

2011 EUROPEAN MEETING OF ISMPP

TRENDS, TRANSPARENCY AND TRUST: FROM INSIGHTS TO ACTION

15–16 NOVEMBER 2011

ALDERLEY PARK CONFERENCE CENTRE

ALDERLEY PARK, CHESHIRE, UK




DEAR COLLEAGUES

It is with great pleasure that ISMPP welcomes you to the 2011 European Meeting, 'TRENDS, TRANSPARENCY AND TRUST: FROM INSIGHTS TO ACTION'. The meeting content addresses many of the key challenges we face as medical publication professionals and provides solutions that we can integrate into our daily practice.

We would like to extend a warm welcome to our keynote presenters. Andrew Powrie-Smith, Director of the Association of the British Pharmaceutical Industry (ABPI) Scotland and the UK ABPI Trust Imperative Lead, will share his perspectives on the dominance of compliance in publication planning and delivery. Dr Ben Goldacre, best-selling author, broadcaster, medical doctor, academic, and author of the 'Bad Science' column in *The Guardian*, will engage us with his thoughts on medical publication in the current environment. Additional faculty includes representatives from several renowned medical journals, including *The Lancet*, *British Journal of Haematology* and the BioMed Central journals, who will be joining representatives from industry, medical publications and communications agencies, and publishing, through didactic and panel presentations.

In addition to attending the important educational offerings, please be sure to visit our exhibits and participate in the ever-exciting networking opportunities available over the course of the meeting.

Reminder: Several of the pre-conference workshops and general session presentations qualify for continuing education credits that can be used towards the fulfilment of your CMPP recertification. Check the programme for those courses marked with 

On behalf of ISMPP, welcome!

Yours sincerely,



Robert J Matheis, PhD

*Director, Medical Communications
Evidence Based Medicine
Sanofi
ISMPP President (2011–2012)
ISMPP CMPP™*





Sarah L Feeny, BMedSci

*Head of Scientific Direction
Complete Medical Communications
ISMPP 2011 European Meeting
Programme Committee Chair
ISMPP CMPP™*

PROGRAMME AGENDA

Tuesday, 15 November 2011

8:00–8:30	Registration for pre-conference workshops
8:30–10:00	Pre-conference workshops
10:00–10:30	Morning break
10:30–12:00	Pre-conference workshops (continued)
12:00–13:00	Lunch for workshop attendees, speakers and exhibitors only; general session registration
13:00–13:15	Opening remarks Robert J Matheis , PhD, President, ISMPP, 2011–2012
Session one	2011 annual review Session moderator: Arjen PP van Willigenburg , MSc, CMPP™, Managing Director, Complete Healthcare Communications Europe
<p>We all try to keep track of the developments in our field, but are probably able to read only half of the stories that hit the news and have almost certainly missed some of the key ones. In this opening session we will present and comment on a selection of the highlights of events that have occurred during 2011. Naturally we expect to get your feedback, and maybe you will even fill us in on things that we may have missed! In this session you will also hear about the latest developments on the European Clinical Trial Register (EudraCT) and what this register means for your day-to-day work.</p> <p>By the end of this session attendees will:</p> <ul style="list-style-type: none"> • Be able to put into perspective the most important developments in our field in 2011 • Have a refreshed and new understanding of what EudraCT version 8 is about and identify those elements that are of relevance to our discipline • Gain an understanding on how to deal with the requirements and work related to the development of trial registries such as EudraCT 	
13:15–14:00	What has 2011 given us in the medical publication planning field? Angela Cairns , BSc, CMPP™, Senior Vice President Medical & Scientific Services and Global Compliance Team Leader, KnowledgePoint360 Group
14:00–14:30	EudraCT update  Ana Rodriguez , PhD, Head of Clinical and Non-clinical Compliance, Compliance and Inspection, European Medicines Agency
14:30–15:00	EudraCT for publication planners: the good, the bad and the ugly  Susan Scott , PhD, Director of Publications and Communications, Ipsen BioPharm
15:00–15:15	Audience poll and discussion of results
15:15–15:45	Afternoon break and visit exhibits

Session two**Ethics and compliance in publications**

Session moderator: **John Gonzalez**, PhD, Director of Publications Policy, AstraZeneca

Patients benefit from the industry and medical professionals working together to tackle healthcare problems; however, this requires trust between the parties. The ABPI routinely commissions research focused on the issues that stakeholders see as important in their interactions with industry. We will hear what this research tells us about the reputation of the industry and what this means for the work done by medical publication professionals. Also in this session, our multidisciplinary panel will discuss real-life compliance-related cases. Whether it is authorship and acknowledgements or disclosures and conflict of interest, this session will provide valuable insight into how to approach common and not-so-common issues and achieve appropriate ethical outcomes.

By the end of this session attendees will:

- Understand the importance of trust and reputation within our industry
 - Gain insight into the types of compliance issues that they may face and how to address these
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15:45–16:30 **Keynote presentation:** The how and why of trust and reputation, and what it means for publication planning and delivery



Andy Powrie-Smith, Director, Association of the British Pharmaceutical Industry, Scotland ABPI Trust Initiative

16:30–17:20 Panel and audience discussion: compliance in practice

Ann-Marie Cavanagh, Senior Clinical Communications Leader, Novartis Pharmaceuticals

Leighton Chipperfield, Publishing Director, Elsevier

Trevor Fitzpatrick, Vice President, PAREXEL

Stuart Spencer, PhD, Executive Editor, *The Lancet*

17:20–17:30 Closing remarks

17:30–20:00 ISMPP poster assembly and evening networking reception

Wednesday, 16 November 2011

7:00–8:00 Registration and continental breakfast

8:00–8:10 Welcome back!

Session three**The Editor's panel: a peek behind the Editor's door**

Session moderator: **Keith Veitch**, PhD, Head of Global Publications, Novartis Vaccines

In this interactive discussion session we are joined by editors who regularly publish medical research; they will be on the stage to answer your questions. In particular, panel members will be asked to reveal the ethical issues that concern them most and debate what new approaches should be adopted to overcome these challenges, including how professional publication managers can support the process. Panel members will also be asked to share with the audience how peer review and publication processes might evolve in the near future.

By the end of this session attendees will:

- Understand the ethical challenges in the publication of medical research that are of greatest concern for editors
 - Become familiar with the various approaches that are being adopted by editors to ensure the ethical publication of medical research
 - Gain an appreciation of how medical publishing models may evolve in the future
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8:10–9:30	<p>Finbarr Cotter, MB, BS, FRCP(UK), FRCPPath, PhD, Editor-in-Chief, <i>British Journal of Haematology</i></p> <p>Jay Magrann, VP & Director, Product Solutions, Informa Healthcare</p> <p>Gordon Mallarkey, PhD, Managing Editor, <i>Therapeutics Advances</i>, SAGE Publications Ltd</p> <p>Jigisha Patel, MRCP, PhD, Series Editor – Medicine, BioMed Central</p> <p>Stuart Spencer, PhD, Executive Editor, <i>The Lancet</i></p>
9:30–10:00	Morning break and visit exhibits
Session four	<p><i>Understanding our critics and being advocates</i></p> <p>Session moderator: Sarah L Feeny, BMedSci, CMPP™, Head of Scientific Direction, Complete Medical Communications</p>
<p>This year has seen articles on medical ghostwriting and publication bias in the lay press across the globe – Europe, USA, Canada, Australia and New Zealand. Some of these reports describe activities that happened several years ago; others are more recent experiences. Dr Ben Goldacre, a medically qualified doctor who has written the weekly ‘Bad Science’ column in <i>The Guardian</i> newspaper in the UK since 2003, explains why items that medical publishing professionals often do not consider ‘new’ are still making the news. Also in this session, our panel (composed of individuals who have been involved in advocating good publication practices, either as individuals, within ISMPP or within other organisations) will highlight what has been achieved so far and in what areas more effort and impact are needed.</p> <p>By the end of this session attendees will:</p> <ul style="list-style-type: none"> • Gain insight into some of the issues that critics of medical publishing practices believe are still to be addressed • Understand what has already been achieved by individuals and organisations in advocating good publication practices • Have practical ideas of what they could do as individuals and within companies and organisations to further improve publication practices and ultimately to eradicate unethical publication practices totally 	
10:00–10:50	<p>Keynote presentation: What makes news?</p> <p>Dr Ben Goldacre, <i>The Guardian</i> newspaper and author of ‘Bad Science’</p>
10:50–12:00	<p>ISMPP and advocacy: current status and ideas for Europe</p> <p>Francis P Crawley, PhL, Executive Director, Good Clinical Practice Alliance – Europe</p> <p>Adam Jacobs, MSc, PhD, FICR, Director, Dianthus Medical</p> <p>Tom Grant, PhD, Publications Director, AstraZeneca</p> <p>Stephanie Tortell, BSc, Client Services Director, Complete Medical Communications</p> <p>Ryan Woodrow, BSc, Scientific Director, Woodrow Medical Communications</p>
12:00–13:00	Lunch
Special presentation	
13:00–14:00	<p>Publishing data on OTC and consumer products: providing evidence and expelling the myths</p> <p>David A Mays, PharmD, MBA, Johnson & Johnson Consumer & Personal Products Worldwide Director, Global Scientific Engagement – Baby</p>

The practice of evidence-based medicine calls for the integration of rigorously derived scientific data and sound clinical judgment. As medical publication professionals, we strive to provide these data for prescription products to healthcare practitioners to support their practice approach. But what about OTC and consumer products? Literature searches reveal only a minimal number of peer-reviewed publications on their safety and efficacy. So how do clinicians make decisions regarding which to recommend, how does the dearth of published data affect those decisions, and what can we as medical publication professionals do to help?

At the end of this session attendees will:

- Understand the need for peer-reviewed literature in the OTC and consumer product arena
- Be familiar with where the unpublished data reside
- Recognise the stakeholders who need this information

14:00–14:30 Afternoon break and visit exhibits

Session five *Developments in on-line publishing and implications for publication professionals*

Session moderator: **Holger J Gellermann**, MD, Head Global Scientific Affairs, Boehringer Ingelheim Pharma GmbH & Co KG

Recent innovations in technology have provided new ways to publish, evaluate, consume and share scientific content. Selecting a publication medium now requires a more complex consideration of the article's treatment before and after publication. This session will explore some of the trends, successes and failures in on-line publishing including funding models, discovery, accessibility, pre- and post-publication evaluation, measures of impact and methods of consumption by healthcare professionals.

At the end of this session attendees will:

- Understand current trends in on-line publishing
- Be familiar with methods of evaluating on-line publications
- Be conversant in metrics associated with on-line publications

14:30–15:10 Publishing model diversity and on-line community judgement: what are we gaining?

Vitek Tracz, Chairman, Science Navigation Group

15:10–15:55 Consumption of articles in the digital age

Daniel Pollock, Associate Director, Nature Publishing Group



15:55–16:00 Closing remarks and meeting adjourns

WORKSHOP DESCRIPTIONS

Pub Planning 201: Ethical and regulatory challenges: optimising your publication process in the age of transparency

Prerequisite: This 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 will be discussed. In addition, this workshop will help frame current guidelines that regulate the discussion of publications with healthcare professionals. These practices ensure consistency with recognised 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 following 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

Workshop faculty

John Gonzalez

Director of Publications Policy, AstraZeneca

Sheelah Smith

Vice President, Scientific and Editorial Services, PAREXEL

Pub Planning 301: building a strategy to guide your medical publication plan*



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

This workshop focuses on the role and key building blocks of strategy in publication planning. It will cover the components of a strong strategy; the interface between brand, clinical and publication strategies; the challenges of working within alliances; and the role of publication steering committees. The workshop also includes how to manage issues and overcome barriers associated with publishing terminated trials and negative data.

The workshop is strongly interactive, and active participation in the discussions is encouraged. Throughout the workshop, attendees will be participating by sharing their ideas and experiences as publication professionals and will be asked to benchmark their experience and practices against those of others in the group.

Learning objectives

At the end of this workshop, attendees will:

- Understand the role and key components of a publication strategy
- Clarify the interface between the brand, clinical and publication strategies
- Recognise the differences between strategic and tactical plans
- Identify what makes a strong strategy
- Identify external factors that might require changes to the tactical plan

Workshop faculty

Farah Dunlop

Manager, Publications, Ipsen Biopharm

Bryce McMurray

General Manager, UK & N EU, Wolters Kluwer Pharma Solutions

Magdy Fahmy

Vice-President, Gardiner-Caldwell Communications

*Please note that both the Publication Planning 301 and Global Publication Planning workshops will be held from 08:30 to 12:00 at Mottram Hall. Continental breakfast and refreshment breaks will be provided to delegates attending these programmes, as well as transport to the Alderley Park Conference Centre following their conclusion.

Global Pub Planning: issues and challenges in global publication planning*



Prerequisite: This half-day interactive workshop based on a series of real-life scenarios is designed for experienced publication planning professionals with an interest in or responsibility for publication planning and tactical execution at a global level.

Delivering publication outputs and ensuring compliance with good publication practice are fraught with everyday challenges. These challenges are increased when working with multiple regions, sometimes with partner companies, or with different requirements regarding the timing of publications or the need to address different regulatory situations. In addition, national activities and the need for global-to-local coordination efforts make the publication planner's decision-making even more complex.

Facilitated by representatives from pharmaceutical companies and medical communications agencies, this interactive workshop provides an overview of considerations in global publication planning and delivery, as well as the opportunity to work in small groups to discuss how to handle a series of real-life scenarios. Attendees will also be able to 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 for global publication plans
- Be conversant in the issues affecting global publication planning and tactical execution
- Be knowledgeable in 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

Workshop faculty

Catherine Bégard

Director – Global Head of Publications, UCB

Jane Nunn

Head of Editorial and Scientific Services,
Complete HealthVizion

*Please note that both the Publication Planning 301 and Global Publication Planning workshops will be held from 08:30 to 12:00 at Mottram Hall. Continental breakfast and refreshment breaks will be provided to delegates attending these programmes, as well as transport to the Alderley Park Conference Centre following their conclusion.

The joy of gap analysis

Prerequisite: This half-day workshop is appropriate for individuals with all levels of strategic publication planning and implementation experience who are interested in conducting a gap analysis.

Using an interactive format, workshop leaders will guide participants through the process of conducting a gap analysis, 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 information sources.

Learning objectives

At the end of this workshop, attendees will:

- Define a gap analysis 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 gained from a gap analysis

Workshop faculty

Russell Traynor

Director, UBC-Envision Group
President Elect, ISMPP, 2011–2012

Neil Baker

Division Lead, UBC-Envision Group

HEOR: What constitutes a good health outcomes manuscript?



Prerequisite: This workshop is intended for individuals with at least 3 years of publication planning and/or writing experience, including 1 year of working with health economics and outcomes research (HEOR) publications or having attended a HEOR workshop.

This will be a highly interactive workshop, designed to educate ISMPP members on more specific aspects of creating high-quality HEOR manuscripts, and to help them gain more insight into the effective interpretation and communication of health economic outcomes data. An initial didactic presentation will elaborate on the basic vocabulary and define the elements of a good HEOR publication, which will be followed by breakout groups evaluating examples of well and poorly written HEOR publications, especially pointing out the presence or absence of essential elements. The breakout groups will then 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

Workshop faculty

Keith Evans

Director, Global Health Outcomes, inScience Communications

Alan Lyles

Henry A Rosenberg Professor of Public, Private and Nonprofit Partnerships, University of Baltimore, USA

Docent of Pharmaceutical Policy and Pharmacoeconomics, University of Helsinki, Finland

Adjunct Faculty, Johns Hopkins Bloomberg School of Public Health, USA

2011 EUROPEAN MEETING OF ISMPP EXHIBITORS AND SPONSORS

ISMPP would like to express its sincere appreciation to the exhibitors and/or sponsors for the 2011 European Meeting of ISMPP.



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On behalf of ISMPP, we would like to express our sincere appreciation to the European Programme Committee for an outstanding meeting.

Catherine Bégard
Sarah L Feeny (Chair)
John Gonzalez
Janet Johnson
Bejal Joshi
Fiona Matheson
Laura McGovern

Jane Nunn
Iain Spray
Kirstin Stricker
Russell Traynor
Remon Van Den Broek
Arjen PP van Willigenburg
Keith Veitch

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Michele Kantrowitz
Sue Marek
Kim Pepitone

Finally, ISMPP would like to thank the following people for editorial support.

Lisa Baker
Jean Barilla
Todd Parker
Kimberly Pfleeger
Anca Serban

See you at the 8th Annual Meeting of ISMPP! April 23–25, 2012, Baltimore, Maryland, USA

Note: Speakers and agenda are subject to change without notice. In the event of a speaker cancellation, every effort will be made to find a suitable replacement.

DISCLAIMER: The opinions of the faculty are their own and do not necessarily reflect those of the companies they represent or the International Society for Medical Publication Professionals.