

Dear Colleague:

First Annual Meeting of

The International Society for Medical Publication Professionals (ISMPP)

Driving the Value of Publications: An Integrated Approach

April 25–26, 2005

The Doral Forrestal Conference Center and Spa Princeton, NJ The First Annual Meeting of the International Society for Medical **Publication Professionals** (ISMPP), *Driving the Value of Publications: An Integrated Approach* will be held in Princeton, NJ commencing April 25, 2005.

Our ambition is to provide attendees with both the best practices within the industry as well as the best in education. Our program will cover all aspects and areas of publication planning and execution as well as guidelines and the potential impact on your plans. Special emphasis will be placed on clinical trial registries, a topic attracting more and more attention. Leaders in the field, representing pharmaceutical organizations, agency partners, journals and publishers, have developed a high-quality program.

In preparing the content for the inaugural conference, the founding members wish to convince even more colleagues that ISMPP is a unique forum for sharing innovative practices and expertise in publication planning. To this end, we will continue to develop new programs and expand future programs to offer enhanced interactivity and availability to all members and sponsors of ISMPP.

This newly created not-for-profit organization will bring together all those working in publication planning and execution under one umbrella, to create a forum for increased collaboration, and better interaction, which we hope will inject renewed momentum into our profession.

We trust that you will share our excitement about what promises to be a stimulating and great educational event. Plan ahead and join colleagues and professionals from around the world in Princeton to share and celebrate our common passion.

Sincerely,

The ISMPP Steering Committee

Timothy D. Bacon PeerView, Inc

Ross A. Baker, PhD, MBA Organon International Inc

Carolyn S. Clark, MBA Peloton Advantage

Joanne Conaty AstraZeneca Pharmaceuticals

Elizabeth Faust, PhD Amgen Inc.

Elizabeth (Betts) Field, PhD EMD Pharmaceuticals, Inc. Stan Heimberger, PhD, MBA Current Medical Research & Opinion

Laurence J. Hirsch, MD Merck Research Laboratories

Richard F. Lamb Sanofi-Aventis

Gary McQuarrie, PharmD, MBA Thomson Scientific Connexions

Robert Norris Complete Healthcare Communications, Inc.

Gene P. Snyder, MBA Pfizer Inc

Day 1: Monday, April 25, 2005

7:30 AM - 8:30 AM

Continental Networking Breakfast: Meet Your Fellow ISMPP Members

8:30 AM - 9:15 AM

ISMPP: The Power Behind the Profession

Professionals engaged in supporting publication planning initiatives find the process to be increasingly complex and scrutinized. ISMPP represents an innovative initiative designed to support constructive evaluation of existing process, and to stimulate ongoing evolution of best practice that satisfies internal needs while embracing external drivers.

At the introduction to this inaugural annual conference, members of the Steering Committee present their vision for the Society, and outline opportunities for active member participation. Please join us for this groundbreaking meeting in which our medical publications community unites for the first time to collectively advance our profession.

9:15 AM - 10:00 AM

Achieving Excellence in Publication Planning: A Look at the Industry's Best Practices

This session takes a look at how leading companies within the pharmaceutical industry achieve excellence in publication planning. Based upon research conducted over the past year, we examine best practices in the areas of publication strategy development, planning and implementation, tracking activities, archiving publications, interacting with external vendors, working with external authors and communicating with internal stakeholders. Additionally, discussion regarding the pros and cons of early planning versus late planning when it comes to manuscript development will be highlighted.

Paul Meade

President CLEAR POINT HEALTH, LLC

10:00 AM - 10:30 AM

30-Minute Networking and Refreshment Break

10:30 AM - 11:15 AM

Publication Planning Platforms: How to Tell if You Need One

Professional publication planners are increasingly held accountable for their work, both by corporate management and the biomedical community at large. The drive now is to ensure rapid publication of novel clinical findings, and to also make sure that any protocol whose results are not otherwise publicly disclosed are reported out in a timely fashion through emerging clinical trial repositories. As publication programs become more complex, an increasing number of companies are considering adopting one of the new platforms that helps to both manage and provide an audit trail that tracks a company's activities. During this discussion, this presenter explores the evolution from simple Word' and Excel' reports to today's sophisticated workflow and program management applications, and provides a pragmatic methodology to help you determine if your program could benefit from deploying one.

Timothy D. Bacon

President and CEO PEERVIEW, INC.

11:15 AM - 12:00 NOON

Implementing an Effective Internal Review Process

Implementing an effective internal review process for publications can be a challenge for a large, mid-size or small organization. Where do we begin? Who are the most appropriate reviewers? How do we keep the process manageable? How do we maintain transparency and keep to deadlines? Most importantly, how do we benchmark the process and track results? This presentation shares best practices for implementing an effective internal review process through:

- Early process planning
- Identifying the most appropriate reviewers
- Establishing the ground rules
- Establishing the key milestones
- Maintaining transparency
- Benchmarking and tracking results
- **Gene Snyder**

Director, Publishing PFIZER INC.

ISMPP Working Mission and Objectives

ISMPP's mission is to support publication professionals through education in fields associated with publication development and planning. The society strives to promote excellence in publishing effectiveness via open exchange and debate of relevant issues, as well as dissemination of practical information through high-quality conferences and training programs.

The society serves publishing professional's interest by the following means:

- Providing a forum to facilitate the further development and awareness of best practices in publication planning and execution
- Facilitating and encouraging communications among publication professionals within the pharmaceutical industry, medical publishers, medical communications companies, and other research, regulatory, and educational groups
- Fostering consensus for policies related to publication planning
- Supporting career growth, training and the development of individuals involved in publication development and planning

Day 1: Monday, April 25, 2005

12:00 NOON - 1:30 PM

Day 1 Luncheon for all ISMPP Members and Speakers

Please join us for an extended lunch to meet your fellow ISMPP members, as well as to briefly hear from those running for office.

*Please note that all meals served will be appropriate for those celebrating Passover.

1:30 PM – 3:30 PM Issues About Clinical Trial Registration and Disclosure of Results

Evidence Based Medicine (EBM) and Publication Bias

It takes a long time before clinical trial evidence makes its way into clinical practice. Finding the evidence can be an arduous task. An integral component of the practice of EBM is the ability for the physician to gain quick access to complete and unbiased systematic reviews. EBM requires that the best external evidence be integrated with individual clinical expertise and patient-choice in a bottom-up approach. Publication bias makes this process difficult. During this instrumental session, Dr. Thompson discusses how:

- Well-done meta-analyses are critical components that facilitate the practice of EBM
- Systematic reviews or meta-analyses lose their credibility when done with missing data
- A complete clinical trial registry will provide a path to ensure completeness of information
- Failure to obtain the totality of the evidence is likely to result in a biased selection

Desmond Thompson, PhD

Senior Director, Medical Communications MERCK RESEARCH LABORATORIES

Recent Developments for Clinical Trial Registries and Disclosure/Publication of Trial Results

There has been intense discussion over the past few years of clinical trial publication practices and apparent bias in the published medical literature. Amplified by a few high-profile cases of non-publication or suppression of clinical trial publication, mandatory trial registration at study inception has been proposed by leading medical journals (ICMJE) as a prerequisite for possible publication of subsequent results. Trial registries are starting to appear in several countries, and in some cases, by different parties. Legal and legislative actions have been taken and/or proposed. PhRMA and other trade organizations as well as some pharmaceutical companies have developed positions or taken steps to address these issues. During this session, Dr. Hirsch:

- Reviews the major events that have influenced today's environment
- Discusses the ICMJE position on trial registration, as well as the PhRMA and Joint Position statements on trial registries
 and disclosure of trial results
- Examines the implications for publication of clinical research

Laurence J. Hirsch, MD

Executive Director, Medical Communications MERCK RESEARCH LABORATORIES

The Efforts of Pharmaceutical Companies to Increase Transparency and Make Public Clinical Trial Results

Beginning as early as the mid-1990s, companies learned that academics, ethicists, and journal editors were suspicious of the process and end results of their efforts to publish clinical trial results, partly because of some high-profile cases and partly because of the presumed conflict of interest implicit in commercial enterprises. Scientists at several companies attempted to clarify and promote the usual good practices of data publication by writing and publishing *Good Publication Practice for Pharmaceutical Companies*. Individual companies developed internal policies or clinical trial registries, which they shared. In light of the current climate, those companies and more are going further. Some companies are struggling to find the appropriate process and resource to use the new tools of online registries and results databases. At this time, Dr. Field:

- · Reviews the previous grassroots work in developing pharma publication policies, like GPP
- Describes current efforts by individual companies to launch registries, results databases, and publicly revealed policies
- Shares the practical issues that companies must solve to use the new tools
- Provides a case study from the viewpoint of a mid-size global company
- Discusses the implications for publication of clinical research

Elizabeth (Betts) Field, PhD Director, Medical Communications EMD PHARMACEUTICALS

Following their presentations, Drs. Thompson, Hirsch and Field will conduct a panel discussion open to the audience for further examination of these pertinent and timely issues. Come prepared with your questions.

3:30 PM – 4:00 PM 30-Minute Networking and Refreshment Break

Day 1: Monday, April 25, 2005

4:00 рм – **4:45** рм

Setting Publication Planning Objectives: Noise vs. Impact

The success of a publication plan is measured by the attainment of the objectives set out at the inception of the plan. Of course diversions such as data not delivering, competitors, investigators and multiple other distractions along the way can make hitting these objectives more than challenging. This session discusses the importance of setting publication plan objectives, issues to consider in setting objectives, as well as the types of objectives that you may want to consider in developing your plan. Key topics include:

- Noise vs. impact
- Speed to publication
- Developing multiple publications from the same dataset
- Filling publication gaps
- · Gaining publication team buy-in of objectives

Robert Norris

President

COMPLETE HEALTHCARE COMMUNICATIONS, INC.

4:45 рм – **5:30** рм

The Great Debate: Outsourcing or In-House Development and Implementation of Publication Plans

Within the medical publications field, the age-old question of outsourcing or in-house development is always present. Is it more effective to structure your programs one way or another? Which direction makes the most sense for your group and why? During this engaging session, panelists will discuss the pros and cons of outsourcing or in-house development of the initial publication strategy and implementation of the plan. This discussion addresses:

- Pros and cons of outsourcing vs. in-house development, including cost, size of company or agency, and geographical considerations
- How to leverage an external agency when you have an in-house writing group
- How to establish communication with your external agency if outsourcing the entire publication plan
- Should there be a publication agency involved to manage the process between pharmaceutical teams and external authors?
- The various components and processes of the publication plan and which should be managed in-house vs. outsourcing

Carolyn Clark, MBA

President PELOTON ADVANTAGE

Elizabeth (Betts) Field, PhD

Director, Medical Communications EMD PHARMACEUTICALS, INC.

Julie Gilmore, PhD

Manager, Scientific Communications/US Medical Division ELI LILLY AND COMPANY

Robert Norris

President COMPLETE HEALTHCARE COMMUNICATIONS, INC.

> 5:30 PM – 7:00 PM ISMPP Cocktail Reception

Join your friends and colleagues for lively and enjoyable discussion of the day's events over refreshments at the conclusion of Day 1.

Day 2: Tuesday, April 26, 2005

7:30 AM - 8:15 AM

Continental Networking Breakfast and Committee Sign-Up

8:15 AM - 9:15 AM

A Win-Win Process: Selecting and Then Working With an Agency

Selecting a publication planning and communications agency to partner with is critical to initiating a mutually beneficial working relationship, but is only the beginning step for both pharmaceutical company publications personnel and the agency. Then the real work begins! In this session, common expectations and approaches are discussed to optimize the partnership process, including:

- What factors are most important in selecting an agency?
- Providing direction to the selected agency
- Setting resource expectations
- · Agreeing on processes and keeping them moving
- Importance of 2-way communications in managing the partnership

Jeffrey Fletcher, PhD

Clinical Publications Lead ASTRAZENECA PHARMACEUTICALS LP

Gary McQuarrie, PharmD, MBA

President & CEO THOMSON SCIENTIFIC CONNEXIONS

9:15 AM - 10:00

Planning and Developing Review Articles

Publications planning is a cyclical activity which is an integrated part of a products overall Brand strategy process. The publications plan includes the publications strategy, key messages, and the clinical plan to create a fully integrated plan. This includes recommendations for secondary publications. The goal of this session will be to describe the various components involved in the planning and development of review articles. This includes identifying unmet needs and message gaps, determining what type of publication will meet the need(s), authorship, target audience(s), and the steps/issues involved in creating a review article.

Al Weigel, MEd

Head of CV/Thrombosis Publications SANOFI-AVENTIS

10:00 AM - 10:30 AM

30-Minute Networking and Refreshment Break

Hotel Check-Out

10:30 ам – 11:30 ам

Guidelines on Professional Medical Writing

There has been a great hue and cry in the editorial pages of a number of prestigious journals (eg, JAMA, BMJ) concerning the use of professional medical writers to prepare manuscripts for publication. Their role is often seen as a conflict of interest in that they are employees of the commercial ventures (often pharmaceutical companies) who have the most to gain from a favorable presentation of data. More often, science and medicine are seen as commodities and the goal of the "popular" or "commercial" press is to sell a product: the publication itself, or advertising space. Thus, it has been proposed that fair balance has been sacrificed and that the Medical Writer is the agent for this corruption. In response, a number of organizations have promulgated standards for authorship. These include the International Committee of Medical Journal Editors (ICMJE); PhRMA; Good Publication Practices (GPP); and the American Medical Writers Association (AMWA) Code of Ethics. In addition, task forces have been formed within AMWA and the European Medical Writers Association (EMWA), charged with issuing Position Statements to address these authorship issues and to clarify the rights of professional medical writers. This session includes a presentation of the Position Statements from AMWA and EMWA. This issue has vital impact on the professional medical writing community, and affects both the writer employed by the pharmaceutical industry, as well as the freelancer.

Art Gertel

Vice President/Clinical Services, Regulatory, & Medical Writing BEARDSWORTH CONSULTING GROUP, INC.

7:30 AM – 8:15 AM Continental Networking Breakfast and Committee Sign-Up

Join us for breakfast and learn about the many ISMPP committees you may volunteer to serve on. Sign-up sheets will be available for your convenience.

To learn about the available committees beforehand, please visit <u>ismpp.org</u>.

Day 2: Tuesday, April 26, 2005

11:30 ам – 12:15 рм

Publication Planning Outlines that Work

Publication planning extends far beyond writing a manuscript after data becomes available and placing it in a convenient journal. True publication planning provides a strategic "big picture" perspective that enhances a product's image and credibility by educating physicians through sound scientific methods. A sound and comprehensive plan encompasses all product-related communications and drives the strategic dissemination of key messages, resulting from many months of extensive planning or responses to sudden changes in market dynamics. This session highlights a variety of publication plans, including samples for both large and small market products.

Carolyn Clark, MBA President PELOTON ADVANTAGE

12:15 NOON - 1:30 РМ

ISMPP Brainstorming Luncheon

Join us for lunch as each table engenders a lively discussion regarding what ISMPP should provide for its membership, as well as its place within the Industry. An account of each table's thoughts will be compiled and reported on during the final session of the day. This is your opportunity to make ISMPP your premier resource and reference for your medical publications practice.

*Please note that all meals served will be appropriate for those celebrating Passover.

1:30 рм – 2:15 рм

Successful Strategies for Outsourcing Medical Writing

Once you've decided to outsource the medical writing aspects of your publication plan, finding the right medical writer can be challenging. How do you identify a good medical writer from all the rest? Do you line up freelance writers, work with a vendor, house contractors on site, or engage a CRO? During this enlightening discussion, the following points are addressed:

- Evaluating writing skills (samples, tests, resumes)
- Contracting (rates, payments schedules, termination agreement)
- Matching the project with the provider
- Communicating with your writer

Elizabeth Faust, PhD

Director, Global Medical Writing AMGEN INC.

2:15 рм – 3:00 рм

"We need to be in the *New England Journal of Medicine*... Right?": Selecting the Right Journal for Your Publication

To many pharmaceutical marketing professionals, selecting journals for a publication plan usually means looking for one with a high Impact Factor. Is that the best way to evaluate a journal for publication planning? This presentation discusses the value of the Impact Factor and points to many other sources of information that can give more, and sometimes better, guidance on where to place your publication. It concludes with concrete advice on how to improve journal selection for publication planning. Specifics addressed include:

- The Impact Factor: What is it and where does it come from?
- Other sources of objective, quantitative information about journals
- A report on exclusive survey results:
- Examine medical professionals' actual understanding of the Impact Factor
- Other factors that are actually more important than the Impact Factor in journal selection
- Actionable recommendations on more effective ways to select journals for publication planning (including, making effective use of the Impact Factor)
- A look at online journals for publication planning

Frank J. Rodino, MHS, PA President CHURCHILL COMMUNICATIONS

The First Annual ISMPP Elections

ISMPP exists to serve the medical publications community, and therefore relies upon member participation to determine the shape and scope of the Society. One outstanding way to get involved is to run for office or a position on the Board of Directors at this first annual meeting.

During the Day 1 luncheon, candidates will have the opportunity to introduce themselves to the Society and speak regarding their qualifications and desire to serve. Following, elections will take place by ballot and the result will be announced at the final session of the meeting.

If interested in running for office or a seat on the Board, please contact Kimberly Goldin, executive director at kgoldin@ismpp.org or 914 945 0507. Intent to run must be received by April 11, 2005.

Day 2: Tuesday, April 26, 2005

3:00 PM – 3:30 PM 30-Minute Networking and Refreshment Break

3:30 РМ - 4:45 РМ

Future Trends in Medical Publishing

Have you looked into your crystal ball lately? Our Panel Experts have, and they are willing to share their thoughts on future trends in the medical publishing arena. A number of new areas are emerging to challenge and test traditional publishing models. Our panelists will touch on topics such as "open access" journals and the impact of data disclosure via websites, as well as how these initiatives may change the peer-review process, dissemination of data, journal audiences, etc. Following a brief presentation, the discussion will be opened to the audience for what promises to be a robust discussion.

Panel Moderator:

Joanne Conaty

Senior Director, Medical Communications ASTRAZENECA PHARMACEUTICALS

Participants:

Glenn P. Campbell Senior Vice President, US Health Sciences Journals ELSEVIER

Peter Clarke, PhD Group Publisher LIBRAPHARM/CURRENT MEDICAL RESEARCH & OPINION Christine Laine, MD, MPH Senior Deputy Editor ANNALS OF INTERNAL MEDICINE

Paul O. Weislogel, PhD Executive Vice President, Journals Publishing Lippincott Williams & Wilkins WOLTERS KLUWER HEALTH

4:45 PM - 5:00 PM Where Do We Go from Here?

This brief but important session will be full of energy. We will summarize the results of the lunchtime discussion groups on what the membership at large is looking for ISMPP to provide. We will also announce the results of the first ever elections of ISMPP officers. Stay around for this to see who will lead our association over the next year. Even better, throw your name into the hat to actively take part in directing ISMPP and setting the course for the future of the organization and publication planning professionals!

Conference Concludes

Please remember to submit your evaluations before departing.

Have a safe journey home.

General Information

ISMPP Sponsorship and Exhibit Opportunities

During this exciting time, ISMPP is offering special sponsorship and exhibit opportunities to those organizations that would like to invest in the future of the Society. These programs are detailed below, as well as on our website, <u>ismpp.org</u>. Also, please note that if you act before March 31, 2005, you will receive a 20% discount off the published rates.

To take advantage of these programs, please contact the ISMPP executive director, Kimberly Goldin at 914 945 0507 or kgoldin@ismpp.org.

Corporate Sponsorship

Corporate Sponsor

Cost \$25,000 one time fee

Includes 5 annual memberships and 1 annual meeting registration

Includes logo and link on ISMPP sponsor webpage

Recognized on all appropriate ISMPP materials

Note: If a Corporate Sponsor does not have at least 5 registered members and annual conference delegates at all times, they relinquish their sponsorship rights and will have to reapply and repay if they desire to renew their sponsorship at a future time

Charter Corporate Sponsor

A company may become a "Charter Sponsor" if they commit and pay prior to the end of March, 2005. A Charter Sponsor will receive a nonvoting seat on the Board of Directors.

Annual Sponsor

Cost \$5,000 annually

Includes 3 annual memberships

Includes logo and link on ISMPP sponsor webpage (listed alphabetically after Corporate Sponsors)

Recognized on all appropriate ISMPP materials

An Annual Sponsor may become a Corporate Sponsor by paying the additional \$20,000 within the same calendar year as they became an Annual Sponsor

Exhibitors for 2005 Inaugural Annual Meeting

Open only to sponsors who have paid their fees in full at least one month before the annual meeting

Cost 3,000 (non-negotiable), must be paid one month in advance of the meeting

Each exhibit space is 10' x 10' and includes a table and chairs. Electrical service is the responsibility of the exhibitor. Multiple contiguous exhibit spaces may be purchased in increments of \$3,000 on a space available basis

Includes listing in all annual meeting promotional and educational materials

Includes listing on the ISMPP exhibitor webpage listed alphabetically. Listing will be posted on the website for 6 months after the close of the annual meeting

Includes one-page B&W ad in the conference book/binder Attendee mailing list

Other Sponsorship Opportunities

ISMPP is open to other creative sponsorship opportunities, i.e., breaks, conference bags, special functions, etc. and will be considered by the Program Committee on a case-by-case basis.

In addition it is the goal of ISMPP to create a newsletter and additional training/workshop events (both in person and online) that will provide additional sponsorship opportunities.

If you have any suggestions, please send them in writing to kgoldin@ismpp.org or ISMPP, PO Box 2523, Briarcliff Manor, NY 10510.

Registration

The cost to attend the Inaugural Annual ISMPP Meeting is \$950.00. Please note that registration for the meeting includes 2005 ISMPP membership.

To register, please fill out the form on the next page and return it in one of the following ways:

Email: registration@ismpp.org

Fax: 914 945 0307

Mail: ISMPP PO Box 2523 Briarcliff Manor, NY 10510

If you have any additional questions or request for information, please contact Kimberly Goldin, executive director, at 914 945 0507 or kgoldin@ismpp.org.

Venue Information

The Doral Forrestal Conference Center and Spa 100 College road East Princeton, NJ 08540 609 452 7800

When calling to make a hotel reservation, please let the agent know you are with the International Society for Medical Publication Professionals to receive the negotiated rate of \$176.00 for ISMPP attendees. **Please note this rate is only good through April 15, 2005.**

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 individual 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 another 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 individual 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 another ISMPP event within the following twelve-month period.

Less than 2 weeks prior to the event:

You may substitute another individual 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.

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

ISMPP Membership Application/1st Annual Meeting Registration

	International Society
	for Medical
5	Publication Professionals

Please print out this form, complete it (print legibly or type) and mail to **ISMPP, PO Box 2523, Briarcliff Manor, NY 10510**. Please remember to include your dues payment of \$150.00 or your full meeting registration (which is inclusive of membership) for \$950.00. Checks should be made out to ISMPP. If you are paying by credit card, you may also fax to 914 945 0307. All applications should allow 3-4 weeks for processing.

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Registering for the ISMPP *Registration fee includes 2	Annual Meeting, April 25-26, 20 2005 ISMPP membership	05	\$950.00*
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trainings for the medical publication	ck, ISMPP strives to continuously cons community. Please indicate yo present the strives of the strict of the str		
I am interested in the following 2006 European Annual Me 2006 US Annual Meeting WebEx Lunch and Learning Quarterly Trainings Newsletter Contributions Other Ideas:	eting □ Attending □ Attending	 Participa Participa Participa Participa Participa Editing 	ating ating