MAPPING SUCCESS:
NEW RULES OF THE ROAD FOR MEDICAL PUBLICATIONS

THE 4TH ANNUAL MEETING OF ISMPP

APRIL 28 – 30, 2008
SHERATON PHILADELPHIA CITY CENTER HOTEL
PHILADELPHIA, PA

ISMPP International Society for Medical Publication Professionals

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DEAR COLLEAGUES:

On behalf of the International Society for Medical Publication Professionals (ISMPP), we are pleased to invite you to attend the 4th Annual Meeting of ISMPP. It is hard to believe that in only three short years, ISMPP has grown to more than 600 members from diverse backgrounds such as the pharmaceutical, biotech, and device industries, medical communications and publication planning agencies, medical writers, journal editors, and medical publishers.

With all of the change that's going on around us, the world of medical publishing is becoming ever more complex. As the field continues to develop and grow, so do both the number of stakeholders across multiple disciplines and the technology that supports us. Increasing complexity requires more solutions, coupled with clear direction on how to best integrate them into our daily professional lives. This year's Annual Meeting—Mapping Success: New Rules of the Road for Medical Publications—will focus on many of the recent changes, and provide us with insights and perspectives that will help us all succeed as medical publication professionals.

The meeting presentations are divided into four key topic segments: Clinical Trial Registries and Results: Recent Changes and Their Impact; Technology Advances Affecting Publication Professionals; Global Publication Planning: Does One Size Fit All?, and Point/Counterpoint: The Journal Editors Speak. As many of our members have requested, all sessions will have extended Q&A/panel discussions, plus the added benefit of an interactive audience response system—an exciting opportunity to capture live audience feedback from your peers! We have some great speakers from academia, industry, and prominent medical journals, as well as "tech gurus" to make this a memorable conference.

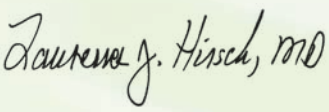
In addition, this year's program will once again feature full-day workshops, designed specifically to allow significant hands-on, case-based learning that can be applied to our day-to-day practice. In response to overwhelming demand from our members, Publication 101/201, Publication 301, and Life of a Manuscript have become workshop staples for ISMPP. Two new workshop topics this year are The Principles of Evidence-Based Medicine and Research Reporting Guidelines. Reminder: all workshops are filled on a first-come first-served basis, and each has room for a maximum of 40 attendees. Don't delay signing up if you're interested!

Member posters will be available for viewing throughout the course of the meeting in the main presentation hall, and on Wednesday morning, you will have a chance to review the posters and ask questions of the presenters during our special "Poster Showcase Breakfast." 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 experience the exhibits and not miss any of the workshops, presentations, and other networking opportunities. We also hope you will join us for the annual ISMPP business meeting on Tuesday, when we will enlighten you on all of the current activities of the Society.

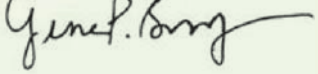
As is our tradition, we will open the meeting with our Sunday evening Welcome Reception, and we have plans to once again enjoy the food and ambiance of Bookbinders at our now-famous Tuesday Evening Networking Reception.

As much as things change, there is one thing for ISMPP that remains the same—the importance of you, our members. On behalf of ISMPP, we'd like to thank you for your support of our organization. We look forward to seeing you in Philadelphia!

Sincerely,



Laurence Hirsch, MD
President



Gene P. Snyder
President-Elect and 2008 Program Chair

SUNDAY, APRIL 27, 2008

Afternoon–Registration

7:00 PM	Welcome Reception

For those who want to "check-in" when they check-in, come and join the ISMPP Board of Directors in the Horizons Rooftop Ballroom for cocktails and hors d'oeuvres before retiring for the night. The view alone is worth the trip!

MONDAY, APRIL 28, 2008

Day's Schedule for All Workshops:

8:00 AM	Continental Breakfast
9:00 AM	Program Begins
10:30 AM	30-Minute Networking and Refreshment Break
12:00–12:45 PM or 12:45–1:30 PM*	Luncheon for Workshop Participants
12:45–1:30 PM	Workshops Resume
3:30 PM	30-Minute Networking and Refreshment Break
5:00 PM	Workshops Conclude

WORKSHOP SELECTIONS

Publication Planning 101/201

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

This full-day workshop provides attendees with an interactive and instructive introduction to strategic publication planning. The workshop includes didactic presentations by leaders in the publication planning field, as well as interactive exercises and group discussions tailored toward newly appointed publication planners in the pharmaceutical/biotech industry or in communications agencies; experienced publication planners with responsibilities for training and mentoring; publication planning support staff; professional medical writers and editors; journal editors; and, allied members of a publication planning team (eg, regulatory, legal, medical, and marketing functions).

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
- Gain insights into journal selection and publishers' perspectives
- Understand ethical publication planning activities, policies, and guidelines
- Appreciate the importance and benefits of a collaborative team environment
- Define and assess measures of success

Workshop Facilitators

Joe Brown, Director
Envision Technology Solutions

Chris Brune, MLS
Knowledge Manager, Information Services, Churchill Communications

Jeffrey E. Fletcher, PhD
Senior Clinical Publications Lead, AstraZeneca

Terri Greenley
Business Unit Group Director, Complete Healthcare Communications, Inc

Jeremy Hayes
CEO, Adelphi Inc

Erica Johansson-Neil
Senior Director, Quest MedEd

Donna Simcoe
Clinical Publication Lead, AstraZeneca

*Luncheon is staggered between programs

WORKSHOP SELECTIONS

Publication Planning 301: Building a Strategy to Guide your Plan

This highly interactive full-day workshop is designed for publication professionals with at least 3 years' experience.

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.

At this end of this workshop, attendees will

- Understand the role of strategy in publication planning
- Understand key building blocks and components of a publication strategy
- Be able to interface between the brand, clinical, and publication strategies
- 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 tactical plan

Workshop Facilitators

Tim Bacon
President & CEO, PeerView, Inc

Richard F Lamb
President, Complete Publication Solutions, LLC

The Life of a Manuscript: From Initial Concept to Publication (and Beyond)

This full-day interactive workshop is intended for new publication planners in pharma/biotech/medical device industries or in communications agencies; seasoned publication planners with responsibilities for training and mentoring medical writers and medical editors; journal editors and allied members of a publication planning team (e.g., regulatory, legal, medical, and marketing functions).

The course is broken into 2 distinct areas of exploration:

1. Getting it Written: Types of manuscripts and considerations specific to each; logistics (e.g., who will write it, 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 time lines for each step.

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

At the end of this workshop, attendees will

- Understand 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
- Increase their knowledge of medical publishing, which will enable them to more successfully prepare, submit, and publish their manuscripts

Workshop Facilitators

Chris Graf
Publisher, *International Journal of Clinical Practice*, Wiley-Blackwell

Richard McCabe
Vice President, MHCC

Gordon Muir-Jones
Executive Vice President, Oxford PharmaGenesis Inc

Mark Pollack
Editor-in-Chief, CNS Neuroscience & Therapeutics, Director, Center for Anxiety & Traumatic Stress Disorders, Massachusetts General Hospital, and Professor of Psychiatry, Harvard Medical School

William Stark, PhD
Senior Manager, Global Medical Writing, Amgen

C. Michael Stein, MD
Editor-in-Chief of *Archives of Drug Information*

Amy Walencik
Senior Publications Manager, Organon, a part of Schering-Plough Corporation

WORKSHOP SELECTIONS

Introduction to the Principles of Evidence-Based Medicine (EBM)

This half-day workshop is intended for all publication planning professionals with an interest in evidence-based medicine. It is combined with the afternoon workshop on research reporting guidelines. If you select this program, please note that you will be registered for the afternoon as well.

This workshop will begin by defining EBM in its historical context. Workshop leaders will then lead an interactive session to review the study designs used in clinical research, describe how these designs are used to address various types of clinical questions, and explain how these designs contribute to the evolution of the evidence base that leads up to and beyond approval by the US Food and Drug Administration (FDA). Workshop leaders will also introduce frameworks used to incorporate published evidence into medical decision making. The workshop will end with a note on the current challenges in EBM and a review of the best EBM resources available.

At the end of this workshop, participants will be able to

- Define evidence-based medicine
- Define the major study designs used in clinical research
- Describe which study designs can best answer a given clinical question
- Describe where in the regulatory processes of the FDA particular study designs are used
- List 1 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, Director, 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, Associate Scholar, Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania

Research Reporting Guidelines

This half-day workshop is intended for all publication planning professionals with an interest in the current and evolving reporting standards and guidelines as they pertain to the publication of medical research. It is combined with the morning workshop on EBM. If selecting this program, please note you will be registered for the morning as well.

Transparent and accurate reporting of research findings is a necessary component of good research practice. Sound knowledge of the principles of high-quality reporting of various types of health research is crucial for professionals involved in the publication of medical research. This workshop will provide an intensive overview of major scientific and ethical issues relating to the quality of health research reporting. The key reporting guidelines, as well as examples of good and bad research reports, will be discussed. Participants will be alerted to the new initiative the EQUATOR Network, which provides resources and training for the facilitation of research reporting. New knowledge acquired during this workshop should benefit professionals in various positions associated with publishing of medical research.

At the end of the workshop participants will

- Understand the importance of transparency and accuracy in reporting health research and be familiar with common deficiencies in reporting of randomized controlled trials (RCTs), meta-analyses, and observational studies
- Understand the key concepts of reporting guidelines and their efficient use by different professional groups (researchers, medical writers and publication professionals, editors, and publishers)
- Learn about the main elements of the selected reporting guidelines: CONSORT Statement (reporting RCTs); QUOROM Statement (reporting meta-analyses of RCTs) and STROBE (reporting epidemiologic studies)
- Understand and efficiently use the EQUATOR Network Internet-based resource center and training program

Workshop Facilitators

Professor Douglas G. Altman
Centre for Statistics in Medicine, University of Oxford, UK

Dr John Hoey
Queen's University, Kingston, Ontario, Canada

Dr Iveta Simera
Centre for Statistics in Medicine, University of Oxford, UK

TUESDAY, APRIL 29, 2008

7:15 AM **Standards & Best Practices Committee Round Table Breakfast**

8:00 AM **Opening remarks**
Gene P. Snyder, Program Co-Chair

8:15–9:00 AM **Keynote Presentation: The Changing Academic Landscape**

Robert Califf, MD
Vice Chancellor, Clinical Research and Professor of Medicine, Division of Cardiology, Duke University

This presentation will center on the changing academic landscape with regard to the relationship between academia and the pharmaceutical and device industries: Friends or foes? These two stakeholders face many forces pulling them together and pushing them apart; however, each must understand the importance of greater collaboration with the other to meet the challenges of developing and delivering better treatments to patients.

9:00 AM–1:00 PM **Clinical Trials Registries and Results: Recent Changes and Their Impact**
Session Moderator: **Laurence Hirsch, MD**

The pharmaceutical industry has been under constant pressure to disclose a wide variety of clinical trial information through not only the registration of trials on a public web site but also the posting of trial results. To date, many companies have either created their own company web sites to disclose clinical trial information or are participating in established registries or results databases, or both, to meet the data transparency requirements. With the recent passing of the FDA Amendments Act (FDAAA), legal requirements have added increased dimension–including shortened disclosure timelines as well as significant penalties for failure to comply. This session will discuss the immediate impact of this legislation as it affects publication planning and publication/ dissemination of clinical trial results.

9:00 AM **World Health Organization: Mapping Global Clinical Trial Transparency Today and in the Future**
Jesse Berlin, ScD, Vice President, Pharmacoepidemiology, Johnson & Johnson PRD
Member of the WHO Clinical Trial Registry Platform Working Group

9:25 AM **US Clinical Trial Registration and Results: Regulatory Update and Global Activity**
Rebecca J. Williams, PharmD, Assistant Director, ClinicalTrials.gov

9:45 AM **Interpreting and Understanding FDAAA and the Impact on Publication Planning**
Scott Lassman, Esq, Partner, WilmerHale
Former General Counsel, FDA

10:10–10:40 AM **Refreshment and Networking Break**

10:40 AM **FDAAA: Implications of Mandatory Transparency Rules in Publication Planning**
David Dorsey, JD (Senator Edward Kennedy's Office)
Senior Fellow, Senate Committee on Health, Education, Labor and Pensions, US Senate

11:10 AM **There's Transparency and Then There's Transparency … How Much More Can We Do?**
Alan Goldhammer, PhD, Associate Vice President, Regulatory Affairs, PhRMA

11:30 AM **What is the Right Road to Take: Mapping Transparency**
John Kamp, PhD, Executive Director, Coalition for Healthcare Communication

12:00 PM **Panel Discussion**

12:30–1:30 PM **Lunch for all attendees and exhibitors**

1:30–1:45 PM **Special Presentation**
Science Journal Editors' Views on Publication Ethics: Results of an International Survey
Chris Graf, Publisher, *International Journal of Clinical Practice*, Wiley-Blackwell

1:45 PM **Annual ISMPP Business Meeting**

2:15–3:25 PM **Technology Advances Affecting Publication Professionals***
Session Moderator: **Peter Hunter Johnston**

Extraordinary advances in technology are affecting us all in countless areas of our daily life, and publication professionals are not immune from evolving innovative technologies. This session will provide an opportunity for ISMPP members to peek inside, to see how technology may affect their work. The focus will be relevant and practical, and provide some key insights into what is happening now and in the near future. Attendees will walk away with a clear answer to the question, "how can technology help me do my job better now?"

2:20 PM **Collaborative Authorship and Review**
David Cornwell, CEO, PleaseTech

2:45 PM **Knowledge Management Technology**
Moish Tov, Chairman and CEO, Skila

3:10 PM **Plagiarism Detection Software and the Crossref Project**
Robert Creutz, General Manager, iParadigms, LLC

3:40–4:10 PM **Refreshment and Networking Break**

4:10 PM **Google Scholar**
Darcy J. Dapra, Strategic Partner Manager, Google, Inc.

4:35 PM **The New England Journal of Medicine**
Edward W. Campion, MD, Sr. Deputy Editor and Online Editor, *The New England Journal of Medicine*

5:00 PM **Changes in Literature Retrieval**
Bonnie Snow, Research Director, Clinical Content and Applications, Pharmaceutical and Chemical, Markets, Thomson Scientific

5:25–5:30 PM **Closing Remarks/Day's Adjournment**

*Audience questions will be taken after each presentation

Annual Networking Reception

Exit the Sheraton Philadelphia City Center, hop on the trolleys waiting outside the hotel, and join your fellow friends and colleagues for an enjoyable start to your evening at Old Bookbinders. Come hungry and thirsty… leave relaxed. It's a perfect excuse to ignore your E-mail, mobile phones, and PDAs just a bit longer!

ISMPP would like to thank Complete Healthcare Communications for their generous support of the evening's reception and continued support of the Society as a whole.

CHC
Complete Healthcare Communications, Inc.

WEDNESDAY, APRIL 30, 2008

7:15–8:00 AM **Annual ISMPP Member Poster Showcase Breakfast**

This special breakfast session is an opportunity to view the poster presentations of your colleagues, selected via the blinded abstract review process instituted last year. Poster presenters will be stationed at their posters for discussion and to answer questions. Support your colleagues by browsing the ISMPP member posters!

ISMPP would like to thank Watermeadow Medical for their generous support of this breakfast.

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8:00 AM **Keynote Presentation:**
The Changing Pharmaceutical Industry

P. Roy Vagelos, MD
Chairman, Regeneron Pharmaceuticals
Chairman, Theravance, Inc
Former Chairman and CEO, Merck & Co. Inc

9:05 AM Opening Remarks/Day One Recap
Gene P. Snyder

9:15–11:45 AM **Global Publication Planning: Does One Size Fit All?**
Session Moderator: **Kim Pepitone**

Publication planning in a pharmaceutical company is sometimes managed by a single group responsible for creating and executing an integrated global plan. Frequently, however, multiple groups manage separate plans by geographic region. Factors that influence how a plan is devised and managed include the location of the headquarters, the company, franchise or brand approach to publication of clinical trial results, where the product development and clinical trials are conducted, and the range of different launch timings around the world. With the scientific literature being instantly available anywhere in the world, can there be such a thing as a regional publication plan? But can a global plan developed in a headquarters office meet the needs of local operating companies around the world? This session will help the audience understand the key challenges—and potential solutions—to deliver effective global publication planning and execution by looking in detail at 3 of the world's largest markets—the United States, Europe, and Asia-Pacific.

9:15 AM **Overview**
Julia Ralston, RPh, President and CEO, MedErgy

9:30 AM **European Publication Planning:**
Translating Global Fundamentals into European Practices
Stephen Jones, VP,
Medical & Scientific Services, ACUMED

9:50 AM **Global Publication Planning:**
US-based Company Perspective
Larry Kovalick, PharmD, Director,
Global Medical Writing, Amgen, Inc.

10:10–10:40 AM **Refreshment and Networking Break**

10:40 AM **Global Publication Planning—Does One Size Fit *Asia?***
Steve Fermer, Vice President - Asia, Adelphi Group

11:00 AM **Panel Discussion and Audience Q&A**

11:30 AM–1:45 PM **ISMPP Member Abstract Presentations**
Session Moderator: **Richard Lamb**

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 in professional medical publication planning.

11:30 AM **Can a Data Dissemination Plan Be Both Ethical and Effective? The Results of a Survey of Medical Publication Professionals**
Frank J. Rodino, MHS, PA, Churchill Communications

11:45 AM **Effective Implementation of Good Publication Practice**
Russell Traynor, Envision Pharma Limited, Horsham, UK

12:00 PM **Evidence-Based Medicine: Too Much Evidence?**
Keith Evans, WoltersKluwer

12:15-1:15 PM **Lunch for all attendees and exhibitors**

1:15 PM **Member Abstract Presentations Continue**

1:15 PM **The Metrics of Client-Agency Satisfaction in Medical Publication Planning**
Amy Walencik, Organon,
a part of Schering-Plough Corporation

1:30 PM **The Voice of the Patient: Finally Being Heard?**
Tim Mills, WoltersKluwer

1:45 PM **Using Online Compliance Tests to Enhance Learning**
Angela Cairns, EVP, Medical & Scientific Services,
KnowledgePoint360 Group, Macclesfield, Cheshire, UK

2:00-2:25 PM **Special Presentation: Who Will Champion Integrity?**
William L. Lanier, MD, Editor-in-Chief,
Mayo Clinic Proceedings

2:25–4:10 PM **Point/Counterpoint: The Journal Editors' Speak**
Session Moderator: **Gene P. Snyder**

Come to this engaging and informative session to hear journal editors debate issues that could affect the timely publication of clinical findings. Each attendee will have the opportunity to interact via an audience response system. The moderator will present the distinguished and diverse editorial panel with case studies representing various issues faced in medical publishing. Find out how each editor would react to the given scenario—their answers might surprise you!

The following prestigious journal editors will be on the panel:

- **William L. Lanier, MD,** Editor-in-Chief, *Mayo Clinic Proceedings*
- **Edward (Tad) Campion, MD,** Sr. Deputy Editor and Online Editor, *The New England Journal of Medicine*
- **Arthur M. Feldman, MD, PhD,** Editor-in-Chief, *Clinical and Translational Science*
- **Charon A. Pierson, RN, PhD,** Editor-in-Chief, *Journal of the American Academy for Nurse Practitioners*
- **Brian F. Mandell, MD, PhD,** Editor-in-Chief, *Cleveland Clinic Journal of Medicine*

3:50–4:00 PM **Closing Remarks and the Future Ahead**

2008 ISMPP EXHIBITORS & SPONSORS

Make sure you take the time to visit the exhibitors located in the registration area. ISMPP would like to express their sincere appreciation to the following companies currently exhibiting at or sponsoring this year's Meeting:

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Postgraduate Medicine

See you at the 5th Annual Meeting of ISMPP!
April 20 – 22, 2009
Philadelphia, PA

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

Program Committee

Gene Snyder, Chair
Karen Brimson
Joanne Conaty
Janet Galliera
Kimberley Gertsen
Chris Graf
Peter Hunter Johnston
Richard Lamb
Kim Pepitone
Sadie Whittaker

Workshop Committee

Kim Pepitone, Chair
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