

THE 6TH ANNUAL MEETING OF ISMPP

**DELIVERING VALUE AND
DRIVING ADVOCACY IN
MEDICAL PUBLICATIONS**

**APRIL 19-21, 2010
CRYSTAL GATEWAY MARRIOTT
ARLINGTON, VIRGINIA, USA**



DEAR COLLEAGUES:

It is with great pleasure that we welcome you to the 2010 Annual Meeting of ISMPP. This year's meeting, **Delivering Value and Driving Advocacy in Medical Publications**, comprises presentations and information of critical interest to our profession. Check out the agenda and you'll see how these two important issues will be addressed.

We will once again follow our new meeting format, which, as last year, allows for an expanded presentation agenda and shorter, more diverse workshops. And don't forget that workshop attendance is limited to 25 per group, with registration on a first-come, first-served basis.

We will also feature member abstracts as both oral and poster presentations during the course of the meeting. As is often the case, our peers are the best source for information, and this year's member presentations will certainly follow suit. All accepted abstracts will be published in a supplement to *Current Research and Medical Opinions*.

The meeting opens on Monday with a special keynote address from Mark B. McClellan, MD, PhD, former Commissioner of the US FDA and Administrator of the Centers for Medicare and Medicaid Services. Dr McClellan currently serves as the Director of the Engelberg Center for Health Care Reform at the Brookings Institution, and will speak to us about delivering value in healthcare and medical research.

What follows on Monday is a compelling session called the **The Publication Soapbox and Black Box**—an interactive session that will help us all take a fast-paced and provocative look at the world of publications and the publication planning professional, and provide us with some pearls to take back to our everyday jobs. Monday's program closes with a special ceremony honoring our second group of **Certified Medical Publication Professionals**, which now numbers over 150! This ceremony is followed by our new **Monday evening poster assembly**, where you will have a chance to end the day by viewing the poster presentations developed by your peers and wind down with a pre-dinner cocktail.


Tuesday morning opens with a keynote presentation by David Verbraska, Vice President, Worldwide Regulatory Policy and Intelligence, at Pfizer Inc, and a member of the International Federation of Pharmaceutical Manufacturers and Associations Regulatory Policy and Technical Standards Committee. He will share his thoughts and experience on industry transparency in posting and publishing clinical trial results.

The **ISMPP Business Meeting** will be held on Tuesday, where we will share information on all of the current activities of the Society. In addition, you'll be hearing details about ISMPP's Advocacy Program in a special session on Tuesday, which includes a **keynote presentation by Stephanie Vance, The Advocacy Guru**, who will share her secrets for effective advocacy, including why advocacy is important to ISMPP issues, how advocacy connects to the organization's mission, and the factors that influence elected officials.

Our Wednesday opening keynote session features Rita F. Redberg, MD, MSc, Professor of Medicine at UCSF School of Medicine and Editor of the *Archives of Internal Medicine*. Dr Redberg will don her editor's hat, and share her views on the relationship between industry and peer-reviewed journals. **Wednesday's closing session will feature** the debut of the authors' manuscript submission "tool kit" developed by the Medical Publishing Insights and Practices (MPIP) initiative. This session includes a presentation by the journal editors and industry representatives who participated in this important initiative.

Exhibitors are invited to set up their booths on Sunday and keep them open throughout the meeting. This way, you will have plenty of time to visit the exhibits and not miss any of the workshops, presentations, and other networking opportunities. As is our tradition, we will open the meeting with our **Sunday evening Welcome Reception**, and we look forward to seeing you at our **Tuesday Evening Networking Reception**.

On behalf of ISMPP, thank you for your continued support of our organization. Welcome to Arlington!



Al Weigel

ISMPP President 2009-2010
Director, Medical Publications
Boehringer Ingelheim Pharmaceuticals



Julia Ralston

ISMPP President-elect 2010-2011
President & CEO
MedErgy HealthGroup

SUNDAY, APRIL 18, 2010

7:00 PM Welcome Reception

For those who want to “check-in” when they check-in, come and join the ISMPP Board of Trustees at the bin1700 Lounge for cocktails and hors d'oeuvres before retiring for the night.

WORKSHOP DESCRIPTIONS

This year, we've expanded our workshop offerings. Please check below to see what's new and when each workshop is offered.

WORKSHOP SCHEDULE OVERVIEW

Monday Morning		Wednesday Afternoon	
7:30 AM	Continental Breakfast	1:30–2:00 PM	Luncheon for Workshop Participants
8:30 AM	Program Begins	2:00 PM	Program Begins
10:00 AM	30-Minute Refreshment Break	3:30 PM	30-Minute Refreshment Break
10:30 AM–12:00 PM	Workshops Continue	4:00–5:30 PM	Workshops Continue
12:00–1:30 PM	Luncheon for Workshop Participants		

WORKSHOP DESCRIPTIONS

Monday only

Pub Planning 101: The Best of the Basics for New Publication Planning Professionals

Prerequisite: This workshop is appropriate for new entrants in the field of strategic publication planning and implementation

The Publication 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 industry or communication 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
- Become familiar with publication planning terminology and good publication practices
- Appreciate the importance and benefits of a collaborative team environment
- Understand the criteria used when selecting a journal

Workshop Facilitators

Gregory Bezkorovainy

Vice President, Scientific Services, Adelphi Eden Health Communications

Terri Greenley

Vice President, Client Services and Business Development, Gardiner-Caldwell Communications

Carol Sanes-Miller

Global Publication Manager, AstraZeneca Pharmaceuticals

Tamara Rahim-Grow, PhD

Senior Scientific Communications Manager, AlphaBioCom

Craig Smith

Senior Supplements Editor, Elsevier

Monday only

Pub Planning 201: Optimizing Your Publication Process in the Age of Transparency

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

This will be an interactive session designed to discuss the need for transparency in order to maintain the credibility of industry-sponsored clinical publications. Best practices for presenting data in a balanced and fair-minded manner as well as guidance on authorship choice, requirements, and engagement will be discussed. In addition, this workshop will help frame current FDA guidelines that regulate the discussion of publications with healthcare professionals. These practices should be consistent with recognized publication policies and guidelines; adherence to these standards can promote greater efficiency in achieving publication goals.

Learning objectives: at the end of this workshop, attendees will

- Understand why ethical publication practices and guidelines are important
- Identify best practices in achieving publication goals (eg, author interactions, journal interactions, publication dissemination)
- Identify key steps in working with authors to ensure that Good Publication Practices 2 (GPP2) is followed
- Understand the need to keep up with a constantly evolving environment

Workshop Facilitators

Jeffrey E. Fletcher, PhD, CMPP

Senior Clinical Publications Lead, AstraZeneca Pharmaceuticals

Wendy P. Battisti, PhD

Associate Director, Scientific & Medical Publications, Johnson & Johnson Pharmaceutical Research & Development, LLC

Robin Serody

Vice President, Account Services, PPSI

Sheelah Smith, PhD

Vice President of Scientific and Editorial Services, PAREXEL MMS Europe

WORKSHOP DESCRIPTIONS (CONT'D.)

Monday/Wednesday

Pub Planning 301: Building a Strategy to Guide Your Plan

Prerequisite: Appropriate for those with at least 3 years of experience in publication planning or who have taken Pub Planning 101 and 201

This highly interactive half-day workshop is designed for publication professionals with at least 3 years' experience. The goal of this workshop is to help publication professionals understand how to develop a strategy for release of their publications that will maximize the impact of those publications on the target audience. Many publication professionals find themselves focusing on tactics at the expense of a clearly articulated 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 environmental and competitive activities and the emerging results of your clinical development program. Workshop attendees will be divided into small groups to work up components of a strategy, 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
- Differentiate the tactical plan from the strategy plan
- Understand key building blocks and components of a publication strategy
- Recognize a "strong" strategy from a "weak" one
- Understand what triggers a change to strategy
- Build in checks and balances to evaluate when changes in the environment might require changes to the tactical plan

Workshop Facilitators

Janet Galliera

Director, Client Services, Complete Healthcare Communications, Inc.

Rick Lamb

President, Complete Publication Solutions, LLC

William Glass, PhD

Senior Publications Manager, Abbott

Monday/Wednesday

Pub Planning 401: Issue-Based Workshop

Prerequisite: Appropriate for those with at least 5 years of pub planning experience and have met the requirements of Pub Planning 301

The Publications Planning 401 workshop is an advanced course in strategic and tactical publication planning. In small groups and discussion sessions, participating seasoned publication professionals will tackle real-world challenges to gauge and expand their current knowledge of ethical publication planning practices. This workshop is aimed at publication professionals with at least 5 years of publication planning experience.

The workshop is an advanced course in strategic and tactical publication planning based around the key challenges and opportunities faced by the advanced publication planning professional and focused on the development of policies and processes to meet and overcome these challenges. The workshop facilitators will present background information on timely difficult issues, and will then facilitate small group discussions and report back to the whole group. The workshop facilitators will continue to challenge/question the approaches posed by the teams in order to support continued learning and development. In advance of the workshop, participants will be asked to submit publication planning issues that they have encountered (blinded for confidentiality) for discussion in the workshop. These issues will be in addition to those proposed by the workshop facilitators, to ensure the workshop addresses key real-world challenges faced by the participants.

Learning objectives: at the end of this workshop, attendees will

- Better understand current standards of ethics in publication planning and implementation
- Apply sound, ethical publication practices to challenging real-world scenarios
- Consider all available options when applying one's experiences and expertise to problem solving to ensure consistent application of current standards

Workshop Facilitators

Gene P. Snyder

Divisional Lead, UBC-Envision Group, ISMPP President, 2008-2009

Russell Traynor

Strategic Business Unit Head, UBC-Envision Group, ISMPP European Board Member

Michael Wittek

Senior Manager, Health Policy and Planning, Medtronic Inc.

WORKSHOP DESCRIPTIONS (CONT'D.)

Monday only

Global Pub Planning: Issues and Challenges in Global Pub Planning

Prerequisite: This half-day interactive workshop is based on a series of real-life scenarios and is designed for experienced publication planning professionals with an interest in or responsibility for publication planning and tactical execution at the global level

Facilitated by representatives from pharmaceutical companies 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 gain advice on issues they are currently facing through an anonymous submission process, which 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 pub plans
- Discuss 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 Facilitators

Sarah (was Bartlett) Feeney, BSc, CMPP

Head of Scientific Direction, Complete Medical Communications

John Gonzalez

Global Skills Lead, Publications, AstraZeneca Pharmaceuticals

Tom Grant

Publications Director, AstraZeneca Pharmaceuticals

Monday only

Evidenced-Based Medicine: Intro to the Principles of EBM

Prerequisite: Appropriate for all publication professionals with an interest in evidence-based medicine

This workshop will begin by defining EBM and the four steps used to practice it. Workshop leaders will then lead an interactive session to illustrate each of the steps in detail, including the frameworks used to ask clinical questions, resources used to best answer those questions, methods to critically appraise research, and approaches to effectively combine research results to answer a clinical question. The session will include a review of the major study designs used in clinical research, describe how these designs are used to address various types of clinical questions, and explain their strengths and limitations. The workshop will end with a note on the current challenges in EBM and a review of the best EBM resources available.

Learning objectives: at the end of this workshop, attendees will

- Define evidence-based medicine and the four steps to practicing it
- Describe a framework for asking clinical questions
- Determine the best approach to finding evidence to answer a clinical question
- Describe the major study designs used in clinical research, the clinical questions they best answer, and their strengths and limitations
- Construct a framework used to incorporate published evidence into medical decision making

Workshop Facilitators

Craig A. Umscheid, MD, MSCE

Assistant Professor of Medicine

Co-Director, Center for Evidence-based Practice

Co-Director, NIH CTSA Health System Informatics Core

Associate Scholar, Center for Clinical Epidemiology and Biostatistics

University of Pennsylvania

Kendal Williams, MD, MPH

Assistant Professor of Clinical Medicine

Director, Center for Evidence-based Practice

Service Chief, Department of Medicine

Penn Presbyterian Medical Center

WORKSHOP DESCRIPTIONS (CONT'D.)

Monday only (new this year)

Effectively Searching Online Databases: PubMed and Beyond

Prerequisite: None

The content will focus on search strategies and specialized query tools of databases such as PubMed (MEDLINE) from the National Library of Medicine. In particular, emphasis will be placed on the use of advanced features such as the MeSH database, special queries, and the use of personalized settings and search filters. While a majority of the workshop will be devoted to covering key database resources such as PubMed, some time also will be spent exploring advanced uses of common and alternative search engines. Interactive discussion and instruction-by-example using live Internet demonstration will provide participants with an improved understanding of online search strategies and a helpful list of Web-based information resources.

Learning objectives: at the end of this workshop, attendees will

- Understand how to incorporate advanced techniques into search strategies for finding desired information
- Be familiar with a variety of resources for finding information related to clinical trials, published literature/evidence, therapeutic guidelines, etc
- Grasp how certain online resources and search techniques may be applied for information assessment and publication planning purposes

Workshop Facilitator

Thomas Gegeny, MS, ELS

Team Lead and Senior Medical Writer, Envision Scientific Solutions

Monday only (new this year)

Regulations and Ethics in Medical Publication Planning

Prerequisite: This workshop is appropriate for all publication managers, medical writers, medical editors, journal editors, and allied members of a publication planning team (eg, regulatory, legal, medical, and marketing functions)

This workshop will begin with a review of the revised ISMPP Code of Ethics, followed by an interactive discussion of ethical challenges we face as writers, editors, and publication managers, and the impact of efforts by organizations and governments to drive ethical practice through guidelines and regulations. The workshop will use an interactive case approach to exploring ethical issues and the current regulations providing oversight and guidance for publication processes. Issues to be discussed include author accountability and access to data, disclosures and conflict of interest, impact of disclosure and sunshine laws on working with authors, use of authorship criteria, and roles of sponsors and professional medical writers.

Learning objectives: at the end of this workshop, attendees will

- Describe the new changes to the ISMPP Code of Ethics and the rationale for those changes
- Explain how current federal and state regulations address the ethics of publications, including transparency for authors, sponsors and professional medical writers, data accuracy, and availability and documentation of the publication processes
- Discuss differences and similarities among the various codes of practice developed to provide standards for publication and presentation of research

Workshop Facilitators

Jon Druhan, PhD

Associate Director, Publications, AstraZeneca Pharmaceuticals

Colleen Gilbert, PharmD

Vice President, Clinical Affairs, CommGeniX, LLC

WORKSHOP DESCRIPTIONS (CONT'D.)

Monday only (new this year)

Metrics: Practical Application and Experiences

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 at least one year of experience in a publication planning role

The goal of this 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. The session is divided into a lecture and interactive case study. The lecture will cover ways to identify publication objectives, quantitative and qualitative metrics to measure success, and factors that influence achievement of these goals. A case study will be presented and participants will be asked to 1) identify questions or additional data that would help in identifying publication goals and priorities, 2) develop a series of publication plan metrics appropriate for the publication plan, and 3) consider potential issues and solutions in achieving these goals.

Learning objectives: at the end of this workshop, attendees will

- Understand the process of developing publication plan metrics
- Identify different types of publication metrics
- Apply metrics that are appropriate for various types of publication plans
- Develop processes and identify resources to help achieve publication plan goals

Workshop Facilitators

Juli Clark, PharmD

Director, Global Medical Writing, Amgen

Kelly Reith, MS, MBA

Group Medical Director, Complete Healthcare Communications

Lisa Abraham

Account Director, Complete Healthcare Communications

Monday/Wednesday

CMPP Review Course: CMPP Examination Workshop

Prerequisite: Workshop participants must meet eligibility requirements for the CMPP exam, which can be found in the Candidate Handbook or in the "Application and Exam Details" flyer at www.ismpp.org

The workshop is designed for those who are planning to take the CMPP examination. Attendees are expected to have direct and significant publication planning experience or to have previously taken ISMPP courses (Publication Planning 101, 201, and 301). The workshop will consist of didactic components and case studies. During the case studies, participants will apply theory/knowledge to real-world situations/problems and present their solutions to other participants.

Learning objectives: at the end of this workshop, attendees will

- Understand the scope and depth of material covered during the CMPP examination
- Identify their own publication planning knowledge gaps
- Know what resources are available to fill their knowledge gaps in preparation for the examination

Workshop Facilitators

Kim Pepitone, CMPP

Director of Credentialing and Professional Development, ISMPP

Danita Sutton, PhD, CMPP

Executive Vice President, MedErgy HealthGroup

Angela Cairns, CMPP

Senior Vice President, Medical and Scientific Services, KnowledgePoint360

Tricia Deja, PharmD, CMPP

Senior Manager, Medical Publications, Astellas Pharma Global Development, Inc

Jason McDonough, PhD, CMPP

Vice President, Medical Strategy, MedErgy HealthGroup

Suzann Schiller, CMPP

Vice President, Client Services, ApotheCom

WORKSHOP DESCRIPTIONS (CONT'D.)

Wednesday only

The Manuscript: Challenges and Roadblocks (formerly Life of a Manuscript)

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

The course is broken into two distinct areas of exploration with particular emphasis on potential challenges and roadblocks:

Getting It Written: Types of manuscripts and considerations specific to each; logistics (eg, who will write the manuscript, scope of involvement of external authors, authorship criteria); essential components/optional components (including discussion of reporting standards); internal and external review; appropriate journal selection and submission protocol; issues with data disclosure; and timelines for each step.

From Submission to Publication: Review by journal staff, including editorial office screening; editorial decision making; dealing with correspondence from the journal; rejection; addressing reviewers' comments, including those reflecting a hostile review; next steps following acceptance; and all forms of publication; plus copyright issues; fixing errors, minor and major; and what constitutes the need for manuscript withdrawal.

Learning objectives: at the end of this workshop, attendees will

- Describe the steps involved in developing a manuscript, from initial concept through submission, peer review, publication, and beyond
- Define the responsibilities of each of the stakeholders involved in the manuscript process
- Apply an improved knowledge of medical publishing, which will enable participants to more successfully prepare, submit, and publish scientific manuscripts

Workshop Facilitators

Bill Deluise

Senior Editor, Health Sciences, Wiley-Blackwell, John Wiley & Sons

Mark J. Fedele, PhD, MBA

Clinical Communication Leader, Novartis Pharmaceuticals Corporation

Gordon Muir-Jones, CMPP

Executive VP, Oxford PharmaGenesis Inc.

Charon A. Pierson, PhD, RN, FAANP

Editor-in-Chief, *Journal of the American Academy of Nurse Practitioners*

Wednesday only (new this year)

Health Economics and Managed Care—Impact on Publication Planning and Implementation

Prerequisite: Minimum 3+ years of experience of medical publication planning with interest in gaining better understanding of health economics and outcomes environment

Lately, we have observed the increasing value of economic and health outcomes data in today's determination of healthcare policy and therapy decisions. This new workshop has been developed to provide a more in-depth understanding of health economics and outcomes research (HEOR) to medical publication professionals. The lecture portion of the workshop will briefly introduce HEOR, types of analyses used in HEOR, how HEOR data are collected, as well as how to translate HEOR data into publications. The integration of outcomes research into drug development and portfolio management will also be discussed.

Case studies will be presented to describe how outcomes data can be integrated into drug development strategies, presented in manuscripts, and evaluated by publishers.

Learning objectives: at the end of this workshop, participants will be able to:

- Describe different types of HEOR analyses and explain methods of data collection
- Gain an understanding of the integration of outcomes research into drug/device development and portfolio management
- Effectively and accurately translate HEOR information into publications

Workshop Facilitators

Mohan V. Bala, PhD

Director, Health Economics and Outcomes Research, GlaxoSmithKline

Charles A. Stevens, JD, MBA

Vice President, Global Reimbursement and Market Access, PAREXEL

WORKSHOP DESCRIPTIONS (CONT'D.)

Wednesday only

The Joy of Gap Analysis

Prerequisite: This half-day 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, locating appropriate source material, and assessing the findings 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
- Analyze potential ways that a gap analysis can go astray
- Describe how to use the information learned from the gap analysis

Workshop Facilitators

Paul O'Grady

Director, Oncology New Products, Novartis Pharmaceuticals Corporation

Thomas Gegeny, MS, ELS

Team Lead and Senior Medical Writer, Envision Scientific Solutions

MONDAY, APRIL 19, 2010

7:30–8:30 AM

Registration and Continental Breakfast

8:30–10:00 AM

Workshops I

10:00–10:30 AM

Morning Break and Visit Exhibits

10:30 AM–12:00 PM

Continuation of Workshops I

12:00–1:30 PM

Lunch for Workshop Attendees, Speakers, and Exhibitors

1:30–1:45 PM

Welcome to ISMPP 2010

Kim Goldin, Executive Director, ISMPP

Al Weigel, President, ISMPP 2009–2010

1:45–2:45 PM

Keynote: Delivering Value in Healthcare and Medical Research

Mark B. McClellan, MD, PhD

Director, Engelberg Center for Health Care Reform

The Brookings Institution



Made possible by an educational grant from



2:45–3:45 PM

The Publication Soapbox and Black Box

*Cindy Hamilton, Hamilton House Medical & Scientific Communications;
Past President, American Medical Writers Association*

*Larry Hirsch, MD, Vice President, Global Medical Affairs, Diabetes Care,
BD Medical – Diabetes Care; Past President, ISMPP*

*Kirby P. Lee, PharmD, MA, Assistant Professor, Department of Clinical
Pharmacy, University of California, San Francisco; Advisory Board,
The International Publication Planning Association*

*Gene P. Snyder, Divisional Lead, UBC-Envision Group, ISMPP President,
2008–2009*

*Session Moderator: Karen Woolley, PhD
CEO, ProScribe® Medical Communications*

Take a fast-paced and provocative look at the world of publications and the publication planning professional... First, the soapbox... picture yourself in Hyde Park on a Sunday afternoon listening to the rhetoric of orators speaking their mind... and then transport to the world of the publication professional. Hear what thought leaders have on their mind. Are you convinced by their arguments? Next comes the black box (not a warning, but a source of information)... do you really know what our organizations are doing to

address the issues raised on the soapbox? If there are great ideas within these organizations, they will definitely come out of the black box at this session! Compliment, complement, or challenge the soapbox and black box speakers—the choice will be yours during this session.

3:45–4:15 PM

Afternoon Break and Visit Exhibits

4:15–5:15 PM

The Global Outsourcing of Medical Writing—Visions of What “Value” Means in a Flat World

*Renu Juneja, PhD, Director, Strategic Scientific Communications,
Novo Nordisk*

*Donald D. Samulack, PhD, VP, Medical Affairs and Strategic Partnerships,
Cactus Communications, Inc.*

Keith Veitch, Head of Global Publications, Novartis Vaccines

*Session Moderator: Mark J. Fedeles, PhD, MBA, Clinical Communications
Leader, Novartis Pharmaceuticals Corporation*

On the horizon of a flat world, no job is immune from the reality of global outsourcing—this includes medical writing and publication planning. Companies are concerned about reducing costs while maintaining quality and compliance. What does this mean for publication professionals? How do we adjust, demonstrate value, and cope? How will global relationships shift the dynamic of a publication team? This session offers an overview of the current landscape, looks at the pros and cons of outsourcing medical writing, addresses logistics, and explores where value is created for a pharmaceutical company, CRO, or agency.

5:15–5:45 PM

Travel the Road to CMPP

*Robert J. Matheis, PhD, CMPP, Chair, Credentialing Board of Trustees
(Interim), ISMPP; Director, Medical Communications, sanofi-aventis*

By the time of the 2010 Annual Meeting, there will have been three seatings of the CMPP exam—and, if the current trend in test taking continues, more than 200 holders of the prestigious CMPP credential. Join your peers as they are recognized for their achievement, and hear an update of CMPP activities to date, including information on the road to recertification.

5:45–6:00 PM

Closing Remarks

Al Weigel

6:00–7:00 PM

ISMPP Member Poster Presentation Assembly

In its 4th year, the ISMPP member abstract program has grown tremendously and we would like to provide you with sufficient time to browse through the many poster presentations of your colleagues—selected via the blinded abstract review process. A nice end to Day 1—wind down your day with a stroll through the displays with some light refreshments.

TUESDAY, APRIL 20, 2010

7:00-7:45 AM

Committee Members Meet-and-Greet Breakfast

7:45-8:00 AM

Opening Remarks

Al Weigel

8:00-9:00 AM

Keynote: Industry Transparency in Posting and Publishing Clinical Trial Results

David Verbraska, Pfizer Inc, IFPMA



As Vice President, Worldwide Regulatory Policy and Intelligence, at Pfizer Inc, Mr. Verbraska represents the company at PhRMA (US) and IFPMA (global). His experience with these organizations are certain to provide stimulating discussion on new guidelines and enhanced standards in increasing transparency in clinical trials and improving disclosure to manage

potential conflicts of interest in medical research.

Join us as we discuss how publication teams and planners can collaborate with investigators to manage the timing of publishing in a peer-reviewed journal prior to the posting of trial results on www.clinicaltrials.gov. Healthcare professionals and other audiences who read uninterpreted results on such a site may not find the data relevant without the valuable introduction, methodology, and discussion that a peer-review manuscript offers. Mr. Verbraska looks forward to sharing his thoughts with you on this timely topic.

9:00-10:00 AM

Making an Impact: New Publishing Approaches to Increasing the Value of Publications

Michael T. Clarke, Founder and Principal, Clarke Publishing Group

Tom Easley, Managing Director, The New England Journal of Medicine

Deborah Kahn, Publishing Director, BioMed Central

Session Moderator: Leighton Chipperfield, Executive Publisher, Elsevier

In a highly competitive environment, medical journals and publishers continue to invest in new ways to add value to their published content. Through case studies, each speaker will demonstrate ways that peer-reviewed titles are leveraging the use of new and emerging technologies, and the opportunities these approaches offer to empower readers, authors, and editors alike. This session provides a thought-provoking take on the role of publication planning going forward as journals themselves continue to evolve.

10:00-10:30 AM

Morning Break and Visit Exhibits

10:30 AM-12:00 PM

Defining Value in Healthcare: A New Challenge for Medical Research and Publications

John W. Draper, Senior Vice President, Health Care Management, Peloton Advantage

Clifford Goodman, PhD, Vice President, The Lewin Group

Session Moderator: Kim Pepitone, CMPP, Director of Credentialing and Professional Development, ISMPP

In 2009 as part of the American Recovery and Reinvestment Act, the US Congress allocated 1.1 billion USD to comparative-effectiveness research. However, designing these types of trials is only one aspect of developing a successful payer proposition. The evidence required is rapidly changing, and efficacy and safety data alone are not enough to ensure patient access to new therapies. Increasingly, payers and bodies that perform health technology assessments are significantly influencing access to new medicines. In this session, we will explore the types of evidence required by a diverse set of customers and the impact of reporting these data on publication plans.

12:00-1:00 PM

Lunch for All Attendees and Exhibitors and Annual Business Meeting

1:00-2:00 PM

Keynote: Delivering Value and Driving Advocacy in Medical Publications

Stephanie Vance, The Advocacy Guru



Stephanie Vance, The Advocacy Guru, shares her secrets for effective advocacy, including why advocacy is important to ISMPP issues, how advocacy connects to the organization's mission, and the factors that influence elected officials. We'll also look at the four keys to effective advocacy, specifically, knowing what you want, who to ask, how to ask, and how to

follow-up. In addition to sharing a message formula that will have policy makers sitting up and taking notice, Stephanie will tell you the top ten things elected officials and staff hate to hear, as well as the number one tool in the effective advocate's arsenal (shh...it's a secret). Come prepared to have some fun, develop some strategies, and even win some fabulous prizes!

TUESDAY, APRIL 20, 2010 (CONT'D.)

2:00–2:30 PM

ISMPP Advocacy Activities

Julia Ralston, ISMPP President 2010–2011

During the past year, ISMPP has developed a formal plan to support the organization's mission relative to advocacy. This plan, developed through the efforts of your co-member Issues and Actions Working Group volunteers, addresses the value of medical publications and the role of the medical publication professional with relevant audiences, focusing on ongoing areas of misunderstanding and related best practices. Come and hear what the ISMPP Advocacy Plan entails, what has been done to date, and what future activities look like. You can also learn more about the role you can play in the organization's advocacy initiatives.

2:30–3:30 PM

Advocacy Roundtable Discussions

Session Moderator: Jim Gurr, Pfizer Inc

Having heard from advocacy experts and ISMPP leadership on advocacy, it's your turn! Join your fellow ISMPP members in discussing ISMPP's plans for advocacy, and, in particular, how you can serve as an advocate in your day-to-day work. Participants will have an opportunity to talk through ISMPP's plans, offer additional suggestions, and come up with their own plan to serve as an advocate and extend support for the profession.

3:30–4:00 PM

Afternoon Break and Visit Exhibits

4:00–5:00 PM

Reaching the Non-Physician Provider Through Publications—Insights and Advice From a Nurse Practitioner, Pharmacist, and Physician Assistant

James F. Cawley, MPH, PA-C, Professor and Vice Chair, Department of Prevention and Community Health, School of Public Health and Health Services, Professor of Health Care Sciences, School of Medicine and Health Sciences, The George Washington University

David A. Mays, PharmD, MBA, Director, Aesthetic and Medical Dermatology, Medical Relations and Communications, Johnson & Johnson Consumer and Personal Products Worldwide

Frances M. Rankin, PhD, ARNP, FAANP, Director, Doctorate of Nursing Practice (DNP), Clinical Doctorate of Nursing Practice (DNP), University of South Florida, Colleges of Nursing and Medicine

Session Moderator: Frank Rodino, CMPP, President, Churchill Communications

As healthcare roles continue to diversify, the "physician-centric" publication plans of the past are giving way to more targeted approaches, with streamlined publications that specifically address the educational needs of nurses, pharmacists, physician assistants, or other members of the healthcare team. In such endeavors, publication planners must consider the needs and perspectives unique to these audiences in order to communicate effectively. With this goal in mind, three representatives from several non-physician audiences will sound out in this session, each discussing the prevailing attitudes toward publication planning and preferred communication tactics associated with their respective professions.

5:00–5:55 PM

ISMPP Metrics Survey Results

Jon Druhan, Associate Director, Publications, AstraZeneca Pharmaceuticals LP

Jodie Gillon, Director, Worldwide Publication Management, Pfizer Inc.

Robert J. Matheis, PhD, Chair, Credentialing Board of Trustees (Interim), ISMPP; Director, Medical Communications, sanofi-aventis

Ruth Rutledge, Lead Publications Manager, Medical Communications, Merck & Co, Inc.

Caroline Suh, PharmD, CMPP, Associate Director, Global Oncology Medical Information, Novartis Pharmaceuticals

Session Moderator: Al Weigel, ISMPP Immediate Past-president 2009–2010

How do you measure the success of your publication plan? Currently, there is much variation in how pharmaceutical companies measure the success of their publication plans. Success is typically measured by using a variety of quantitative and qualitative measures. To date, there have been no best practices defined on how best to collect metrics against publication plans. In order to better understand current industry practices around metrics, ISMPP has conducted a survey of pharmaceutical member organizations. The results of this survey will be presented in this session as a means to begin to develop industry best practice recommendations around medical publication planning metrics and value.

5:55–6:00 PM

Closing Remarks

Julia Ralston

6:15–8:00 PM

Annual Networking Reception

Sky View Lounge



WEDNESDAY, APRIL 21, 2010

7:00–8:00 AM

Registration and Continental Breakfast

8:00–8:05 AM

Welcome and Introductions

Julia Ralston, ISMPP President 2010–2011

8:00–9:00 AM

Keynote: Industry and Peer-reviewed Journals: One Editor's Perspective

Rita F. Redberg, MD, MSc, Professor of Medicine, UCSF School of Medicine
Editor, Archives of Internal Medicine



9:00–9:45 AM

The Journal of Family Practice and Industry: the Good, the Bad, and the Ugly

Speaker: Jeffrey Susman, MD

Professor and Chair, Family Medicine, University of Cincinnati

Editor-in-Chief, The Journal of Family Practice

9:45–10:30 AM

ISMPP Member Abstract Presentations and Poster Awards

Session Moderator: Joanne Conaty, Senior Director, Clinical Strategy and Planning, AstraZeneca Pharmaceuticals

This program segment provides an opportunity for ISMPP members to present their abstracts that have been accepted as oral presentations. These presentations will be practical in nature, and will provide the opportunity for peer-to-peer sharing of key insights and best practices related to our theme of “Delivering Value and Driving Advocacy in Medical Publications.”

9:45–10:00 AM

Information Derived From the ClinicalTrials.gov Database: Analyses and Applications to Strategic Publication Planning
Kelly Reith, MS, MBA, Group Medical Director, Complete Healthcare Communications

10:00–10:15 AM

Awareness and Attitudes for Guidelines and Policies on Authorship of Clinical Publications
Ramana Yalamanchili, PhD, MBA, Chief Clinical Strategist, Health Learning System

10:15–10:30 AM

Round Up the Usual Suspects? Involvement of Medical Writers and the Pharmaceutical Industry in Retracted Publications
Karen Woolley, PhD, CEO, ProScribe® Medical Communications

10:30–11:00 AM

Morning Break and Visit Exhibits

11:00–11:45 AM

ISMPP Member Abstract Presentations and Poster Awards (Continued)

11:00–11:15 AM

Acceptance Rate Analysis for Pfizer-Supported Manuscripts
LaVerne Mooney, DrPH, Publications Management, Chief Medical Office, Pfizer Inc

11:15–11:30 AM

Sponsored Reviews and Supplements: Current Approaches and Future Trends
Elizabeth Crane, Senior Manager, Medical Publications, Astellas Pharma Global Development, Inc.

11:30–11:45 AM

Assessing the Impact and Value of Health Outcomes Publications Using Citation Data from Indices of Scholarly Literature
Diana L. Fisher, MS, Scientific Communications Consultant, Eli Lilly and Company

11:45 AM–12:00 PM

Poster Awards Presentations

Joanne Conaty

12:00–1:20 PM

Editor and Publisher Panel—Best Practices in Manuscript Submission

Organized by the Medical Publishing Insights and Practices (MPIP) Initiative

Speakers

Robert Edwin Enck, Editor-in-Chief, The American Journal of Hospice and Palliative Medicine

Trish Groves, Deputy Editor, BMJ

LaVerne Mooney, Director, Publications Management, Pfizer Inc

Ann Murphy, Managing Editor, The Oncologist

Panelists

Leighton Chipperfield, Executive Publisher, Global Medical Research Journals, Elsevier Health Sciences

Juli Clark, Director, Global Medical Writing, Amgen

John Gonzalez, Global Skills Leader—Publications, AstraZeneca

Jay Magrann, Publisher, Current Medical Research and Opinion

Bernadette Mansi, Scientific Communications Strategy Head, CVM, GlaxoSmithKline

Phil Watson, Editor-in-Chief, Clinical Therapeutics

Session Moderator: Al Weigel, ISMPP Immediate Past-president 2010–2011

WEDNESDAY, APRIL 21, 2010 (CONT'D.)

At this year's roundtable, top editors and publishers will discuss the most pressing challenges to transparent and effective manuscript submission and how to overcome them. The session will feature the roll out of an authors' guide to submission "best practices," developed by a joint journal-industry working group organized by the MPIP Initiative. You'll be able to leave this session with valuable hands-on information that will be of significant help in your day-to-day professional activities.

1:20-1:30 PM

Closing Remarks and the Future Ahead

Julia Ralston

1:30-2:00 PM

Box Lunch for Workshop Participants

2:00-3:30 PM

Workshops II

3:30-4:00 PM

Afternoon Break

4:00-5:30 PM

Continuation of Workshops II

5:30 PM

Conference Adjourns

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 this faculty do not necessarily reflect those of the companies they represent, or the International Society for Medical Publication Professionals.

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