



Ensuring Integrity in  
Medical Publications:  
*Conflicts, Credibility  
& Collaboration*

3rd Annual Meeting of ISMPP

April 23 – 25, 2007

The Sheraton Philadelphia City Center  
Philadelphia, PA

## Dear Colleagues:

On behalf of the International Society for Medical Publication Professionals (ISMPP), we are pleased to invite you to attend the 3<sup>rd</sup> Annual ISMPP Meeting, April 23-25, 2007, in Philadelphia at the Sheraton Philadelphia City Center Hotel. As many of you know, ISMPP was founded a little less than two years ago to serve the educational and networking needs of those in medical publication planning and development in the pharmaceutical and biotech industries. Our members — now over 450 strong and growing — come from pharmaceutical, biotechnology and device companies, medical education and communication companies, medical writers, and medical journal editors and publishers. We've had two annual meetings with many of the most influential speakers in biomedical publication, and the forthcoming meeting will continue that tradition of excellence, rest assured!

The theme of this year's conference — "Ensuring Integrity in Medical Publication: Conflicts, Credibility, and Collaboration" — could not be more timely. The scrutiny that surrounds the presentation and publication of health care research has grown significantly over the past decade, with great emphasis now being placed on the "quality" and timeliness of communication of clinical trial information. These factors make it ever more important to increase and, yes, defend the credibility of our medical publication practices.

Join us at this year's conference to hear perspectives and to glean answers — with practical application — to many of the pressing issues in the current scientific/medical publications environment. The format of the 2007 Meeting continues our tradition of a two-day General or Plenary Session (April 24-25) and our popular peer-interaction opportunities; in addition, we've expanded meeting activities in response to feedback from you, as outlined below.

Among the topics that will appear on the General Session agenda are:

- Managing conflicting interests and promoting collaboration among industry, agencies, publishers, editors and investigators — all of whom have a key stake in clinical studies and the publication of their findings
- Ensuring transparency among all stakeholders that participate in industry-sponsored studies, while respecting the competitive forces and protection of intellectual property that are key to product development
- Publishing within the legal and regulatory constraints that surround the pharma-biotech industry

In addition, we are proud to feature a choice of four full-day, interactive workshops on Monday, April 23. We will once again offer *Publication Planning 101/201* for those new to the profession, and *Publication Planning 301* for those a bit more seasoned. Two new workshop additions are *The Life of a Manuscript: From Initial Concept to Publication*, a practical dissection of best practices and useful tips on writing, submitting, responding to journal feedback, and (finally) publication of a manuscript, as well as a complementary pair of half-day sessions, *Statistics for Non-Statisticians* and *Publication of Outcomes Research*. All of these workshops will be based on practical information that will help publication professionals like yourselves in your daily activities.

**Please note workshops are limited to 40 attendees each, and will be filled on a first-come, first-served basis.**

We've also added two new features of special interest this year:

- Oral presentations based on abstracts submitted by your peers, and selected by the ISMPP abstract peer-review committee
- A Round Table Breakfast, featuring key topics that you will be able to debate with your peers on the morning of the final day of the conference

Publishers' Row will once again be part of the annual meeting, as will an extensive Exhibit Hall, Poster Presentations by your peers, a special Tuesday evening networking reception at the Franklin Institute, followed by a private tour of the acclaimed King Tut Exhibit, and the Annual ISMPP Business Meeting, where you will learn about the progress the Society has made during the course of this past year as well as get a glimpse of our exciting future plans.

We're very pleased with the progress and growth our burgeoning society has made over these past two years. We look forward to seeing you at the 2007 meeting, April 23-25, in Philadelphia.

Sincerely,



Robert Norris  
President



Laurence Hirsch, MD  
President-Elect & 2007 Program Chair

## 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!



*ISMPP would like to thank Merck & Co. for its generous support of the evening's reception and continued support of the Society as a whole.*

## Day's Schedule:

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

## Choose from 4 Full-Day, Interactive Workshops

### Publication Planning 101 / 201

This full-day workshop provides attendees with an interactive and instructive introduction to the world of strategic publication planning. It is 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 (e.g. regulatory, legal, medical and marketing functions).

The learning objectives are to:

- 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
- Identify & understand the needs of internal & external stakeholders
- Define and assess measures of success

The workshop includes didactic presentations by leaders in the publication planning field, as well as interactive exercises and group discussions focused around key issues.

#### Workshop Facilitators

##### Chris Brune, MLS

Knowledge Manager, Information Services  
CHURCHILL COMMUNICATIONS

##### Daniel Donovan

Principal  
ENVISION PHARMA

##### Elizabeth (Betts) Field, PhD

Manager/Member  
FIELD ADVANTAGE MEDICAL COMMUNICATIONS

##### Jeffrey E Fletcher, PhD

Senior Clinical Publications Lead  
ASTRAZENECA

##### Jeremy Hayes

CEO  
ADELPHI INC

##### Erica Johansson-Neil

Managing Partner  
P-VALUE COMMUNICATIONS

##### Gary McQuarrie, PharmD, MBA

President & CEO  
SCIENTIFIC CONNEXIONS

##### Andrew Robinson

Global Director of Medical Publishing  
BLACKWELL PUBLISHING

### Publication Planning 301

#### Developing a Strategic Publication Plan

This workshop provides attendees with an opportunity to develop a strategic publication plan for a particular brand.

**It is tailored toward individuals who have either attended a previous publication planning conference, or who have more than three years of publication planning experience.**

The learning objectives are to:

- Identify all the major components of a strategic publication plan
- Gain experience formulating publication objectives and scientific communications
- Identify appropriate targets (journals and congresses) for data dissemination
- Discuss in detail the planning of data roll-out over time
- Evaluate the importance of impact and timing as they relate to publication and presentation
- Review the scientific literature for competitive publications
- Understand the utility of and be able to carry out a gap analysis
- Effectively present key aspects of a publication plan to senior management

Workshop attendees are divided into small working groups and provided with a clinical overview of Drug X (e.g. MOA profile, safety and efficacy summaries, anticipated product profile, clinical plan, launch date, list of competitors, etc). Based on this clinical profile, the groups are asked to formulate a strategic publication plan, and to present it to the larger group at the conclusion of the workshop.

#### Workshop Facilitators

##### Tim Bacon

Immediate Past President  
ISMPP BOARD OF TRUSTEES/  
President  
PEERVIEW

##### Richard F. Lamb

General Manager  
COMPLETE PUBLICATION SOLUTIONS

##### Amy Van Note

Account Director, Product Development & Support  
COMPLETE HEALTHCARE COMMUNICATIONS

##### Lois Wehren, MD

Associate Director, Medical Communications  
MERCK RESEARCH LABORATORIES

## 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 objectives of this course are to examine, understand and appreciate the steps involved in developing a manuscript from initial concept through submission, peer review, publication and beyond. The course is broken into two distinct areas of exploration:

**Getting it Written:** Types of manuscripts and considerations specific to each; logistics (e.g., who will write it, scope of involvement of external authors, etc.); essential components/optional components; internal and external review; appropriate journal selection and submission protocol; and timelines for each step.

**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.

### Workshop Facilitators

#### Chris Graf

Publisher  
INTERNATIONAL JOURNAL OF CLINICAL PRACTICE  
BLACKWELL PUBLISHING

#### Richard McCabe

Vice President  
MENISCUS HEALTH CARE COMMUNICATIONS

#### Gordon Muir-Jones

Executive Vice President  
PHARMAGENESIS INC.

#### William Stark, PhD

Senior Medical Writer, Global Medical Writing  
AMGEN

#### C Michael Stein, MD

Editor, *ARCHIVES OF DRUG INFORMATION*  
Professor of Medicine and Pharmacology  
VANDERBILT MEDICAL SCHOOL

## Simplifying the Process: Statistics for the Non-Statistician and Publishing Pharmacoeconomics and Outcomes Research

This unique course combines two complementary workshops, one in the morning and one in the afternoon, packaged as a full-day program. Both of these areas are critical to the development of sound, scholarly articles, and yet both can be daunting to those who are not experts in either statistics and/or pharmacoeconomics and outcomes research. Please note, the single registration fee covers both sessions.

### Morning Program: 9:00 AM Statistics for the Non-Statistician

Over the past few decades, randomized controlled trials (RCTs) have emerged as the gold standard of clinical evidence upon which to base healthcare treatment decisions. Indeed, data derived from RCTs are considered the foundation for the practice of evidence-based medicine (EBM). RCTs offer the potential to eliminate or substantially reduce several sources of experimental bias that can introduce systematic errors and cloud or distort the veracity of study findings. However to avoid these experimental biases and to ensure veracity, the RCT must be properly designed, planned, and executed.

The overall objectives of this presentation are to discuss key issues pertinent to the proper design of and analysis of data from RCTs and review a number of common pitfalls and overlooked aspects of study design and methodology that can blur interpretation of study findings. With a clear understanding these issues, you, as a writer and reader of medical literature, will be better equipped to critically present and review the results of clinical trials, determine their validity and veracity, and discern the relevance of study findings to patients.

### Workshop Facilitator

#### Desmond Thompson, PhD

Executive Director, Clinical Development Scientific Services  
MERCK RESEARCH LABORATORIES

### Afternoon Program: 1:00 PM Pharmacoeconomics and Outcomes Research

This program includes an overview of outcomes research topics that appear commonly in literature and the methods that are used to conduct and analyze this type of research. This is especially important given today's economic climate, which has imposed greater scrutiny than ever over the cost of drugs. This research plays a significant role in helping to determine the true value of a particular pharmacologic agent by assessing not only the acquisition cost, but also the cost implications of selection of an agent, and the long-term implications of either not treating for a long enough duration or taking the watch-and-wait approach.

Participants will have opportunities to discuss terminology, problems and pitfalls faced when writing outcomes research reports and manuscripts, and journal selection tips. In addition to a didactic presentation, attendees will participate in an interactive exercise on designing and writing outcome studies on topics identified by workshop participants.

### Workshop Facilitators

#### Seema Sonnad, MS, PhD

Associate Professor, Department of Surgery  
Director, Penn-SCORE  
UNIVERSITY OF PENNSYLVANIA

#### Alex Loeb, PhD

Senior Medical Director  
COMPLETE HEALTHCARE COMMUNICATIONS

7:00 AM

**Registration  
Continental Breakfast**

8:00 AM

**President's Address****Robert A. Norris**

President

ISMPP BOARD OF TRUSTEES/

President

COMPLETE HEALTHCARE COMMUNICATIONS

8:05 AM

**KEYNOTE PRESENTATION*****The Crisis of Confidence  
in Clinical Research:  
The Role of the Press*****Robert J. Levine, MD**Professor of Medicine and Pharmacology  
Co-Director, Interdisciplinary Bioethics Center  
Director, Donaghue Initiative in Biomedical  
and Behavioral Research Ethics  
YALE UNIVERSITY SCHOOL OF MEDICINE

Dr. Levine is Professor of Medicine and Lecturer in Pharmacology at Yale University School of Medicine, Director of the Law, Policy and Ethics Core of Yale University's Center for Interdisciplinary Research on AIDS and Co-Director of Yale University's Interdisciplinary Bioethics Center. He is a Fellow of The Hastings Center, the American College of Physicians and the American Association for the Advancement of Science; a member of the American Society for Clinical Investigation and American Society for Pharmacology and Experimental Therapeutics, Past-President of the American Society of Law, Medicine & Ethics, and a Director of PRIM&R (Public Responsibility in Medicine and Research). In the past he was also Chair of the Institutional Review Board at Yale-New Haven Medical Center (1969 - 2000), Chief of the Section of Clinical Pharmacology at Yale, Chair of the Section on Medico-Legal Matters and R&D Administration of the American Society for Clinical Pharmacology and Therapeutics, Associate Editor of *Biochemical Pharmacology* and Editor of *Clinical Research*. Dr. Levine is the founding editor of *IRB: A Review of Human Subjects Research* (Editor 1979 - 2000 and currently Chair of the Editorial Board) and has served as consultant to several federal and international agencies involved in the development of policy for the protection of human subjects. He is the author of numerous publications including the book, *Ethics and Regulation of Clinical Research*. In the last 30 years, most of Dr. Levine's research, teaching and publications have been in the field of medical ethics with particular concentration on the ethics of research involving human subjects.

## ACADEMIC-INDUSTRY RESEARCH AND PUBLICATION: *LEARNING FROM RECENT EXPERIENCE*

This session presents a case study of several of the most significant issues confronting medical publication professionals today. The case study is based on questions of data accuracy and transparency surrounding the paper: Eastell, R, et al. Relationship of early change in bone resorption in the reduction in fracture risk with risedronate, *Journal of Bone and Mineral Research*, 2003;18:1051-6. These questions were raised after publication by Dr. Aubrey Blumsohn, an investigator in the central laboratory at the U. of Sheffield, UK, which performed many of the analyses reported in the published paper, although he was not a co-author. The study (post-registration) was sponsored by the company that manufactures and markets risedronate.

Some of the issues to be highlighted during the session include: an investigator's right to full access to the complete data for the study in which they participate – Can we define "complete data"? Who owns the data and who determines access to the database? How do editors "know" that manuscript authors have had full data access? If the published results of a clinical trial are called into question, how should the investigators, the academic institution, journal editor, journal publisher and sponsoring company respond? Who is responsible for ensuring the accuracy of the scientific record? Are there published guidelines that address these issues?

**Moderator: Laurence Hirsch, MD**  
President-Elect  
ISMPP BOARD OF TRUSTEES/  
Vice President, Medical Affairs  
Diabetes Care  
BECTON DICKINSON

9:00 AM

**Aubrey Blumsohn, MBBCh, PhD, MSc, BSc(hons), MRCPath**  
Laboratory Medicine  
SHEFFIELD TEACHING HOSPITALS, UK

9:30 AM

**John A. Eisman, PhD, MBBS**  
Editor-in-Chief  
*JOURNAL OF BONE & MINERAL RESEARCH*  
Director, Bone & Mineral Research Program  
GARVAN INSTITUTE OF MEDICAL RESEARCH

10:00 AM

*Morning Refreshment Break*

10:30 AM

**Diane Scott-Lichter, CSE**  
Vice President & Publisher, Medical Journals  
BLACKWELL PUBLISHING

11:00 AM

**Philip D. Ross, PhD**  
Senior Director, Medical Communications  
MERCK RESEARCH LABORATORIES

11:20 PM

**Q&A**

Take advantage of this rare assembly of thought-leaders. Be prepared to ask our morning speakers challenging questions regarding their views on the current publication landscape. You just may be surprised at what you will hear!

NOON

**Luncheon**

for All Attendees, Exhibitors and Speakers

1:00 PM

**ISMPP Membership Abstract Podium Presentations**

This session is new to ISMPP. Eight abstracts were selected following blinded review by the Abstract Review Committee based on the significance. An author from each abstract has been invited to present the details of their abstract. Authors have 10-12 minutes each for their presentation followed by a brief Q&A. The format is two concurrent sessions with four presentations each.

**Session I**

Stop the Paper Chase! *Optimizing Review and Approval Processes to Enhance Publication Cycle Times*

Developing an Organizational Publication Policy

Clinical Trial Investigators: *Collaborators or Consultants?*

Impact of Clinical Trial Data Disclosure on Publication Disposition

**Session II**

A Novel Approach to Measuring the ROI of Strategic Communication Planning

Taking an Ethical Standpoint: *Developing the Caudex Medical Authorship & Acknowledgements Policy*

Evaluation and Protection of Business Information During the Preparation of Medical Publications

The Evolving Role of Marketing in Publication Planning

2:00 PM

**Poster Presentations & Afternoon Refreshment Break**

Come and stretch your legs for an extended break to view the abstract poster presentations authored by your peers. Posters will be on display throughout the Meeting in the Exhibit Hall.

3:00 PM

**Moderator:****Peter Hunter Johnston**At-Large  
ISMPP  
BOARD OF TRUSTEES/  
Managing Director  
PEERVIEW EUROPE**PUBLISHING RESEARCH:*****Please Don't Make My Job Any Harder***

The process by which industry-sponsored studies get published is complex and entails collaboration between a number of very separate disciplines. While the discrete groups share some objectives, all too frequently their differing perspectives, priorities and values come to the fore in the development of a publication. The resulting tensions lead to misunderstandings and, overall, just makes everyone's job harder that it is already.

Other sessions during this year's ISMPP conference debate the overarching ethical issues, questions of disclosure and conflict of interest etc. In this session we will take a more practical and down to earth approach. Each speaker is asked to review their role in the process of getting a manuscript (from an industry-sponsored study) published and, in particular, look at what they expect from the other members of the "team" outlined within this presentation, and what it is that the 'other parties' can sometimes do that irritates, annoys, makes things more complicated and difficult. What would they want the other parties to do to make the process easier, less stressful, faster and simpler? The answers may just surprise you!

This session highlights the perspectives of the following disciplines:

Industry: **Jessica Colon**, Global Clinical Communication Leader, NOVARTIS  
 Agency: **Charlie Buckwell**, Chief Executive, COMPLETE MEDICAL GROUP  
 Publisher: **Andrew Robinson**, Director of Medical Publishing, BLACKWELL PUBLISHING  
 Editor: **Hal Sox, MD**, Editor-in-Chief, *ANNALS OF INTERNAL MEDICINE*  
 Investigator: **David H Henry, MD**, PENNSYLVANIA HOSPITAL, PHILADELPHIA

4:45 PM

**Panel Discussion**

Be prepared for an engaging and entertaining exchange between the afternoon panelists, as they field questions from delegates.

5:30 PM

Meeting concludes for the day.

**Annual  
Networking  
Reception****6:00 PM – 8:00 PM**

Join your fellow friends and colleagues for an enjoyable start to your evening down the street from the hotel at **The Franklin Institute**. Come hungry and thirsty... leave relaxed. It's a perfect excuse to ignore your email, mobile phones and PDAs just a bit longer!

And for a special treat, ISMPP invites you to join us for a private tour of the highly acclaimed **King Tut Exhibit** featured at the *Institute*. Entrance to the exhibit begins at 8:00 PM.

If you are interested in sponsoring the cocktail reception, the private tour of the King Tut Exhibit or both, please contact Kimberly Goldin at +1 914 945 0507 or [kgoldin@ismpp.org](mailto:kgoldin@ismpp.org).

7:30 AM

### Round Table Breakfast

Breakfast is the most important meal of the day, and now it is also the most interesting. Come join us and pick a table with a topic of discussion you would like to sink your teeth into. Debate your peers in an informal setting that promises to be most enjoyable.

If you are interested in sponsoring the Round Table Breakfast please contact Kimberly Goldin at +1 914 945 0507 or [kgoldin@ismpp.org](mailto:kgoldin@ismpp.org).

### REGULATORY AND LEGAL PUSH-PULL AND THE IMPACT ON PUBLICATION PLANNING

**Moderator: Kim Pepitone**  
Senior Consultant,  
Medical Communications  
Cottrell & Cottrell  
Consulting  
Vice Chair, ISMPP Program  
Committee

Health care communications by manufacturers and promoters of products and devices are highly regulated. There are various oversight bodies within the government and within pharmaceutical and biotech companies that regulate the “whats” and “hows” of these communications, especially things like on- and off-label promotion and free versus commercial speech. In addition, the recent mandates regarding posting of clinical trial protocols and results have compounded the complexity.

In this session, we will take a close look at what we loosely term the regulatory and legal push-pull, and its impact on publication planning. Each speaker is asked to present the issues (and where possible, answers) on the roles of the various regulatory and legal bodies, and what industry and agencies are doing in order to stay both compliant and successful in this highly regulated and complex arena.

8:25 AM

### KEYNOTE PRESENTATION

#### The Complicated Relationship between the FDA/DDMAC and Industry Regarding Release of Clinical Trial Data and Peer-Reviewed Publications

**Lucy Rose, PA-C, MBA**  
President  
Lucy Rose & Associates  
*former Director*  
DIVISION OF DRUG MARKETING, ADVERTISING & COMMUNICATIONS (DDMAC)  
FDA'S CENTER FOR DRUG EVALUATION & RESEARCH (CDER)

Ms. Rose's combination of education and experience, coupled with her extensive experience as a trainer and educator, provides a unique perspective to our audience. From 1995-97, Ms. Rose served as the Director of the Office of Training and Communications for the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration. There she designed and implemented programs to improve external communications with the pharmaceutical industry, health care professionals, and consumers. Additionally, Ms. Rose led CDER's Division of Drug Marketing, Advertising and Communications (DDMAC) from 1993 to 1995. In this capacity, she was responsible for the regulatory oversight of all prescription drug advertising and marketing to U.S. health care professionals and consumers. Among those challenges encountered during her leadership were the CME (Industry Supported Scientific and Educational Activities) Guidance and Direct to Consumer Broadcast Advertising considerations.

- What role does DDMAC play in review of materials that cover dissemination of clinical trials' information?
- How has the environment changed/evolved over the past several years?
- How will DDMAC balance the need for release of good scientific information to improve/enhance medical practice versus on- and off-label promotion concerns?
- What can we expect moving forward, especially with the recent changes in Congress?

9:15 AM

Ken Berkowitz, Esq  
Regulatory & Public  
Affairs Counsel

## Legal Implications for Publications in Regards to Off-Label Communications & Promotions

- What issues are of the greatest concern regarding on- and off-label promotion in the current regulatory environment?
- What are the legal constraints for pharma for communicating clinical trials' results for non-approved indications?
- Is peer-reviewed publication "protected" by the First Amendment?
- What legal issues are "brewing" regarding activity on the Hill and the pharmaceutical industry's ability to communicate clinical trial information?

9:35 AM

## Q&A

Ms. Rose and Mr. Berkowitz will entertain participants' questions following their presentations.

9:50 AM

*Morning Refreshment Break*

10:20 AM

*Session Continues:*

## REGULATORY AND LEGAL PUSH-PULL AND THE IMPACT ON PUBLICATION PLANNING

### How Industry Is Responding

Joanne Conaty

Senior Director, Medical Communications  
ASTRAZENECA PHARMACEUTICALS

### How Agencies Are Responding

Angela Cairns

Medical & Scientific Services  
THE GARDINER-CALDWELL GROUP

11:00 AM

## Panel Discussion & Debate

Join all speakers from the morning segment as they discuss the similarities and differences in their perspectives regarding their respective areas of expertise. Be prepared to spark the conversation with your own engaging questions and comments.

11:25 AM

## ANNUAL ISMPP MEMBERSHIP BUSINESS MEETING

Join us for the 2<sup>nd</sup> official business meeting of the ISMPP membership. During this time, hear from the ISMPP Board of Trustees on current initiatives and plans for the coming year. Topics include an ISMPP credentialing program, a future ISMPP journal and upcoming educational initiatives.

NOON

Luncheon for All Attendees, Exhibitors and Speakers

1:00 PM

**Gene Snyder, MBA**  
Secretary  
ISMPP BOARD OF  
TRUSTEES/  
Executive Vice President  
LE JACQ

### Stuck Between Scylla and Charybdis: *New Implications of the Ingelfinger Rule*

It's been nearly 40 years since the Ingelfinger Rule was adopted by the *NEJM*, to create an embargo to keep scientific findings out of the media until peer-reviewed and published. It's been nearly three years since the ICMJE member journals began to require registration of clinical trials in a public trials registry as a condition of subsequent consideration for publication; this requirement was part of an effort to increase transparency and ensure integrity. In keeping with this spirit, the pharmaceutical industry then voluntarily committed to publicly disclose the results of sponsored clinical trials regardless of outcome, in free and publicly accessible databases, for any medicine approved for marketing in at least one country. The industry Joint Position Statement recommends companies do this within one year from study completion, unless it would jeopardize peer-reviewed publication. Recently, the state of Maine passed legislation requiring results disclosure within one year of study completion, as a condition for the sale of pharmaceutical products there.

Now comes a potentially unintended consequence. Of late, some journals have rejected papers from consideration for publication "because" the results have been being posted publicly, despite that fact that the "prepublication" is only a summary of efficacy and safety results. Where is the middle ground?

This timely presentation briefly reviews the Ingelfinger Rule, provides real-world examples and case reports related to this newest interpretation, and discusses the Rule's practical application within the framework of the current environment, industry commitments and policies of many journals.

1:40 PM

**Thomas Stossel, MD**  
Professor of Medicine  
HARVARD  
MEDICAL SCHOOL  
Co-Director,  
Hematology Division  
BRIGHAM & WOMEN'S  
HOSPITAL

**Faith McLellan, PhD**  
North American  
Senior Editor  
*THE LANCET*

Speaker TBD

### ENSURING INTEGRITY IN BIOMEDICAL PUBLICATIONS: WHERE ARE WE TODAY? *Where Are We Headed?*

#### Moderator:

**Laurence Hirsch, MD**  
President-Elect  
ISMPP BOARD OF TRUSTEES/  
Vice President, Medical Affairs  
Diabetes Care  
BECTON DICKINSON

As evidenced by the theme of this year's conference, and throughout the presentations on the agenda, key issues that face medical publication professionals are transparency, disclosure and fulfillment of authorship responsibilities in the publication of industry-sponsored research. Can a sponsoring pharmaceutical, biotech or device company be a partner to the study investigators, or is it (and the potential financial conflict of interest) the "elephant in the room"?

This session presents a broad array of perspectives on the current challenges encountered by the medical publication professionals who support the publication of industry-sponsored trials, and seeks to elicit recommendations from our renowned speakers as to what we as "industry" can do to enhance the communication of clinical trial results through their publication, while respecting sponsors' needs to develop their products in a highly competitive environment.

3:00 PM

**Closing Remarks**

**Laurence Hirsch, MD**  
 President-Elect & Program Chair  
 ISMPP BOARD OF TRUSTEES/  
 Vice President, Medical Affairs  
 Diabetes Care  
 BECTON DICKINSON

3:30 PM

Meeting Concludes

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

**Program Committee**

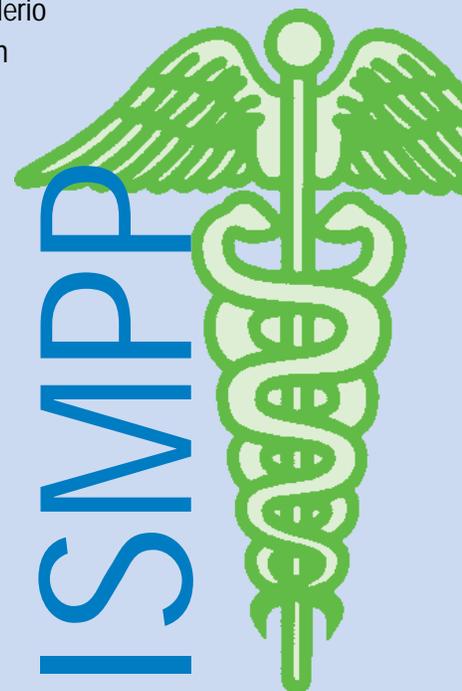
Laurence Hirsch, Chair  
 Kim Pepitone, Vice Chair  
 Carolyn Clark  
 Joanne Conaty  
 Kimberley Gertsen  
 Chris Graf  
 Peter Hunter Johnston  
 Richard Lamb  
 Gary McQuarrie  
 Lois Wehren  
 Sadie Whittaker

**Education Committee**

Erica Johansson-Neil, Chair  
 Nancy Bormann  
 Kevin Doty  
 Jeffrey Fletcher  
 Chris Graf  
 Richard McCabe  
 David Peters  
 Stephen Valerio  
 Lois Wehren

**See you at the  
 4th Annual  
 Meeting of ISMPP!**

**April 28 - 30, 2008  
 Philadelphia, PA**



## ISMPP CORPORATE SUPPORTERS

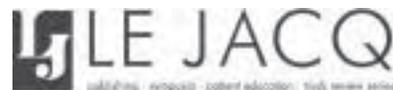
ISMPP wishes to thank the following organizations for their continued support of the Society.






COMPLETE HEALTHCARE COMMUNICATIONS, INC.












## 2007 ISMPP EXHIBITORS

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:

ApotheCom Associates	<a href="http://www.apothe.com">www.apothe.com</a>
AstraZeneca Pharmaceuticals	<a href="http://www.astrazeneca.com">www.astrazeneca.com</a>
Blackwell Publishing	<a href="http://www.blackwellpublishing.com">www.blackwellpublishing.com</a>
Complete Healthcare Communications	<a href="http://www.CHCinc.com">www.CHCinc.com</a>
Complete Medical Communications	<a href="http://www.complete-mc.com/index.html">www.complete-mc.com/index.html</a>
Complete Publication Solutions	<a href="http://www.C-PubS.com">www.C-PubS.com</a>
Current Medical Research & Opinion	<a href="http://www.cmrojournal.com">www.cmrojournal.com</a>
Envision Pharma, Inc.	<a href="http://www.envisionpharma.com">www.envisionpharma.com</a>
Future Science Group	<a href="http://www.future-science-group.com">www.future-science-group.com</a>
Gardiner-Caldwell Group, The	<a href="http://www.thgc-group.com">www.thgc-group.com</a>
LeJacq	<a href="http://www.lejacq.com">www.lejacq.com</a>
MedErgy HealthGroup	<a href="http://www.medergygroup.com">www.medergygroup.com</a>
Merck Research Laboratories	<a href="http://www.merck.com">www.merck.com</a>
PeerView, Inc.	<a href="http://www.epeerview.com">www.epeerview.com</a>
Peloton Advantage	<a href="http://www.pelotonadvantage.com">www.pelotonadvantage.com</a>
Scientific Connexions	<a href="http://www.sciconnex.com">www.sciconnex.com</a>
Thomson Scientific	<a href="http://www.thomsonscientific.com">www.thomsonscientific.com</a>
Wolters Kluwer Health	<a href="http://www.wolterskluwer.com/WK/">www.wolterskluwer.com/WK/</a>

Please note that if you would like to highlight your company's products and/or services in a target-rich environment, space is still available in the Exhibit Hall, as well as sponsorship opportunities. To learn more, please contact Kimberly Goldin, executive director, at +1 914 945 0507 or [kgoldin@ismpp.org](mailto:kgoldin@ismpp.org).

See you at the  
**4th Annual Meeting of ISMPP!**  
 April 28 - 30, 2008  
 Philadelphia, PA

# General Information

## Program Fees:

**Monday, April 23**

Pre-Conference Workshops  
\$400

**Tuesday, April 24**

Day 1, General Session  
\$400

**Wednesday, April 25**

Day 2, General Session  
\$400

**Those attending all three days will receive \$250 off registration fees for a total of \$950.**

All attendees of the 3<sup>rd</sup> Annual Meeting of ISMPP must be members of the organization.

To join and/or register, please [click here](#).

## Exhibits & Sponsorship Programs:

The 3<sup>rd</sup> Annual Meeting of ISMPP features an extensive Exhibit Hall and sponsorship programs. This meeting provides a unique opportunity for you to put your organization in front of your target audience. If interested in exhibiting and/or sponsoring, please [click here](#) to download the prospectus.

or contact Kimberly Goldin at +1 914 945 0507 or [kgoldin@ismpp.org](mailto:kgoldin@ismpp.org).

## Venue and Hotel Accommodations:

Sheraton Philadelphia City Center (*formerly the Wyndham Franklin Plaza*)

17th & Race Street

Philadelphia, Pennsylvania 19103

Phone +1 215 448 2000 · Fax +1 215 448 2864

To make a reservation at the Sheraton, please call 800 325 3535.

Or [click here](#) to make your hotel reservations online now.

***Make sure you mention ISMPP to receive the negotiated nightly rate!***

## Hotel Rates:

Single/Double Occupancy: \$199

Check-in Time: 3:00 PM

Check-Out Time: 12:00 NOON

**Reservations must be received no later than March 31, 2007. Requests for reservations received after March 31 will be on a space-available basis and the rate will be at the discretion of the hotel.**

All rooms require one-night's deposit by March 31, 2007. Individual guest cancellations will be accepted up to seventytwo (72) hours prior to arrival.

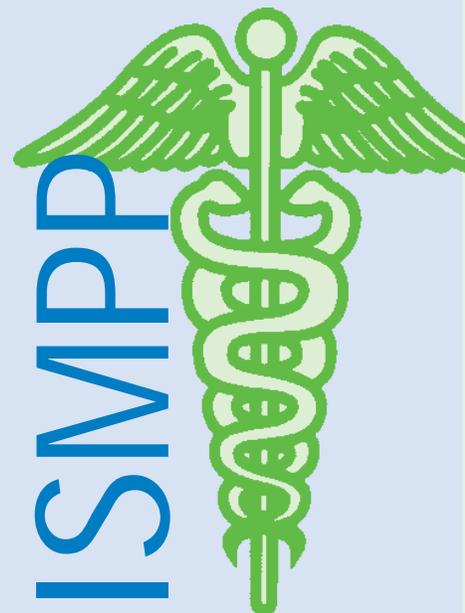
**ISMPP Annual Meeting Cancellation Policy** If you need to cancel your registration, please note the following:

**4 or more weeks prior to event:** You will receive a full refund, minus the inclusive \$150.00 annual membership dues and 10% of the balance for processing fees, or you may substitute another ISMPP member to attend in your place. You may also request a voucher for the full registration fee (minus the inclusive \$150.00 annual membership dues) to be used towards a future ISMPP event within the following twelve-month period.

**2 to 4 weeks prior to event:** You will receive a refund of 30% of the registration fees, less the included \$150.00 annual membership dues, or you may substitute another ISMPP member to attend in your place. You may also request a voucher for the full registration fee (minus the inclusive \$150.00 annual membership dues) to be used towards a future ISMPP event within the following twelve-month period.

**Less than 2 weeks prior to the event:** You may substitute another ISMPP member to attend in your place.

*\*Please note that if you opt for any form of refund, you will retain your membership of ISMPP for that year.*



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.**