

EMPOWERING THE MEDICAL PUBLICATION COMMUNITY TO ADVANCE THE PROFESSION

April 29 – May 1, 2013
Hyatt Regency Baltimore
Baltimore, MD, USA





Dear Colleagues:

We are excited to present the program for the **9th Annual Meeting of ISMPP, *Empowering the Medical Publication Community to Advance the Profession***. Science is advancing daily, the way in which information is analyzed and transmitted to end-users continues to evolve, and global collaborations are ever present. Consequently, continuous examination and improvement of the standards that guide scientific and medical data dissemination are crucial.

So how do we “empower” our profession? Through education and open exchange, particularly with diverse stakeholders, including emerging markets and academia. The 9th Annual Meeting will expose you to these and other groups and equip you with the knowledge and practical tools to work globally, build better relationships and find commonalities with all stakeholder groups, as well as understand the impact of phenomena such as “Big Data,” increased data sharing between pharma and researchers and real-world data, among others.

Each day of the Meeting focuses on a central theme affecting the world of medical publishing.

Day 1: Focus on New Players

Faculty from academia and the patient, NGO, editing and compliance arena will explore how we can better engage with those involved in medical data dissemination beyond the industry model and generate strength from the common goal of ensuring that peer-reviewed medical literature is accurate, credible, and reliable.

Day 2: Focus on New Data Sources

Data – who should have access to it, and how much? How can we best measure its impact? Day 2 will focus on issues related to data and medical publications such as data sharing, data mining, transparency, privacy, and emerging metrics beyond the traditional impact factor.

Day 3: Focus on New Geographies

As the world becomes more decentralized, companies are increasingly forming alliances and partnerships and expanding their reach in emerging markets. Faculty will provide perspectives from big, mid-sized, and small pharma companies on successful global work strategies. Ethical, cultural, and compliance issues will also be explored as they relate to working from a regional level in markets outside the US and Europe.

We are also pleased to highlight several **NEW meeting features for this year**, many aimed at **providing you more opportunities to get your questions answered and interact more effectively with your peers**:

- **Longer general sessions**, allowing for more in-depth coverage and discussions
- **“Table Talk” segments** at the end of select general session presentations, which will allow you to explore issues in greater detail with your counterparts at your table
- A **“Key Takeaways” slide** in each general session presentation, articulating the practical actions and recommended next steps
- **Roundtable proceedings** will be **published in a future issue of CMRO**
- **Workshops on Alliance Partnerships**, managing **Manuscript Challenges and Journal Processes** and working in the **Asia-Pacific region**

As in previous years, many of the meeting presentations and workshops qualify for ISMPP Certified Medical Publication Professional™ (CMPP™) continuing education credits. We encourage you to explore our brochure and take a look at the expert faculty that will be speaking at this year’s meeting.

On behalf of the ISMPP Board of Trustees and staff, **WELCOME.**

Yours Sincerely,

Russell Traynor, MSc, ISMPP CMPP™
Chair, ISMPP Board of Trustees
Business Lead
Envision Technology Solutions

Thomas Gesell, PharmD
Chair, Annual Program Committee
Development Director, Medical Affairs
UBC-Envision Group



PROGRAM AGENDA

Sunday, April 28

7:00 PM – 9:00 PM Welcome Reception

Monday, April 29

MORNING

7:30 – 8:30 AM	Registration and Continental Breakfast
8:30 – 10:00 AM	Pre-conference Workshops (schedule and descriptions on pages 18 - 32)
10:00 – 10:30 AM	Morning Break and Visit Exhibits
10:30 AM – Noon	Pre-conference Workshops (continued)
Noon – 1:30 PM	Lunch for Workshop Attendees, Workshop Faculty, and Exhibitors only

AFTERNOON

Day 1:

General Session

1:30 PM – 5:30 PM

Focus on New Players

We will look beyond the usual players to explore the role of new constituencies that are gaining voice and influence in our industry. This includes both the practical and theoretical drivers that are changing publication planning and management due to a range of factors including: industry practices, the need for rigorous scientific data validation, and a new level of transparency across all activities supporting medical publications. The program will include significant time for questions and answers between academics, physicians, editors, compliance officers, and government officials, both elected and appointed. The 'Focus on New Players' program will provide a forum to learn how and why these new constituencies are influencing how we conduct our publication planning business and relationships between clients, authors, and colleagues.

Learning Objectives

By the end of this day, attendees will:

- Gain insight and better understand the forces outside the industry that are providing external constituencies, with greater influence in publication planning and further pushing transparency within our industry
- Learn how academic institutions, governments, and NGOs influence the changing landscape by affecting the debate regarding publication planning, transparency, and relationships
- Gain appreciation for how medical publications can be and are used to gain knowledge, enhance practice skills, and educate patients and the lay public
- Be informed about MPIP's current activities, including the Author's Submission Toolkit

1:30 PM – 1:40 PM

9th Annual Meeting of ISMPP Welcome

Kim Goldin, *General Manager, ISMPP*

Russell Traynor, MSc, *Chair, ISMPP Board of Trustees (2012 – 2013);
Business Lead, Envision Technology Solutions
ISMPP CMPP™*

1:40 PM – 3:15 PM

New Players: An Internal Perspective

In the first of a two-part section, we will look specifically at some of the new players who are emerging and how they can shape (and are shaping) the internal planning and delivery processes associated with publications

1:40 PM – 2:25 PM



Seeking a Fresh Perspective to Enhance the Status Quo

An authorship advisory board was held at Pfizer recently, to which a number of external experts/department heads from several different disciplines were invited. The purpose of this advisory board was to evaluate Pfizer's existing processes and gain input on how these might be improved. The speakers will share a synopsis of the discussion and the resulting changes that were suggested.

Learning Objectives

By the end of this session attendees will:

- Be exposed to the ideas and perspectives of external experts: how do they view the publication planning and delivery process?
- Identify what works well and what does not and how internal processes can be improved
- Have practical ideas about how they can enhance their own in-house processes through external collaboration

Alan Lyles, ScD, MPH, RPh, *Henry A. Rosenberg Professor of Public, Private and Nonprofit Partnerships, University of Baltimore and Docent, University of Helsinki*

Jodie Gillon, MPH, *Director, Publications Management Team, Pfizer*

2:25 PM – 3:15 PM



Compliance: A New Friend or Foe?

In recent years, we have seen a new player emerge in the field of publications: the compliance team. In this interactive discussion session, the panel will share their experiences of the compliance challenges we face in today's environment. In particular, panel members will reveal the issues that concern them the most and debate their respective interpretations of the current regulations and potential geographical differences. We will also hear the panel's thoughts on practical solutions that can be implemented to ensure that the alliance between the compliance and publication teams is a collaborative and positive one!

Learning Objectives

By the end of this session attendees will:

- Gain insight into the types of compliance issues that may arise
- Better understand the ever increasing role of the compliance team
- Have practical ideas of what they could do as individuals and within their organizations to further improve their communication practices to ensure full compliance while maintaining efficient data dissemination

Carolyn Hustad, PhD, *Executive Director, Publication Management, Global Scientific and Medical Publications, Merck*

Mina Patel, PhD, *Senior Director, Medical Strategy, Education & Publications, Vertex Pharmaceuticals Inc*

Jeffrey Rosenbaum, VP, *Chief Compliance Officer, Vertex Pharmaceuticals Inc*

Karen L. Woolley, BHMS Ed Hons, PhD, *CEO, ProScribe Medical Communications (Australia, China, Japan); Professor, University of Queensland; Professor, University of the Sunshine Coast; Honorary Fellow, American Medical Writers Association; ISMPP Director and Chair, Asia-Pacific Advisory Committee; ISMPP CMPP™*

Moderator: Alice Choi, PhD, *Global Head, Complete Medical Communications, ISMPP CMPP™*

3:15 PM – 3:45 PM

Afternoon Break and Visit Exhibits

3:45 PM – 4:55 PM



New Players: An External Perspective The Evolving Forces in Publication Planning

Our landscape has evolved over the past years from one of internal (industry) management and control to one where external players bear large influence over our activities. There are many questions to ask, and answers to find. During this 70-minute session, our esteemed panelists will explore the following key issues and attempt to provide you with practical, take-home information that you can turn into application:

- Effect of research on transformative healthcare and the role of publications in this transformation
- Comparative effectiveness research and its effect on the clinical trial paradigm
- Alternative uses for the data that traditionally lived within publications
- Growth of population health and population-based research

Learning Objectives

By the end of this session attendees will

- Gain insight and improved understanding of the impact of the global external forces on publication planning and increased transparency
- Learn how academic institutions, governments, and NGOs affect the changing medical publications landscape
- Understand how medical publications are used by practitioners and journalists to gain knowledge, enhance practice skills, and educate patients and the lay public

Sarah L. Feeny, BMedSc, *Head of Scientific Direction, Complete Medical Communications, ISMPP CMPP™*

Fiona Godlee, MD, *Editor-in-Chief, British Medical Journal*

David D. Queen, *Attorney at Law, The Law Office of David Queen*

William Silberg, *Director of Communications, Patient-Centered Outcomes Research Institute (PCORI)*

Moderator: Kim Pepitone, BA, *Scientific Director, Cactus Communications, Inc.; Adjunct Assistant Professor, University of the Sciences in Philadelphia, ISMPP CMPP™*

4:55 PM – 5:25 PM

MPIP Update

Teresa Peña, PhD, CQE, *Global Director, Clinical Publications, AstraZeneca*

5:25 PM – 5:30 PM

Closing Remarks

Russell Traynor

EVENING

5:30 PM – 6:30 PM

ISMPP Poster Presentation Assembly

General Session Foyer

See pages 16 – 17 for a listing of this year's Poster Presentations

Tuesday, April 30

MORNING

7:00 – 8:00 AM

Registration and Continental Breakfast

Day 2:

General Session

8:00 AM – 4:30 PM

Focus on New Data Sources and Data Sharing

Disseminating drug-related information to patients and the healthcare community is a core activity of medical publication professionals. Traditionally, the sources of much of the data have been closely guarded clinical trial databases housed within pharmaceutical companies. However, this landscape is rapidly changing. Journals and investigators are expecting greater access to company data and organizations are now capturing “real world” data from a variety of sources, much of it unstructured (e.g., from web sites and social media). This day will examine emerging trends in the use of real-world data in the pharmaceutical industry, the potential effects of granting increased access to clinical databases on data dissemination and ways to take advantage of the wealth of new analytics to measure the effectiveness of our publication plans.

Learning Objectives

By the end of this day, attendees will:

- Be aware of how real-world data will affect medical publications
- Understand the implications of increased access to clinical databases
- Be able to evaluate new metrics to assess the effectiveness of publication plans
- Gain insight into the Physician Payment Sunshine Act final ruling

8:00 AM – 8:05 AM

Opening Remarks

Russell Traynor

8:05 AM – 9:05 AM

Keynote Presentation

“Big Data”: Implications for Medical Publications

Carol McCall, FSA, MAAA, Chief Strategy Officer, GNS Healthcare

9:05 AM – 10:15 AM

New Data Sources, New Opportunities



Traditionally, most drug-related publications contained data from highly structured company-sponsored clinical trials. However, organizations are now increasingly capturing “real world” data from a variety of new unstructured sources (e.g., from web sites and social media). The panel will discuss the potential insights to be gained from applying real world data (“Big Data”) to drug development, including the use of health outcomes data from real world settings. In addition, we will hear how new data sources can be used to measure the reach and impact of medical publications in clinical practice, thus allowing us to enhance our publication planning.

Learning Objectives

By the end of this session attendees will:

- Gain insights into how the pharmaceutical industry is capturing real world data from a variety of new sources
- Hear how real world data sources can provide new insights into drug efficacy and safety and impact clinical practice
- Understand how new metrics can be used to assess the effectiveness of publication plans

David Anstatt, *Group Director, Center for Observational Research and Data Sciences, Bristol-Myers Squibb*

Martin Delahunty, BA (Nat Mod Sci), MBA, *Associate Director, Academic Journals & Pharma Solutions, Nature Publishing Group*

Moderator: Carol McCall, FSA, MAAA, *Chief Strategy Officer, GNS Healthcare*

10:15 AM – 10:45 AM **Morning Break and Visit Exhibits**

10:45 AM – 12:00 PM **Oral Presentations and Poster Awards**

Four out of 34 abstracts were selected via a blinded peer review process for oral presentation. These four abstracts represent some of the top research and reinforce the value served by medical publication professionals.

The Annual Poster Awards take place immediately after the oral presentations.

10:45 AM – 10:50 AM **Opening Remarks**

Sharon Suntag, MS, *Medical Director, Quintiles; ISMPP 2013 Abstract Committee Chair, ISMPP CMPP™*

10:50 AM – 11:05 AM **A review of manuscript cycle times from 2009 to 2012: Results from a major pharmaceutical sponsor**

Angela Bickford, *GlaxoSmithKline*

11:05 AM – 11:20 AM **Publication of health economics and outcomes research (HEOR) data in non-HEOR journals: A literature analysis**

Jason McDonough, *MedErgy HealthGroup, ISMPP CMPP™*

11:20 AM – 11:35 AM **Success at journal of choice and effect of resubmissions on publication timing for Pfizer-sponsored publications in 2012**

Elizabeth A. Whann, *Pfizer, ISMPP CMPP™*

11:35 AM – 11:50 AM **Increasing and evolving use of smart technology to access congress posters**

Fran Young, *Shire Development LLC, ISMPP CMPP™*

Tuesday, April 30 (continued)

11:50 AM – 12:00 PM **Poster Awards**
Sharon Suntag

12:00 PM – 12:30 PM **Annual ISMPP Business Meeting**

12:30 PM – 1:30 PM **Lunch For All Attendees, Faculty and Exhibitors**

1:30 PM – 3:00 PM **Transparency Takes Center Stage: Data Sharing**



It has been proposed that data from human research studies should be made available for scientific research so that qualified researchers and investigators can confirm and extend research findings. In order to enhance transparency, some journals now require that authors of papers reporting primary results from randomized controlled trials of currently approved drugs or devices make relevant anonymized patient-level data available upon reasonable request. GlaxoSmithKline (GSK) and Roche have recently announced that they will make anonymized patient data from published studies of approved or terminated drugs available to qualified investigators. The panel will discuss journals' efforts to increase transparency, the challenges that pharmaceutical companies are facing in implementing initiatives to make trial data accessible, and the implications of increased data sharing for publication planning and development.

A "Table Talk" segment will follow the panel discussion, during which attendees will be able to discuss with their colleagues topics arising from both Data sessions.

Learning Objectives

By the end of this session attendees will:

- Better understand emerging journal requirements for data sharing
- Learn how GSK is addressing the challenges involved in making patient-level data available to investigators
- Gain insights into the implications of increased data sharing on data dissemination

Cynthia E. Dunbar, MD, *Senior Investigator, Hematology Branch, National Heart, Lung and Blood Institute, National Institutes of Health; Former Editor-in-Chief, Blood*

Robert E. Enck, MD, *Professor of Medicine, Quillen College of Medicine; Editor-in-Chief, American Journal of Hospice & Palliative Medicine, Johnson City, TN*

Pat Iannuzzelli, PhD, *Publications Director, Medical Communications Quality & Practices, GlaxoSmithKline*

Moderator: Carol McCall, FSA, MAAA, *Chief Strategy Officer, GNS Healthcare*

Tuesday, April 30 (continued)

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

3:30 PM – 4:00 PM **Sunshine Act Task Force Presentation**

Kim Pepitone, BA, *Scientific Director, Cactus Communications, Inc.;*
Adjunct Assistant Professor, University of the Sciences in Philadelphia,
ISMPP CMPP™

4:00 PM – 4:15 PM **ISMPP Ethics Committee Update**

Yvonne E. Yarker, PhD, *ISMPP Interim Chief Operating Officer; Chair, ISMPP Ethics Committee; President, Medicite LLC, ISMPP CMPP™*

4:15 PM – 4:30 PM **ISMPP Certified Medical Publication Professional (CMPP™) Update**

Stacy Simpson Logan, ELS, *Chair, ISMPP Certification Board (2012-2013), ISMPP CMPP™*

4:30 PM – 5:30 PM **Roundtable Session**

Roundtable sessions provide a professional forum for attendees to exchange ideas, experiences, and information with their colleagues and peers around preselected topics identified by the ISMPP membership as key areas of interest to the medical publication community. Each session will be moderated by a topic expert and the output captured in a formal fashion and shared with the larger group.

Each attendee will have the opportunity to attend two roundtable discussions.

Please see the next page for a listing of this year's Roundtable topics

Moderator: Donna Simcoe, MS, MBA, *Director, Publications and Medical Information, Cadence Pharmaceuticals*
ISMPP CMPP™

This session was made possible by an Educational Grant from



5:45 PM – 7:45 PM **Annual Evening Networking Reception**

The Rusty Scupper

9th Annual Meeting of ISMPP Roundtable Topics

Advocating for our Profession

Best Practices in Interacting with Authors

Beyond RCTs: Health Outcomes, Clinical Evidence Research and/or Big Data in Your Publication Planning

Challenges with GPP2 and ICMJE Compliance

Collaborative Industry/Agency Relationships

Corporate Integrity Agreements: Navigating Challenges with Publication Practices and Processes

Differences Between Medical Device and Pharmaceutical Publications

Publications in Emerging Markets: Challenges and Opportunities

Review Manuscripts: Challenges Surrounding Development and Submission

The Sunshine Act: Focus on Transfer of Value

Trends and New Opportunities in Publications

Why Become CMPP Certified?: The Value of Certification

Working Effectively with Medical Writers

MORNING

7:00 AM – 8:00 AM

Registration and Continental Breakfast

Day 3:

General Session

8:00 AM – 12:30 PM

Focus on New Geographies

There is an increasing focus on global publications developed by drug and device companies, especially in emerging markets, as they increase their presence and growth in regions other than the United States and Europe. Companies have diverse policies and models so is there a 'right' model? Does one size fit all? What issues arise related to the diverse policies, customs, laws, cultures, and time zones across regions? These sessions will bring together different stakeholders to address key issues and provide insights and best practices when working within today's truly global publications environment.

Learning Objectives

By the end of this day, attendees will:

- Learn how differently sized and structured companies have expanded their publication efforts globally and how they define global publications
 - Understand regional and local-level considerations and issues with publication-related policies and practices developed external to the region to ensure an integrated and comprehensive plan
 - Learn about ISMPP's activities in the Asia-Pacific region
 - Gain insights into the results of the Global Publication Survey
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8:00 AM – 8:05 AM

Opening Remarks

Lorna Fay, *Chair, ISMPP Board of Trustees (2013 – 2014); Director/Team Leader, Publishing, Pfizer*

8:05 AM – 8:30 AM

APAC Update

Karen L. Woolley, *BHMS Ed Hons, PhD, CEO, ProScribe Medical Communications (Australia, China, Japan); Professor, University of Queensland; Professor, University of the Sunshine Coast; Honorary Fellow, American Medical Writers Association; ISMPP Director and Chair, Asia-Pacific Advisory Committee; ISMPP CMPP™*

Wednesday, May 1 (continued)

8:30 AM – 9:45 AM



Going Global

Global collaborations are becoming more prevalent in the world of medical publishing. This session will explore the structure, policies and processes from the perspectives of large, mid- and small-sized pharmaceutical and biotechnology companies. The panel will provide insider perspectives on their journey of “Going Global” – both the challenges and new opportunities. Budgets, resources, personnel needs and regional coordination will be among the many topics discussed.

Learning Objectives

By the end of this session attendees will

- Learn how differently sized and structured companies have expanded their publication efforts globally and how they define global publications
- Understand the training, technology, policies and procedures needed for a successful global operation
- Gain greater perspective on the level of internal staff and external vendor resources that may be required for developing and executing a global publication plans
- Hear how other companies have overcome challenges related to their global expansion

Angela Bickford, PhD, *Director, Medical Communications Quality and Practices, GlaxoSmithKline*

Kristen Mosdell, PharmD, BCPS, *Director, Scientific Affairs, Amgen Inc.*

Karen Pinette, PhD, MS, RAC, *Director, Medical Publications, Biogen Idec*

Susan Scott, PhD, *Director, Publications & Communications, Ipsen Biopharm Ltd, ISMPP CMPP™*

Moderator: Jill Condello, PhD, *Strategic Services Director, CHC Group, ISMPP CMPP™*

9:45 AM – 10:15 AM

Morning Break and Visit Exhibits

10:15 AM – 11:30 AM

View from the Regions



Utilizing a case-based approach, this session will give insights into working in emerging markets from the regional level – how does one effectively implement corporate policies and coordinate across countries? What are the challenges and opportunities? How best to ensure compliance against the backdrop of differing regional standards? Recognizing that best practices need to be universal, panelists will share their perspectives and practical advice – based on direct experience working within the regions both internally within their company and externally with investigators and authors – on how to operate most effectively.

A “Table Talk” segment will follow the panel discussion, during which attendees will be able to further discuss with their colleagues topics arising from the session.

Learning Objectives

By the end of this session attendees will

- Gain insight into the challenges and opportunities in working at the regional level in emerging markets
- Understand how different companies operate on a regional level and interact with global headquarters
- Better understand how to apply publication standards globally while still respecting regional differences

Julie Newman, ELS, *Associate Director Regional Strategic Medical Communications (China, Intercon Asia-Pacific & Japan), Bristol-Myers Squibb*

Michael Platt, *President, MedVal Scientific Information Services, LLC, ISMPP CMPP™*

Ehab Youseif, *Senior Medical Director, Pfizer*

Moderator: Aruna Seth, PhD, *Scientific Team Lead, UBC-Envision Group, ISMPP CMPP™*

11:30 AM – 12:20 PM

**ISMPP Issues and Action Committee Update:
Global Publication Survey Presentation and Panel Discussion**

Viv Adshead, *Executive Vice President, Group Managing Director, Healthcare Communications Network*

Josh Fullam, *Analyst, TGaS Advisors*

John Gonzalez, PhD, *Director of Publications Policy, AstraZeneca, ISMPP CMPP™*

Karen L. Woolley, BHMS Ed Hons, PhD, *CEO, ProScribe Medical Communications (Australia, China, Japan); Professor, University of Queensland; Professor, University of the Sunshine Coast; Honorary Fellow, American Medical Writers Association; ISMPP Director and Chair, Asia-Pacific Advisory Committee; ISMPP CMPP™*

12:20 PM – 12:30 PM

Closing Remarks and Meeting Close

Lorna Fay

AFTERNOON

12:30 PM – 1:00 PM

Box lunch for Workshop participants and Exhibitors

1:00 PM – 2:30 PM

Post-conference Workshops (schedule and descriptions on pages 8-22)

2:30 PM – 3:00 PM

Afternoon Break

3:00 PM – 4:30 PM

Post-conference Workshops (continued)

4:30 PM

Conference Adjourns

9th Annual Meeting of ISMPP Poster Presentations

Title and First Author

A medical writing survey to develop a certification examination
Thomas P. Gegeny, *UBC-Envision Group*

An automated literature analysis tool to enhance literature searches for publication subcommittees (PSCs) and publication planning
Michelle Kissner, *Publications Management, Pfizer*

Attitudes of healthcare professionals towards medical writers and pharmaceutical company involvement in publications
Tom Rees, *PAREXEL International*

Augmented reality: bringing another dimension to scientific publications
Mark Lydiatt, *Nucleus Global*

Celgene history books: an innovative and interactive key publication archiving tool
Manon Boisclair, *Global Medical & Scientific Communications, Celgene Corporation*

Clinical trial data - reducing the time to submission
LaVerne A. Mooney, *Publications Management Team, Pfizer*

Corporate integrity agreements 2012
Thomas Babcock, *Global Publications Group, Shire Specialty Pharma*

Digital dissemination of scientific poster presentations via quick response (QR) codes: implementation and analytics
J.R. Meloro, *Pfizer Oncology Global Medical Communications*

Got GPP skills?' Skill-building initiative for publication professionals in pharmaceutical industry setting
Kimberley Gertsen, *Bristol-Myers Squibb*

Guidelines for literature analyses: an agency perspective
Doug Taylor, *The Medicine Group*

Implementation of an educational program regarding best publication practices and the introduction of publication management software across a global organization
Brian Atkinson, *Global Medical Publications, Bristol-Myers Squibb*

Improving data accessibility through innovations in regional publication planning, training, and implementation
Luis Perez, *Nucleus Global*

Incomplete conflict of interest (COI) disclosures – Contribution of medical journal requirements
Ira Mills, *PAREXEL International*

Introducing good publications practices in China: a case study in nuance and know-how
Julie Newman, *Research and Development, Bristol Myers-Squibb*

Kicking off cost-efficient abstracts: factors influencing abstract development time
Joelle Suchy, *Nucleus Global*

Perception of multimedia content by journal editors
Craig V. Smith, *Multimedia Publishing, Elsevier*

Publication agreements or 'gag orders'? Compliance of publication restrictions with Good Publication Practice 2 (GPP2) for trials on ClinicalTrials.gov
Karen L. Woolley, *ProScribe Medical Communications*

Publication experience in orphan diseases: case study with Cryopyrin-Associated Periodic Syndromes (CAPS)
Carol Hudson, *Regeneron Pharmaceuticals, Inc*

Relationship of citations received for published articles to a journal's impact factor at time of submission
Jeffrey W. Clemens, *Eli Lilly and Company*

Submitting prior reviews with a previously rejected manuscript when seeking publication in another journal: implications for closing the credibility gap in reporting industry-sponsored clinical research
Neil Adams, *Nature Publishing Group*

The evolution of journals from print to enriched media: an assessment of journal digital characteristics
Samantha Collings, *KnowledgePoint360 Group*

Transparency in publications: reporting of funding, conflicts of interest and writing assistance – call for standardized declaration for reporting
Margaret Haugh, *MediCom Consult*

Trends in clinical trial publication in open-access journals
Jillian Gee, *MedThink SciCom*

Trends in the perception of industry-related medical publications
Kanaka Sridharan, *Novartis Pharmaceuticals Corporation*

Twitter hashtag usage at medical conferences: follow-up analysis
Kathryn Robinson, *MedThink SciCom*

Worldwide implementation of a publication planning and development policy
Joelle Urrutia, *Biogen Idec*

Encore Presentations (previously presented at the 2013 European Meeting of ISMPP)

Author attitudes to professional medical writing support
Jackie Marchington, *Caudex Medical*

Conference abstracts: do processes follow best practice?
Godfrey Lisk, *PAREXEL International*

How do we know if we are doing the right thing? Results of a survey to understand current "grey areas" in publication management
Andrea Cole, *Gardiner-Caldwell Communications*

How much do healthcare professionals know about GPP authorship criteria?*
Tom Rees, *PAREXEL International*

***Poster winner, Best Original Research, 2013 European Meeting of ISMPP**

Workshop Offerings

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

Prerequisite: *This workshop is appropriate for new entrants with less than 1 year in the field of strategic publication planning and implementation.*

The Pub Planning 101 workshop provides an interactive and instructive introduction to strategic publication planning. It includes didactic presentations tailored toward newly appointed planners in the pharmaceutical, biotech, and/or device industry, communication and publication agencies, publication support staff, publication writers and editors, and allied members of the publication planning team.

Learning Objectives

At the end of this workshop, attendees will:

- Understand the value and goals of effective publication planning
- Identify the major components of a strategic publication plan
- Be familiar with publication planning terminology and good publication practices
- Appreciate the importance and benefits of a collaborative team environment

Faculty

Kristyn Basile

*Division Lead, Scientific Solutions, UBC-Envision Group
ISMPP CMPP™*

Gregory Bezkorovainy, MA

*Vice-President, Scientific Services, Adelphi Communications
ISMPP CMPP™*

Johnathan C. Maher, PhD

Associate Director, Publication Planning & Medical Writing, Dendreon Corporation

Carol Sanes-Miller, MS

*Director, Scientific Content, Vision2Voice
ISMPP CMPP™*

Craig Smith

Senior Editor and Manager, Multimedia Publishing, Elsevier Ltd.

Publication Planning 201: Ethical and Regulatory Challenges: Optimizing Your Publication Process in the Age of Transparency (Monday only)

Prerequisite: *This introductory workshop is appropriate for those with a 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 workshop will consist of didactic and interactive sessions discussing the need for transparency in order to develop credible publications based on industry-sponsored clinical trials. The US and European laws governing registration and posting of results of clinical studies and their implications for publications will be explored. Best practices for presenting data in a balanced manner as well as guidance on authorship, the Physician Payment Sunshine Act, and corporate integrity agreements will be discussed. In addition, this workshop will help frame current FDA guidelines that regulate the discussion of publications with healthcare professionals. These practices assure consistency with recognized publication policies and guidelines; adherence to these standards can promote greater efficiency in achieving ethical publication goals

Learning Objectives

At the end of this workshop, attendees will:

- Be able to identify best ethical practices in achieving publication goals according to relevant laws and guidelines
- Know the key steps in working with authors and journals to ensure that Good Publication Practice 2 (GPP2) is followed
- Understand the need to keep up with constantly evolving laws and guidelines

Faculty

Jeffery E. Fletcher, PhD

*Publication Lead and Group Manager, US Publications, AstraZeneca LP
ISMPP CMPP™*

Sheelah Smith, PhD

Vice-President, Scientific and Editorial Services, PAREXEL



Publication Planning 301: Building a Strategy to Guide Your Plan (Monday only)

Prerequisite: This workshop is appropriate for those with at least 3 years of experience in publication planning.

This workshop is designed to help publication professionals better understand how to develop a publication strategy to ensure evidence-based, timely, and targeted publication of data to all key audiences. Many publication professionals find themselves focusing on tactics without a clearly defined 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 the emerging clinical results of your product. Throughout the workshop, attendees will be participating by sharing their ideas and experiences as publication professionals and will be asked to benchmark their practices against those of others in the group.

Learning Objectives

At the end of this workshop, attendees will:

- Understand the role of strategy in publication planning
- Understand key building blocks and components of a publication strategy
- 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 overall strategy and/or tactical plan

Faculty

Wil Glass, PhD

Senior Director, Publications Allergan Global Medical Affairs

Rick Lamb

President, Complete Publication Solutions, LLC

ISMPP CMPP™

Jorge Moreno-Cantu, MSc, PhD

Global Scientific and Medical Publications, Merck

ISMPP CMPP™

NEW THIS YEAR!



Alliance Partners: Effective Collaborations and Rules of Engagement (Monday only)

Prerequisite: This workshop is appropriate for those with at least 3 years of experience in publication planning or for those working in alliance partnership publication planning. Participants should have previously taken Publication Planning 101

This workshop is designed to provide publication planning professionals with an opportunity to discuss and develop a plan to better understand and navigate their alliance publication team relationships. In an alliance relationship, two or more publication teams from separate companies work together, resulting in a unique set of challenges. Often publication planning professionals find themselves struggling with company and cultural differences and publication planning goals that are not aligned between partners. Throughout this interactive workshop, different types of alliance structures will be reviewed and attendees will discuss case studies and experiences to recognize good practices that will help achieve more efficient communications and relationships with their publication partners.

Learning Objectives

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

- Understand the types of alliance partnerships, and the benefits and challenges of working within various types of alliance partnerships
- Assess the process and communication needs for their publications alliance partnership
- Start drafting a preliminary charter and/or rules of engagement for consideration within their company and with a collaborative partner

Faculty

Dheepa Chari, MS

Assoc. Director, Scientific Communications, Novartis
ISMPP CMPP™

Tricia Deja, PharmD

Associate Publications Director, Astellas
ISMPP CMPP™

Jodie Gillon, MPH

Director, Publications Management Team, Pfizer

Donna Simcoe, MS, MBA

Director, Publications and Medical Information, Cadence Pharmaceuticals
ISMPP CMPP™

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Publication Planning in the Asia-Pacific Region (Wednesday only)

Prerequisite: This workshop is appropriate for individuals who currently or expect to manage publication activities in Asia-Pacific (AP) region or interact with authors from this area.

The growing demand of publication management in this region calls for involvement and support from publication managers worldwide. Publication management in this diverse area is not an easy task. ISMPP leaders with extensive experience in the region will share their experiences and insights in developing a team of publication managers and working with authors to improve publication planning in the region.

Participants will be encouraged to share their experiences of working with individuals in the AP region and suggest innovative ways to best achieve collaboration.

Learning objectives

At the end of this workshop, attendees will:

- Understand the characteristics of publication practice in the AP region
- Know how to form teams with local authors and managers, and support the local champions in publication practice
- Be able to apply updated publication management skills and principles to an AP regional team

Faculty

Philippa J. Benson, PhD

President and Owner, PJB Consulting, LLC

Donald Samulack, PhD

President, US Operations, Cactus Communications, Inc.

Aya Takemoto Tokaji

*Director, Medical Communication Department, Statcom Co., Ltd., Tokyo, Japan
ISMPP CMPP™*



Comparative Effectiveness Research, Health Economics and Outcomes Research: Their Growing Importance and Implications for Publications (Monday only)

Prerequisite: This workshop is appropriate for publication professionals with at least 2 years of experience in publication planning and those developing publication plans/policies/processes across these disciplines.

Comparative effectiveness research (CER) is becoming an increasingly important component of medical publication strategy. The goal of CER is to help increase quality and decrease costs of healthcare by providing stakeholders with evidence on the relative value of interventions in broad and diverse populations, and in routine settings of care – in brief, to identify what works best for which patients under which circumstances. CER encompasses health economics and outcomes research (HEOR) and diverse study designs and methods. By integrating CER/HEOR into an overall publication strategy, publication professionals can complement core scientific and clinical publications and strengthen a product's evidence base for medical decision makers.

Learning objectives

At the end of this workshop, attendees will:

- Understand the terms encompassed by CER
- Understand trends driving CER/HEOR
- Understand the benefits that a publications department can offer to an internal HEOR group
- Be familiar with different types of CER/HEOR studies and study designs and their relationship to product life cycle
- Know the stakeholders involved in and the target audiences/venues for CER/HEOR publications

Faculty

Shontelle Dodson, PharmD

Senior Director, Head Health Economics & Clinical Outcomes Research, Astellas Pharma

Kirtida Pandya, PharmD

Associate Director, Medical Communications, Novartis
ISMPP CMPP™

The Joy of Gap Analysis (Monday only)

Prerequisite: *This 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, including considerations of appropriate source material, assessment of the findings, and discussions on 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.

Learning Objectives

At the end of this workshop, attendees will:

- Define what a gap analysis is and the purpose of conducting one
- Understand how to conduct a gap analysis that will provide meaningful results
- Learn the potential ways that a gap analysis can go astray
- Describe how to use the information learned from the gap analysis

Faculty

Thomas Gegeny, MS, ELS

*Team Lead, Envision Scientific Solutions, Inc., UBC-Envision Group
ISMPP CMPP™*

Paul O'Grady, PhD

Senior Director, Scientific Communications, Novartis Oncology



Global Publication Planning: Issues and Challenges (Monday and Wednesday)

Prerequisite: *This workshop is appropriate 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 are fraught with challenges. These challenges are increased when working with multiple regions, sometimes with partner companies, with different requirements regarding the timing of publications, or with the need to address different regulatory situations. In addition, national activities and global-to-local coordination efforts make the publication planner's decision-making process even more complex. Facilitated by representatives from industry 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 obtain advice on issues they are currently facing through an anonymous submission process that will allow their cases to be discussed without disclosing confidential information.

Learning Objectives

At the end of this workshop, attendees will:

- Know the guidelines and considerations affecting publications in major world markets
- Understand who the stakeholders are of global publication plans
- Be conversant in the issues affecting global publication planning and tactical execution
- Be knowledgeable of the best practices for planning globally with a partner biopharmaceutical company
- Be able to negotiate the challenges of working with multiple regions and different regulatory situations

Faculty

Sarah L. Feeny, BMedSc

*Head of Scientific Direction, Complete Medical Communications
ISMPP CMPP™*

John Gonzalez, PhD

Director of Publications Policy, AstraZeneca

Teresa Peña, PhD, CQE

Global Director, Clinical Publications, AstraZeneca



HEOR: What Constitutes a Good Health Outcomes Manuscript? (Wednesday only)

Prerequisite: This workshop is appropriate for individuals with 3 years of publication planning and/or writing experience, including 1 year of working with HEOR publications or having attended a HEOR workshop.

This highly interactive workshop is designed to educate participants on specific aspects of creating high-quality HEOR manuscripts, and to provide insight into the effective interpretation and communication of HEOR data. An initial didactic presentation will elaborate on the basic vocabulary and define the elements of a good HEOR publication, followed by breakout groups evaluating examples of well- and poorly-written HEOR publications, focusing on the presence or absence of essential elements. The breakout groups then will present to the whole group in the final discussion period.

Learning Objectives

At the end of this workshop, attendees will:

- Know the components of a high-quality HEOR manuscript
- Be familiar with health outcomes trends
- Understand the implications of HEOR with respect to publication planning

Faculty

Christopher Carswell, MSc, MRPharmS

Editor, Pharmacoeconomics

Keith Evans, PhD

Director, Global Health Outcomes, inScience Communications

NEW THIS YEAR!



Managing Manuscript Challenges and Journal Processes: Pharma, Agency, and Publisher Perspectives (Monday only)

Prerequisite: This workshop is appropriate for individuals in pharma/biotech/device companies, agencies, and publishers who have at least 3 years of experience in the field of publication planning and implementation.

It is becoming increasingly challenging to publish industry-sponsored research. Among the issues are health care compliance laws, concerns about ghost-writing, and the Sunshine Act. These challenges have not only affected how the pharma/biotech/device industry operates, they have also affected the agencies that work with these industries to develop manuscripts, and the publishers who publish them. What does this mean for the future of industry-sponsored research publications, and what are the consequences for stakeholders (Pharma, Agency, or Publisher)? How do we continue to be productive in these uncertain times while maintaining high standards for our profession? In an interactive session, our panelists will present different scenarios for resolving conflicts among the stakeholders and suggest ways in which we can ensure continued support of industry-sponsored research publications.

Learning objectives:

At the end of this workshop, attendees will:

- Understand the challenges currently faced by Pharma, Agency, and Publisher regarding industry-sponsored research publications
- Recognize and describe the conflicts among the stakeholders
- Identify what individuals and their businesses might need to do to secure the future of industry-sponsored research publications

Faculty

Namit Ghildyal, PhD

Associate Director Publications (Oncology), Janssen Research & Development, LLC

Terry Materese

Executive Publisher, Health and Medical Sciences, Elsevier

Ken Youngren, PhD

Scientific Director, PAREXEL

Metrics: Practical Applications and Experiences

(Wednesday only)

Prerequisite: *This workshop is appropriate for those with a basic understanding of publication planning, including the manuscript development process, review and approval processes, prioritizing publication activities and resources, and post-publication reach. Participants should have 1-2 years of experience in a publication planning role.*

The goal of this interactive workshop is to provide a foundation for identifying appropriate metrics of success and identifying gaps consistent with publication plan objectives, data availability, and resources. In addition, newer metrics that are evolving with changes in the publication landscape, such as page views and article downloads based on online publication activities, will be discussed. This year's workshop offers an open forum format with discussions around 3 perspectives related to publication metrics: pharma industry, medical communication agency, and publishing group. The goal is to learn from one another and obtain relevant input. Metrics vary considerably in their value to different stakeholders and this session is designed to explore them and to provide participants with useful options and insights, as there is no one universal metric that applies to all situations.

Learning Objectives:

At the end of this workshop, attendees will:

- Understand the process of developing publication plan metrics
- Review and discuss various types of publication metrics
- Participate in an open forum discussion designed to address the needs of each participant

Faculty

Neil Adams

Publishing Manager, Nature Publishing Group

Bhakti Kshatriya, PharmD

Global Scientific Communications, Novartis Oncology

Kevin Ryder, PhD

Senior Vice President, Clinical Content and Editorial Services, Complete Healthcare Communications

Publication Planning and Management at Smaller Pharmaceutical/Biotechnology Companies

(Wednesday only)

Prerequisite: *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.*

At smaller companies, publication managers may be faced with generating a new publication function that will integrate publication processes and guidelines into the existing company structure. Publication managers may have limited publication budgets and/or resources and may need to perform multiple functional roles beyond publication management. In addition, the publication manager may be required to establish new processes and policies with cross-functional agreement and in doing so, demonstrate the internal value of ethical publication practices and medical writing support. This workshop will consist of didactic and interactive sessions discussing the challenges of publication management at smaller pharmaceutical or biotechnology companies. During the workshop, faculty and participants will discuss how a publication manager maintains a cohesive publication plan in light of employing external medical writers or an agency, which may be a new process for some companies. The need for cost effective, innovative, and flexible publication plans and processes that are aimed at leveraging the internal knowledge base will be explored.

Learning Objectives

At the end of this workshop, attendees will:

- Be able to identify the resource constraints of publication management at smaller companies and learn how to best utilize existing resources
- Understand how to create effective and efficient publication policies and procedures that address the challenges of publication management at smaller companies

Faculty

Kelly Reith, MS, MBA

Director, Scientific Publications and HEOR Management, Incyte Corporation

Donna Simcoe, MS, MBA

*Director, Publications and Medical Information, Cadence Pharmaceuticals
ISMPP CMPP™*

Mindy Yang, PharmD

Director, Medical Education & Publications, NPS Pharmaceuticals



Ethics in Publications Practice: Authorship – ICMJE and Beyond (Monday only)

Prerequisite: *This workshop is appropriate for publication professionals with at least 2 years of experience in development of publications, although professionals at all levels are welcome.*

The issue of who is an author and who is not is becoming increasingly problematic, especially when the ICMJE guidelines do not provide specific guidance. This workshop will provide an interactive and instructive environment for participants to discuss the issues involved with authorship that go beyond the ICMJE guidelines, using real-world case studies to explore ethics, potential solutions, consequences, and potential precedents.

Learning Objectives

At the end of this workshop, attendees will:

- Thoroughly understand ICMJE guidelines and the fact that they do not address all authorship situations
- Explore related ethical considerations and practical options available in these situations
- Discuss potential solutions and what resources are needed to achieve them
- Understand their individual role in achieving consensus and implementing solutions to ethical challenges around authorship

Faculty

Robert Lersch, PhD

Deputy Director Publications, Global Medical Affairs, Sanofi Pasteur

Mukund Nori, PhD, MBA

*Senior Medical Writer, UBC-Envision Group
ISMPP CMPP™*

Evolution of Publications from Print to New Media

(Wednesday only)

Prerequisite: *This workshop is appropriate for individuals in pharma/biotech/device companies, publication agencies, and publishers who have at least 3 years of experience in the field of publication planning and implementation.*

This interactive workshop is designed to explore the types of new media that are available to enhance publications and to identify the best practices for implementation. Attendees will discuss measures to ensure that enhanced media maintain the scientific integrity of the publications. Real-life case studies will be presented from various perspectives, and the role that social media plays in publications will be discussed. Processes will be shared to show how to merge the utilization of new media with publications and how partnering with agencies and publishers to create a solution can meet the needs of all parties. The session will also explore how metrics can be collected and used to validate the utilization of new media. Participants will be encouraged to share their experiences and help define a better process.

Learning objectives

At the end of this workshop, attendees will:

- Know the various types of new media available to accompany/enhance publications
- Understand the measures used to ensure scientific integrity and appropriate presentation of content
- Explore processes used to develop new media for publications
- Learn how new media can affect metrics
- Apply learnings to identify media for use with their publications

Faculty

Grahame Conibear, BSc

Senior VP, Integrated Communications, Adelphi Communications

Laverne Mooney, MPH, DrPH

Director, Publications Management, Pfizer

Kurt Polesky

Business Development Manager, Wiley-Blackwell

Catherine Skobe, MT (ASCP), MPH

Director, Publications Management Team, Pfizer



Mechanisms Behind a Systematic Review: Applying the PRISMA Statement (Monday only)

Prerequisites: This workshop is appropriate for individuals in pharma/biotech/device companies or in communications agencies who have a basic awareness of publication planning (topics covered in Pub Planning 101 and 201) and at least 2 years of experience in the field of publication planning and implementation

Designed for publication planners, medical writers, medical editors, and journal editors with an interest in or responsibility for preparing or evaluating a systematic review, this workshop provides an in-depth review of the PRISMA guidelines, with a step-by-step presentation guiding participants through the preparation of a systematic review. From the first steps of selecting a topic and conducting literature searches through applying study selection criteria and presenting results, this workshop explores each step of the writing process and how to interpret PRISMA guidelines throughout the review. Workshop leaders will also conduct an interactive discussion using sample systematic reviews to determine which papers best adhere to the PRISMA guidelines, which fall short, and which have the best chance of surviving a journal's peer-review process.

Learning Objectives

At the end of this workshop, attendees will:

- Define the differences between traditional and systematic reviews
- Understand the PRISMA guidelines and how to apply them to a systematic review
- Be able to write, edit, or evaluate a systematic review, ensuring that it adheres to the PRISMA guidelines

Faculty

Christopher Carswell, MSc, MRPharmS

Editor, *Pharmacoeconomics*, *Adis Journals*

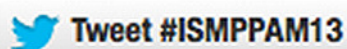
Teri O'Neill

Executive Managing Editor, *Peloton Advantage*

GET THE MOST OUT OF THE 9TH ANNUAL MEETING OF ISMPP

Wish there was a way to capture and share with your colleagues some of the most important takeaways from the 9th Annual Meeting of ISMPP? ISMPP will once again record brief interviews with key faculty, ISMPP leadership and other relevant volunteers and thought-leaders through the INN (ISMPP News Network). Videos will be posted on the ISMPP YouTube Channel throughout the Meeting for you to review and share with your colleagues. To access, visit www.ismpp.org and click on the YouTube icon at the bottom of the page.

ISMPP would like to recognize and thank MedThink SciCom for their continued support of the INN.



ISMPP will be “Tweeting” in real time from the meeting. Hear about exciting events as they happen! Follow ISMPP on Twitter at #ISMPPAM13.

Media Partners



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PharmaVOICE magazine, reaching more than 29,000 BPA-qualified life-sciences executives, is the forum that allows business leaders to engage in a candid dialogue on the challenges and trends impacting the industry. PharmaVOICE provides readers with insightful and thought-provoking commentary in a multiple-perspective format through forums, topics, and articles covering a range of issues from molecule through market. PharmaVOICE subscribers are also kept abreast of the latest trends and information through additional media resources, including WebLinx Interactive WebSeminars, Podcasts, Videocasts, White Papers, E-Surveys and e-Alerts. Additionally, PharmaVOICEMarketplace.com provides a comprehensive directory of products, services, and solutions for the life-sciences industry.

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Many of this year's meeting presentations and workshops qualify for CMPP continuing education credits. Be sure to check the program contained herein, and the ISMPP meeting app, for the full constellation of qualified presentations, denoted with the CMPP recertification credit icon ().

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

On behalf of ISMPP, we would like to express our sincere appreciation to the Program, Abstract, and Global Workshop Committees as well as those who provided meeting support, for an outstanding 9th Annual Meeting.

Program Committee

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ISMPP would like to thank its dedicated staff for their contributions to the 9th Annual Meeting of ISMPP and also acknowledge the contributions from the Creative Department at MedErgy HealthGroup for graphic support and project coordination of all design pieces associated with the Meeting.

**See you at next year's 10th Annual Meeting of ISMPP –
April 7-9, 2014, Arlington, VA, USA**



To view presentations from the 9th Annual Meeting of ISMPP,
visit www.ismpp.org.

Artwork and design provided by **MedErgy**
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