimal capabilities presentation that addresses client needs

Workshop Faculty

Laura LeGower, MBA
Account Supervisor,
Complete Healthcare Communications Inc.

Sheba Mathew, PhD

Senior Manager, Medical Writing, Novo Nordisk

John Smith, PhD

Senior Manager, Medical Writing, Novo Nordisk; ISMPP Certified Medical Publication Professional™

NEW THIS YEAR!

Publication Planning and Management at Smaller Pharmaceutical/Biotechnology Companies (Wednesday only)

Prerequisite: This workshop is appropriate for those with basic awareness of publication planning (topics covered in Pub Plan 101) and/or at least 1 year of experience in the field of pub planning and implementation.

At smaller companies, publication managers may be faced with generating a new publication function that will integrate publication processes and guidelines into the existing company structure. Publication managers may have limited publication budgets and/or resources and may need to perform multiple functional roles that expand beyond just publication management. In addition to these challenges, the publication manager may be required to establish new processes and policies with cross-functional agreement and in doing so, demonstrate the internal value of ethical publication practices and medical writing support. This workshop will consist of didactic and interactive sessions discussing the challenges of publication management at smaller pharmaceutical or biotechnology companies. During the workshop, faculty and participants will discuss how a publication manager maintains a cohesive publication plan in light of employing external medical writers or an agency, which may be a new process for some companies. The need for cost effective, innovative, and flexible publication plans and processes that are aimed at leveraging the internal knowledge base will be explored.

Learning Objectives

At the end of this workshop, attendees will:

- Be able to identify and best utilize the resource constraints of publication management at smaller companies
- Understand how to create effective and efficient publication policies and procedures that address the challenges of publication management at smaller companies

Workshop Faculty

Donna Simone

Publications Director, Cadence Pharmaceuticals; ISMPP Certified Medical Publication Professional™

Kelly Reith, MS, MBA

Director, Scientific Publications and HEOR Management, Incyte Corporation

Mindy Yang, PharmD

Director, Medical Education & Publications, NPS Pharmaceuticals

NEW THIS YEAR!



Working With Steering Committees to Develop Publication Strategies and Plans (Wednesday only)

Prerequisites: This workshop is appropriate for attendees who have taken Publication Planning 201 or 301, and have at least 2 years experience in publication planning.

The utilization of steering committees to oversee publication strategy and plans, especially in the case of very large, complex studies or programs, is becoming more common. However, it is important to distinguish the most appropriate situations to apply this structure. This workshop will consist of didactic and interactive sessions that will review the situations in which steering committees are most warranted and effective, and provide guidance in their composition and operation. The course will also discuss whether the steering committee should become the operating model for all industry-sponsored publications in the future and potential models for the role of the industry publication planner in interacting with the committee. The workshop will include specific case studies, including conflict resolution.

Learning Objectives

At the end of this workshop, attendees will:

- Be able to identify programs or studies warranting a steering committee
- Understand the composition of the committee, including importance of the chairman, adequate representation of key stakeholders
- Have clear definitions of ethical medical publication guidelines, roles, and authorship expectations

Workshop Faculty

Kyle Nahrebne

Associate Director/Group Manager, Clinical Publications, AstraZeneca

Jeff Pfister

Global Scientific & Medical Publications
Publication Management, Merck & Co., Inc.

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Get the most out of the 8TH Annual Meeting of ISMPP!



Introduced last year, we will again record brief interviewswith key presenters—and new this year, ISMPP committee volunteers through INN (ISMPP News Network) will post

them online for you to review and share with your colleagues. If interested in reviewing last year's interviews, please log into the Member Lounge at www.ismpp.org.

FOLLOW US ON twitter

ISMPP will be "tweeting" in real time from the meeting. Hear about exciting events as they happen! Follow ISMPP on Twitter at #ISMPPAM12

Recertification Credit Information for CMPPs

Many of this year's meeting presentations and workshops qualify for CMPP continuing education credits. Be sure to check the program contained herein, and the ISMPP meeting app, for the full constellation of qualified presentations, denoted with the CMPP recertification credit icon ().

Note: 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 the International Society for Medical Publication Professionals.

Media Partners



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On behalf of ISMPP, we would like to express our sincere appreciation to the Program, Abstract, Workshop and Communications Committees for an outstanding Annual Meeting.

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ISMPP would like to thank its dedicated staff for their tremendous contributions to the 8TH Annual Meeting:

Kim Pepitone and Jennifer Ciafullo-content development, oversight, and management of the Annual Program Committee Michele Kantrowitz-management of the Workshop and Abstract Committees, app development and technical support for registrants Lisa Klos and Sue Marek-overall meeting support for the Annual Program Committee

Kim Goldin-logistics oversight and management

Stephen Malek and CHC group-graphic design support for this brochure Debbie Feger and MedEnergy-thank you cards and CMPP materials

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