2013 EUROPEAN MEETING OF ISMPP

DOING THE RIGHT THING AND DOING THINGS RIGHT

22 - 23 JANUARY 2013

200 ALDERSGATE

ST PAUL'S, LONDON, UK

ISMPP International Society for Medical Publication Professionals™

Dear Colleagues

It is with immense pleasure that ISMPP presents the full programme for the 2013 European Meeting, 'DOING THE RIGHT THING AND DOING THINGS RIGHT.'

It is increasingly important that as medical publication professionals we not only work within current guidelines but also strive to improve the regulatory framework to ensure that the industry's reputation for 'doing the right thing' continues to improve. The five main sessions of the European meeting will address many of the key challenges we face as medical publication professionals and provide practical solutions to help ensure that we are 'doing things right' on a day-to-day basis:

1. a review of global insights and trends from 2012 and how these will impact our profession in the year ahead;
2. an opportunity to discuss best practices in compliance and tackle some of the difficult questions that we face on a day-to-day basis;
3. an insight into the role of payors and what they need in terms of an evidence base to help them in their decision making;
4. a chance to meet Editors from a variety of journals and have informal discussions on a range of topics;
5. a thought-provoking view of how bright the future is for the publication planning profession

We will also have a poster presentation session based on research-focused abstracts that will have been reviewed and approved by a committee of your peers, and of course you will have extensive opportunities to ask our expert faculty questions and network with your peers. Additionally, we will be running a series of pre-conference workshops; these, as well as a number of the general session presentations, will qualify for continuing education credits that can be used toward the fulfilment of your CMPP certification.

We look forward to welcoming you to what promises to be an informative, interactive and inspiring meeting.

Yours sincerely

Russell Traynor, ISMPP CMPP™
Chair, ISMPP Board of Trustees
(2012-2013)

Jane Nunn, PhD, ISMPP CMPP™
Chair, European Programme Committee

PROGRAMME AGENDA

Tuesday, 22 January 2013

*Pre-conference workshops: please refer to the workshop schedule and descriptions starting on page 9; workshop descriptions that contain the CMPP credit logo qualify for CMPP continuing education credit hours

MORNING

08:30 – 09:00	Registration for pre-conference workshops
09:00 – 10:30	Pre-conference workshops*
10:30 – 11:00	Morning break
11:00 – 12:30	Pre-conference workshops (continued)
12:30 – 13:30	Lunch for workshop attendees, speakers and exhibitors only; general session registration

AFTERNOON

13:30 – 13:45

Welcome to the 2013 European Meeting of ISMPP

Jane Nunn, PhD, CMPP™
Chair, European Programme Committee

Kim Goldin
Senior Director of Operations and General Manager, ISMPP

13:45 – 15:15

2012 Global Insights and Trends

This session qualifies for 1.5 CMPP Recertification Credits.

Apart from a Diamond Jubilee and Olympic Games, 2012 might be viewed similarly to recent years and certainly for medical publications, as the usual topics and themes continued to figure in the headlines. However, what was new was that certain issues / events were described as a "watershed", and will have a profound impact on our profession, such as The Physician Sunshine Act and its associated "transfer of value"; clinical study data transparency; the "academic spring" - calls for mandatory open access publishing of data; and legal remedies for alleged ghost-writing practices. In addition, Corporate Integrity Agreements continued to be issued with even more stringent operating conditions and clauses; furthermore fiscal constraints, austerity and the proliferation of procurement processes remorselessly impacted industry, publishers and agencies alike. But there was some respite, with plenty of positive activities relating to trust and transparency: ISMPP continued to grow in strength and influence; the Medical Publishing Insights and Practice (MPIP) initiative published a position paper with recommendations to help close the credibility gap in the reporting of industry-sponsored research; and leading UK healthcare organisations developed a document to support best practice in transparency / publication of data from clinical studies. All of this and more will be covered, so if for some reason you missed out on the key influencers of 2012, this session will bring you right up to date.

Learning objectives:

- To recognise the key events and developments of 2012 that medical publications professionals in industry, agencies and publishing should be aware of
- To understand that many of these changes will affect the profession in 2013 and how their working practices might need to be adjusted

Session moderator:
Martin Delahunty, MBA
Associate Director, Academic Journals and Pharma Solutions, Nature Publishing Group

Speakers:
Martin Delahunty, MBA
Associate Director, Academic Journals & Pharma Solutions, Nature Publishing Group

Elif Fincanci-Smith
Director, Scientific Services, Darwin Healthcare Communications

Anna-Lisa Fisher, DPhil
Director, EuroMed Consulting Ltd

15:15–15:45	Afternoon break and visit exhibits
15:45–17:15	**Compliance in practice: Publication planning and execution**

This session qualifies for 1.5 CMPP Recertification Credits.

The pharmaceutical industry is painted as being a for-profit and "never mind the cost" industry; drugs are considered expensive in comparison with their actual manufacturing costs, exemplified by the belief that generic versions can be brought to market at much lower cost. Similarly, publication professionals have often been portrayed as generators of positive propaganda for the industry, emphasising the positive messaging whilst ignoring the hidden side-effects or harms caused by pharmaceutical products. Although there are widely accepted guidelines of what good publication practice should look like, there is no standard approach on how to implement these in-house or guidelines on how we should measure compliance against them.

In this session, the audience will be challenged to consider the important role fulfilled by publication professionals and the symbiotic relationship between pharma, medical communication agencies and journals from different viewpoints. In addition, the faculty and audience will consider ways in which different companies interpret best practice when developing in-house publication policies and what controls should be put in place to demonstrate compliance.

Learning objectives:

- To explore and understand the "pharma" drug development model and the current perception of the industry as it relates to publications
- To explore what controls are in place to support best practice in the absence of mandatory regulation, with discussion of what can go wrong, why and by whom
- To review industry best practice guidelines for medical publications and how to monitor compliance

Session moderator:
Anna-Lisa Fisher, DPhil
Director, EuroMed Consulting Ltd

Panellists:
Douglas Altman, PhD
Director, Centre for Statistics in Medicine, University of Oxford; Senior Statistics Editor, BMJ; Co-Editor-in-Chief, Trials

Lucy Hyatt, PhD
Medical Writing Senior Manager, Therapeutic Area Lead (Cardiology, Nephrology and Bone), Scientific Publications, International Scientific Affairs, Amgen (Europe) GmbH

Stuart Spencer, PhD
Executive Editor, The Lancet

17:15–17:30	**Closing remarks** **Russell Traynor, MSc, CMPP™** *Chair, ISMPP Board of Trustees (2012-2013)*
EVENING	
17:30–18:30	**ISMPP Networking Reception and Member Poster Presentations**

Wednesday, 23 January 2013

MORNING

08:30–08:40

Welcome back!

John Gonzalez, PhD
Secretary, ISMPP Board of Trustees (2011 – 2014)

08:40–10:00

Publications for payors: What evidence do they really need?

The last 10 years has seen significant challenges to the healthcare environment, with increasing demand for healthcare, higher costs associated with introducing new healthcare technologies, and the worldwide economic recession, leaving relatively less money to pay for it all. These challenges have highlighted the need to control the costs of healthcare, of which the drug budget comprises a significant portion. This has led to the increasing influence of the payor: a relatively new customer grouping whose role is often portrayed as a barrier to the success of the new innovative drugs that the pharmaceutical industry has spent considerable time and effort to discover. But is this really a fair portrayal: exactly who are the payors, what is their role, and what do they really want?

This session qualifies for 1 CMPP Recertification Credits.

In this interactive session, our panellists will include representatives from both industry and payor groups. They will discuss what is meant by payors in different marketplaces, what exactly are their needs from academia and from industry, how do they come to the decisions they make, what evidence are they looking for to support decision making, and what sources do they turn to for relevant information? The session will close with the panellists giving their views on how the pharmaceutical industry should respond to payor needs and what manufacturers need to be publishing to help fulfil these needs.

Learning objectives

- To gain an understanding of the various national and regional payors in Europe, their evidence requirements, and the influence of published data on their funding decisions
- To discuss how pharma companies should respond to payor needs and provide appropriate evidence to support payor decision-making
- To be able to build payor evidence requirements into publication plans that incorporate the clinical, humanistic and economic data and overcome the challenges of publishing this evidence

Session moderator:
Ian Pickles, MBA
Consultant, Complete Clarity

Panellists:
Meriem Bouslouk, PhD
Desk Officer, Pharmaceuticals Department, Federal Joint Committee (G-BA)

Michael Drummond, BSc, MCom, DPhil
Professor of Health Economics, University of York; Co-Editor-in-Chief, Value in Health

Paul Hodgkins, PhD, MSc
Senior Director, Global Health Economics and Outcomes Research Department, Shire Pharmaceuticals; Honorary Senior Lecturer, School of Health and Related Research, University of Sheffield

10:00–10:30 Morning break and visit exhibits

10:30–12:00 **Meet-the-Editor: Publish or perish**

"Publish or perish" may be as true for the pharma industry as it is for academia – there have been suggestions that this makes the relationship between academic and industry authors a precarious one. Journal policies such as requiring independent statistical analysis or refusing narrative reviews with industry involvement imply that journal editors are the gatekeepers to protect readers. What is the role of publication professionals here?

This session qualifies for 1 CMPP Recertification Credits.

The intention is to have a lively debate – controversy is good, conflict is allowed, respect and politeness are required at all times. This session will allow delegates to have an informal discussion with journal editors from a variety of backgrounds such as society, ICMJE and value/access journals. The session will be divided into two parts, allowing each delegate to attend 2 of the 3 sessions and meet 4 of the 6 editors.

Learning objectives:

- To identify potential pressure points between publication professionals and journal editors, and seek solutions
- To learn how we can work together to efficiently publish articles that allow clinicians, their patients and those who pay for healthcare access to the information they need

Moderators:

James Butcher, PhD
Publisher, Nature Clinical Sciences, Nature Publishing Group

Rebecca Lawrence, PhD
Publisher, F1000 Research, Faculty of 1000

Bonnie Molloy
Director, Scientific Publications, International Scientific Affairs, Amgen (Europe) GmbH Zug Switzerland

Editors:

Finbarr Cotter, MD, PhD
Professor of Experimental Haematology, Barts and the London School of Medicine; Editor, British Journal of Haematology

Michael Drummond, BSc, MCom, DPhil
Professor of Health Economics, University of York; Co-Editor-in-Chief, Value in Health

	Trish Groves, MBBS, MRCPsych *Deputy Editor, BMJ; Editor-in-chief, BMJ Open, BMJ Publishing Group* **Stuart Spencer, PhD** *Executive Editor, The Lancet* **Piet van der Graaf,** *Editor-in-chief, CPT: Pharmacometrics & Systems Pharmacology; Senior Director, Global Clinical Pharmacology, Pfizer (UK); Professor of Systems Pharmacology, Leiden University (The Netherlands)*
12:00–13:00	Lunch
AFTERNOON	
13:00–14:00	**Keynote presentation** **Professor Jonathon Montgomery** *Professor, Health Care Law, University of Southampton; Chair, Health Research Authority; Chair, The Nuffield Council of Bioethics; Chair, Advisory Committee on Clinical Excellence Awards*
14:00–14:30	Afternoon break and visit exhibits
14:30–15:50	**Medical writing support of industry-sponsored research: How bright (or not) is the future?** Over the past 18 months, medical writing support of industry-sponsored research has continued to be challenged by 'pharma-sceptics' and there have been calls for fraud liability to be imposed on unethical writers (eg ghost-writers). In addition, the ramifications of the Sunshine Act in the United States, and similar initiatives in Europe have been looming. So what does all this mean for the future of publication planning and what are the consequences for medical writers (in industry, agency, or independents) and journals? Moreover, who will our advocators be in these uncertain times, and what more do we need to do to raise standards? In an interactive session, our panellists will discuss: the areas where we are receiving our greatest challenges; different scenarios of our possible futures; and what our businesses need to do to ensure a bright future for medical writing support of industry-sponsored research. The session will close with an overview of the growing number of advocates of our industry (including ISMPP), who are helping to raise the ethical benchmarks associated with publication planning.

Learning objectives:

- To understand the likely pressures that will be facing publication planners and medical writers over the next 5 years
- To recognise and discuss what businesses and individuals might need to do to ensure the continued future of medical writing support for industry-sponsored research
- To learn about advocates (in particular groups and societies) of our industry and positive ongoing initiatives to raise standards.

Session moderator:
Karen Woolley, BHMS Ed Hons, PhD, CMPP™
CEO, ProScribe Medical Communications; Professor, University of Queensland and University of the Sunshine Coast; ISMPP Asia-Pacific Trustee and Chair, Asia-Pacific Advisory Committee; ISMPP CMPP™

Panellists:
Leighton Chipperfield
Head of Publishing, Society for General Medicine

Gary Evoniuk, PhD
Director of Publication Practices, Medical Communications Quality and Practices, Office of the Chief Medical Officer, GlaxoSmithKline R&D

Russell Traynor, MSc, CMPP™
Director, Business Solutions, UBC-Envision Group

Liz Wager, PhD
Publications Consultant, Sideview;
Visiting Professor, University of Split School Medicine, Croatia

Wim Weber, MD, PhD
Associate Director of Neurology, Maastricht University;
Clinical Editor, BMJ

15:50–16:00	**Closing remarks** **ISMPP** **Russell Traynor, MSc, CMPP™**

Poster presentations at the 2013 European Meeting of ISMPP

Authoring industry-sponsored research: results from an investigators' survey
Isabelle Camby, *GlaxoSmithKline Vaccines (GSK-Vaccines)*

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

Incomplete conflict of interest (COI) disclosures – Analysis of recent publications
Christina Campbell, *PAREXEL International*

Conference abstracts: do processes follow best practice?
Charlotte Mulcare, *PAREXEL International*

Digital media integration trends in publication planning: use of non-traditional communication channels and contemporary effectiveness measurement
Gemma Pfister, *KnowledgePoint360 Group*

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

What do healthcare professionals think about professional medical writing support for peer-reviewed publications?
Sheelah Smith, *PAREXEL International*

Systematic reviews have twice the impact of narrative reviews: a bibliometric analysis
Catriona M Turnbull, *Research Evaluation Unit, Oxford PharmaGenesis™ Ltd*

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*

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 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 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 according to relevant laws and guidelines*
- *Know the key steps of how to work with authors and journals to ensure that Good Publication Practice (GPP2) is followed*
- *Understand the need to keep up with constantly evolving laws and guidelines*

Workshop Faculty

Sheelah Smith, PhD
Vice-President, Scientific and Editorial Services, PAREXEL International

Tim Atkinson, DProf MSc CSci CBiol FSB FRSC
Consultant Clinical Development Scientist

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 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 merging 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*
- *Recognise the differences between strategic and tactic plans*
- *Differentiate between a compelling 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*

Workshop Faculty

Thomas Malieckal, PharmD, CMPP™
Director, Global Medical Publications, Bristol-Myers Squibb

Tom Rees, PhD
Scientific Strategy Advisor, PAREXEL International

Global Pub Planning: Issues and challenges in global publication planning

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 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 - this will allow their cases to be discussed without disclosing confidential information.

Learning objectives

At the end of the 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 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

Susan Scott, PhD, CMPP™
Director, Publications & Communications, Ipsen

Jane Nunn, PhD, CMPP™
Head of Operations, Complete HealthVizion; ISMPP Chair of European Meeting Programme Committee

Comparative effectiveness research, health economics, and outcomes research: Their growing importance and implications for publication professionals

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 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*

Workshop Faculty

Peter Mathisen, PhD
Senior Vice President, Clinical Content and Editorial Services, Complete Publication Solutions, LLC; CHC Group

Ethics and regulations in publication planning

Prerequisite: *This workshop is appropriate for all publications managers, medical writers, medical editors, journal editors and allied members of a publication planning team (e.g., regulatory, legal, medical and marketing functions).*

This workshop will begin with a review of the revised ISMPP Code of Ethics followed by an interactive discussion of ethical challenges we face as writers, editors and publication managers and the impact of efforts by organizations and governments to drive ethical practice through guidelines and regulations. The workshop will use an interactive case approach to exploring ethical issues and the current regulations providing oversight and guidance for publication processes. Issues to be discussed include author accountability and access to data, disclosures and conflict of interest, impact of disclosure and sunshine laws on working with authors, use of authorship criteria, and roles of sponsors and professional medical writers.

Learning objectives

At the end of this workshop, attendees will:

- *Describe the new changes to the ISMPP Code of Ethics and the rationale for those changes*
- *Explain how current regulations address the ethics of publications including transparency for authors, sponsors and professional medical writers, data accuracy and availability and documentation of publication processes*
- *Discuss differences and similarities among the various codes of practice developed to provide standards for publication and presentation of research*

Workshop Faculty

Tricia Deja, PharmD, CMPP™
Associate Publications Director, Astellas

Dan Bridges, PhD, CMPP™
Business Unit Director,
Excerpta Medica

Evolution of publications from print to new media

Prerequisite: *This workshop is appropriate for individuals in pharma/biotech/medical device companies 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. Processes will be shared to show how to merge the utilisation of new media with publications, and how partnering with publishers can lead to solutions that meet the needs of all parties. 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*
- *Be able to apply learnings to identify media to use with their publications*

Workshop Faculty

Neil Adams
Publishing Manager,
Nature Publishing Group

Marcel Meijer, PhD
Program Director,
Excerpta Medica

2013 European Meeting of ISMPP Exhibitors and Sponsors

ISMPP would like to express its sincere appreciation to the exhibitors and sponsors of the 2013 European Meeting of ISMPP.

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Recertification Credit Information for CMPP™s

Many of the European Meeting workshops and presentations qualify for recertification credits. One hour of presentation or workshop attendance will earn 1 credit hour. Look for the CMPP™ recertification credit icon () throughout this brochure to identify qualifying sessions.

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 ISMPP.

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

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Neil Thompson, Managing Director, Red White Blue Ltd. – overall meeting and logistical support
Marina Maher, Joe Harvey and Alison Brown, all of Springer Healthcare – graphic design coordination and support for this brochure

See you at next year's European Meeting of ISMPP – January 2014, London, UK