THE 5TH ANNUAL MEETING OF ISMPP

DEFINING PROFESSIONALISM IN MEDICAL PUBLICATIONS: TRANSPARENCY, OBJECTIVITY, AND ETHICS

APRIL 20–22, 2009
SHERATON PHILADELPHIA CITY CENTER HOTEL
PHILADELPHIA, PENNSYLVANIA, USA
DEAR COLLEAGUES:

On behalf of the International Society for Medical Publication Professionals (ISMPP), we are pleased to invite you to attend the 5th Annual Meeting of ISMPP, Defining Professionalism in Medical Publications: Transparency, Objectivity, and Ethics.

This year’s meeting will once again focus on the issues that are most relevant to our profession. We continue to see integrity throughout the entire publication planning process as a critical issue—and we will be addressing this topic through didactic, panel, and workshop sessions throughout the course of the meeting. There is a new meeting format this year allowing for an expanded presentation agenda, in addition to more diverse and shorter workshops—both of which were overwhelmingly requested through member feedback. And don’t forget that workshop attendance is limited to 25 per group, with registration on a first-come, first-served basis.

We will again 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 members’ presentations will certainly follow suit. The ISMPP Business Meeting will be held on Tuesday, where we will share details on all of the current activities of the Society, with special emphasis on some key initiatives that are sure to be of interest to you. There will also be a special ceremony to honor the first group of Certified Medical Publication Planners—the first of your peers to pass the certification examination.

As you peruse the agenda, we ask that you pay special attention to this year’s keynote speakers— Peter Frishauf, founder of Medscape, and Professor Richard Smith, former editor of the BMJ. Each will bring a different and important perspective to the challenges we face in our profession. The sessions that follow are designed to address these challenges, and to identify practical solutions that we can take home and put to work.

Our closing session will feature a panel of journal editors from top-tier scientific journals—a popular segment brought back upon your request. Similar to last year’s closing session, the panel of editors will share their key knowledge and insights regarding our profession, and provide us with information on best practices to continue to maintain the highest standards for scientific publications.

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. We look forward to seeing you in Philadelphia!

Sincerely,

Gene P. Snyder
President
Divisional Lead
UBC-Envision Group

Al Weigel
President-Elect and 2009 Program Chair
Director Medical Publications
Boehringer-Ingelheim Pharmaceuticals
SUNDAY, APRIL 19, 2009

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!

If interested in sponsoring this reception or another event during the meeting, please contact Kim Goldin at +1.914.945.0507 or kgoldin@ismpp.org.

WORKSHOP DESCRIPTIONS

New this year... we’ve heard what you asked for, and are pleased to let you know that all workshops are now a half day in length, and workshops will be conducted both Monday morning and Wednesday afternoon. This schedule will provide an opportunity for you to attend two workshops this year!

WORKSHOP SCHEDULE

<table>
<thead>
<tr>
<th>Monday Morning</th>
<th>Wednesday Afternoon</th>
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<tbody>
<tr>
<td>7:30 AM</td>
<td>12:50–1:20 PM Luncheon for Workshop Participants</td>
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<td>8:30 AM</td>
<td>1:20 PM Program Begins</td>
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<td>10:00 AM</td>
<td>2:50 PM 30-Minute Refreshment Break</td>
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<tr>
<td>10:30 AM–12:00 PM</td>
<td>3:20–4:50 PM Workshops Continue</td>
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<tr>
<td>12:00–1:00 PM</td>
<td>Luncheon for Workshop Participants</td>
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WORKSHOP DESCRIPTIONS

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

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

This 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, publications support staff, publications writers and editors, and allied members of the publications planning team.

At this 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
• Appreciate the importance and benefits of a collaborative team environment

Workshop Facilitators
Molly Connors
Account Director, Complete Healthcare Communications, Inc.

Terri Greenley
Group Account Director, Complete Healthcare Communications, Inc.

Jeremy Hayes
CEO, Adelphi Eden Health Communications

Donna Simcoe, MS
Sr. Clinical Publications Lead, Medical Communications, AstraZeneca

Pub Planning 201 (Monday/Wednesday)
Metrics and Ethics: Optimizing Your Publication Process in the Age of Transparency

This workshop is appropriate for those with 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 interactive session is designed to cover publication metrics and measures of success as well as best practices to achieve these goals. These practices should be consistent with recognized publication policies and guidelines; adherence to these standards can promote greater efficiency in achieving publication goals.

At the end of this workshop, attendees will be able to:
• Define metrics and measures of success
• Understand ethical publication practices, policies, and guidelines
• Identify best practices in achieving publication goals (e.g., journal selection, author interaction)
• Understand how transparency enhances efficiency

Workshop Facilitators
Juliana Clark, PharmD
Director, Global Medical Writing, Amgen

Bill Ferrell
Account Director, Complete Healthcare Communications, Inc.

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

Kimberley A. Gertsen
Account Director, Peloton Advantage

Kelly Reith
Group Medical Director, Complete Healthcare Communications, Inc.

Pub Planning 301 (Monday/Wednesday)
Building a Strategy to Guide Your Plan

This highly interactive half-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
**Pub Planning 401 (Monday/Wednesday)**

*Publication Planning: Case-Based Workshop*

The Publication Planning 401 workshop is an advanced course in strategic and tactical publication planning based around real-world, case-based scenarios. Seasoned publications professionals who participate will tackle real-world publication planning challenges, testing and expanding their current knowledge of ethical practices through small working groups and discussion sessions. This 401 workshop is aimed at publication professionals with at least 5 years of publication planning experience.

At the end of this workshop, attendees will be able to:

- Better understand current standards of ethics in publications planning and implementation
- Apply sound, ethical publications 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 Snyder  
  Divisional Lead, UBC-Envision Group  
  Current President, ISMPP
- Russell Traynor  
  Strategic Business Unit Head, UBC-Envision Group
- Michael Wittke  
  Senior Manager, Health Policy and Planning, Medtronic Inc.

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**Life of a Manuscript (Monday only)**

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

This half-day workshop is intended for mid-level (3+ years’ experience) in publication planning 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 will be a highly interactive blend of presentations, case studies, and discussions among faculty and participants. To this aim, registrants will be invited to submit two slides outlining their own real-life case studies prior to the workshop. Selected case studies will be reviewed and discussed by the group.

The course is broken into two 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 timelines 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 reviewer; 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**

- Mark J. Fedele, PhD, MBA  
  US Medical and Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation
- Chris Graf  
  Associate Editorial Director, Wiley-Blackwell  
  Publisher, *International Journal of Clinical Practice*
- Fadia Matouk  
  Business Development Director, Wiley-Blackwell
- Gordon Muir-Jones  
  Executive Vice President, Oxford PharmaGenesis, Inc.
- Charon A. Pierson, PhD, GNP, BC, FAAN  
  Editor-in-Chief, *Journal of the American Academy of Nurse Practitioners*  
  Director, Center for Aging, School of Nursing, University of Texas at El Paso
Evidence-Based Medicine (Monday only)

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 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.

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

• Define evidence-based medicine and the four steps to practicing it
• Describe a framework for asking clinical questions
• Describe 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
• Describe a framework used to incorporate published evidence into medical decision making

Gap Analysis (Monday/Wednesday)

The Joy of Gap Analysis

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, considerations of appropriate source material, assessment of the findings, and discussions of 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.

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
• Identify the potential ways that a gap analysis can go astray
• Describe how to use the information learned from the gap analysis

Workshop Facilitators

Craig A. Umscheid, MD, MSCE
Assistant Professor of Medicine
Co-Director, Center for Evidence-based Practice
Co-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

Thomas Gegeny, MS, ELS
Team Lead, Envision Scientific Solutions

Paul O’Grady, PhD
Associate Director, Specialty Care Publications, Global Medical Information
Schering-Plough
Global Pub Planning (Monday only)
Issues and Challenges in Global Publication Planning

This half-day interactive workshop based on a series of real-life scenarios is designed 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 is fraught with everyday challenges. These challenges are increased when working with multiple regions, sometimes with partner companies, and often with different needs with regard to the timing of publications or the requirement 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 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 that will allow their cases to be discussed without disclosing confidential information.

At the end of this workshop, attendees will:

- Identify guidelines and considerations affecting publications in major world markets
- Identify stakeholders of global publication plans
- Understand the issues affecting global publication planning and tactical execution
- Understand how best to plan globally with partner biopharm companies
- Confidently approach the challenges of working with multiple regions and different regulatory situations

Workshop Facilitators
Sarah Bartlett
Global Head of Editorial and Scientific Services, Complete Medical Communications
John Gonzalez
Global Skills Lead, Publications, AstraZeneca
Tom Grant
Publications Director, AstraZeneca
Jane Nunn
Global Head of Editorial and Scientific Services, Complete HealthVizion

CMPP Review Course (Monday/Wednesday)
CMPP Exam Preparation Review Course

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.

After completing this workshop, participants should:

- Understand the appropriate application of guidelines in determining authorship of scientific/medical publications
- Understand the different roles and responsibilities of various members of a cross-functional publication group and what may be appropriate or inappropriate input by the different constituencies during the development of scientific/medical content
- Recognize and avoid questionable practices associated with developing publication plan tactics and strategy

Workshop Facilitators
Angela Cairns
Senior Vice President, Medical and Scientific Services, KnowledgePoint360 Group
Errol Gould, PhD
Director, Medical Affairs, Endo Pharmaceuticals, Inc.
Rob Matheis, PhD
President, Credentialing Board of Trustees (Interim) Publications Manager, sanofi-aventis
Kim Pepitone
Director of Certification and Professional Development, ISMPP Scientific and Editorial Director, PHOCUS Inc.
Kevin Ryder
Group Medical Director, Complete Healthcare Communications, Inc.
Suzann Schiller
Group Director, Client Services, Apothecom Associates, LLC
Mike Smith
Executive Vice President, PHOCUS, Inc.
MONDAY, APRIL 20, 2009

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

12:00–1:00 PM
Lunch for Workshop Attendees, Speakers, and Exhibitors

1:00–1:15 PM
Welcome to ISMPP '09
Kim Goldin, Executive Director, ISMPP
Gene P. Snyder, President, ISMPP

1:15–2:15 PM
New Business Models for Medical Publishers
Peter Frishauf, Founder of Medscape
Made possible by an educational grant from Abbott

2:15–3:30 PM
Good Publication Practice: A Historical Perspective
Betts Field, Field Advantage Medical Communications
Elizabeth Wager, Publications Consultant

GPP2 Update and Highlights
Chris Graf, Associate Editorial Director, Wiley-Blackwell and Publisher, International Journal of Clinical Practice

3:30–4:00 PM
Afternoon Break and Visit Exhibits

4:00–4:50 PM
How Do You Describe Your Profession?
Roundtable of Past Presidents and Founders
Session Moderator: Al Weigel, Director, Medical Publications, Boehringer-Ingelheim Pharmaceuticals

Panelists
Tim Bacon, President and CEO, PeerView, Inc.
Richard F. Lamb, President, Complete Publications Solutions
Robert Norris, President, Complete Healthcare Communications, Inc.
Gene P. Snyder, Divisional Lead, UBC-Envision Group

4:50–5:20 PM
Panel-Directed Questions and Q&A from the Audience

5:20–5:25 PM
Closing Remarks

TUESDAY, APRIL 21, 2009

7:00–8:00 AM
Annual ISMPP Member Poster Showcase and Continental Breakfast

This special breakfast session is an opportunity to view the poster presentations of your colleagues—selected via the blinded abstract review process. Support your colleagues by browsing the ISMPP member posters!

8:00–8:10 AM
Opening Remarks
Gene P. Snyder

8:10–10:50 AM
ISMPP Member Abstract Presentations
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 in professional medical publication planning.

8:10 AM Review of Online Publication Policies: Pharmaceutical Companies and Medical Colleges
Donna Simcoe, AstraZeneca

8:25 AM Benchmarking Medical Publication Policies, Procedures, and Practices Across Pharmaceutical Companies
Nicholas Combates, PhD, sanofi-aventis

8:40 AM Clinical Trial Data Disclosure: Impact on Publication Policies and Disposition
Ed Paluch, Complete Healthcare Communications, Inc.

8:55 AM The Role of Medical Publications in Determining Access, Coverage, and Reimbursement Policy for Health Plans
John Draper, Peloton Advantage

9:10 AM Observations on Shifting Preferences for Planning, Writing, and Management of Scientific Publications
Christina Rogers, PhD, RPS, Inc.

9:25–10:00 AM Morning Break and Visit Exhibits

10:00–10:45 AM Continuation of Member Abstract Presentations

10:00 AM Development of Clinically Impactful, Scientifically Relevant and Wholly Transparent Academic Publications: An 8-Step, Best-Practices Approach to Quality and Compliance
Henry Singer, Clinical Connexion

10:15 AM Beliefs of US KOLs Regarding Professionalism in Pharmaceutical Company-Sponsored Medical Publications
Jennifer Rubio-Flood, Advanced Clinical Concepts

10:30 AM When the Door Is Closed: An Observational Study of Medical Journal Dispositions Regarding Industry Contributions
Jeff Frimpter, sanofi-aventis
As the world gets smaller, pharmaceutical companies are getting larger—enfolding many of the smaller biotech companies within their borders or forming ‘megacompanies’—all through mergers and acquisitions. How publication groups merge when these transactions occur differs depending on a number of factors—including geography, size and scope, and operational culture. This segment will provide an opportunity to hear about some recent mergers, and their effect on the publication planning teams.

Authorship remains one of the most important areas for medical publication professionals. A roundtable panel of key subject matter experts will come together to share their opinions, and answer your questions, about criteria for authorship, the definition of significant contribution, the relationship between industry and authors, the role of medical writers, and other key issues. Their insights will help us all to better navigate this ‘hot’ arena.
WEDNESDAY, APRIL 22, 2009

7:00–8:00 AM
Committee Members Meet-and-Greet Breakfast

8:00–8:10 AM
Opening Remarks, Recap of Days 1–2, Overview of Day 3
Al Weigel, President, ISMPP

8:10–9:10 AM
Keynote: The Future of Scientific Communication
Professor Richard Smith
Former Editor of the BMJ

9:10–10:10 AM
Global Standards
Session Moderator: Elizabeth Wager, Publications Consultant
Francis P. Crawley, Executive Director, Good Clinical Practice Alliance – Europe (GCPA)

The world keeps getting smaller, the time lines tighter, and the rules remain more confusing than ever. Despite our globalization, there remain differences in process and culture between the US and the EU, especially when it comes to drug approvals and publication of clinical trial results. Hear what the experts are saying about the following:

• What are the most important key differences between information needed for EU versus US product approval and reimbursement?
• How do approvals differ between EMEA and individual countries?
• What is the role of NICE?
• Are there best practices around guidelines that publication managers should know/follow?
• What guidance can be offered in terms of working with sponsors and/or authors?

10:10–10:40 AM
Morning Break and Visit Exhibits

10:40–11:10 AM
Medical Publishing Insights and Practices (MPIP) Initiative
Frank S. David, MD, PhD, Leerink Swann Strategic Advisors

ISMPP was invited to participate in a research project, spearheaded by GSK and supported by other pharmaceutical companies, to help us all better understand the journal process from the editors’ perspective. Join us as we hear results from this research, and what it may mean to us as publication professionals.

11:10 AM–12:40 PM
Journal Editor Panel
Session Moderator: Al Weigel
Peter Frishauf, Founder of Medscape
Melissa Norton, MD, Editor-in-Chief, BMC series
Anil K. Rustgi, MD, Editor, Gastroenterology
Professor Richard Smith, Former Editor of the BMJ
Harold C. Sox, MD, MACP, Editor, Annals of Internal Medicine
Maja Zecevic, PhD, MPH, North American Senior Editor, The Lancet

Once again, we close our annual meeting with a roundtable panel of top-tier journal editors who will be addressing the key issues/concerns that we are dealing with at this juncture in medical publication planning. Be prepared to hear some new and startling information as this group of editors helps us distinguish fiction from fact in this ever-changing environment.

12:40–12:50 PM
Closing Remarks and the Future Ahead

12:50–1:20 PM
Box Lunch

1:20–2:50 PM
Workshops II

2:50–3:20 PM
Afternoon Break and Visit Exhibits

3:20–4:50 PM
Continuation of Workshops II

4:50 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.
ISMPP CORPORATE SUPPORTERS

ISMPP wishes to thank the following organizations for their continued support of the Society.

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

Program Committee
Al Weigel, Program Chair
Rick Lamb, Committee Chair
Karen Brimson
Joanne Conaty
Patricia Driver
Maria Engler
Maureen Garrity
Michael Gazeley
Kimberly Gertsen
Chris Graf
Beth Kamp

Abstract Committee
Mike Malia
Beth Ann McGhee
Kristen Mosdell
Ed Paluch
Jenna Steere
Alex Torre-Tasso
Keith Vecitch

Workshop Committee
Greg Giblin, Committee Co-chair
Janet Galliera, Committee Co-chair
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Marion Enie
Susan Glasser
Terri Greenley
Sharon SunTag
Susan Sutch
Greg Thompson
2009 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 and/or sponsoring this year’s Meeting:

- Abbott
- Medscape CME
- RBS
- complete healthcare solutions
- Complete Medical Communications
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- Thomson Reuters
- UBC envision group
- BIOMETRIC INC
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See you at the 6th Annual Meeting of ISMPP!

April 19-21, 2010
The Marriott Crystal Gateway
Arlington, Virginia, USA