



*News from the  
International  
Society for  
Medical  
Publication  
Professionals*



First Quarter 2012, Vol. 17

## *Special Edition*

In keeping with our commitment to provide timely and relevant information to the ISMPP membership, here is a special edition of the map. In lieu of our regular 1Q issue, this special edition presents highlights from the 2011 European Meeting of ISMPP held November 15-16, 2011 at Alderly Park, Cheshire, UK. The theme for this year's meeting was "Trends, Transparency and Trust: From Insights to Action." Over 200 delegates and 30 exhibitors attended. The presentations featured below are a selection of the many excellent sessions at the meeting. The full program is available [here](#) on the ISMPP website.

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Copies of Meeting presentations are posted in the Members' section of the ISMPP website ([www.ismpp.org](http://www.ismpp.org) > Member's Lounge > ISMPP Archive > European Meeting Archive).



## *Keynote presentation: The how and why of trust and reputation, and what it means for publication planning and delivery*

*Contributed by Ryan Woodrow,  
Woodrow Medical Communications Ltd, Bollington, UK*

Andy Powrie-Smith (Director, Association of the British Pharmaceutical Industry [ABPI], Scotland ABPI Trust Initiative) provided a fascinating and lively insight into action the ABPI is taking to overcome issues that undermine the trust and reputation of the pharmaceutical industry in the UK. Mr Powrie-Smith began by highlighting that, contrary to common belief, the pharmaceutical industry is well respected in the UK: according to a large survey, pharma is regarded as a top five industry in the country in terms of reputation. However, as would be expected from its size and complexity, the pharma industry does have some issues. A survey revealed that healthcare professionals and payers consider the pharmaceutical industry's reputation as tarnished by its approach to various "ethical" issues, including:

- Honest and credible communications
- Responsible marketing
- Access in developing countries
- Transparency about healthcare relationships
- Contribution to local communities
- Openness about clinical trials
- Value for money and value of medicines

***"...contrary to what many of us believe, the pharmaceutical industry is well respected in the UK... However, as would be expected from any industry of its size and complexity, the pharma industry does have some issues, which have led to a somewhat lower reputation amongst healthcare professionals and payers."***

The ABPI has taken a number of steps to address these concerns. Firstly, this is not a pharma story; many of the issues are a product of the dynamic that has developed over many years between industry and healthcare professionals. Both sides have been a partner in this equation, and for progress to be made we need shared ownership of the issues and solutions delivered in partnership. The ABPI has started working in closer collaboration with healthcare professional groups, such as the medical Royal Colleges, through a quarterly forum called the Ethical Standards in Health and Life Sciences Group (ESHLSG). As an example, the ABPI and Royal College of Physicians have recently written joint responses to negative press, which has had a positive effect—in one case leading to the withdrawal of a negative article about the industry.

*Continued on following page...*

The association has examined what the industry needs to do better, and has investigated ways to do certain things differently. Industry needs to improve the way in which it communicates some issues, as there is often a gap between public perception and reality. For example, pharmaceutical companies invest considerable amounts of money to build healthcare capacity in developing countries; however, often the public and other groups are not aware of this. Finally, the ABPI has updated its code of practice to better reflect how employees of the industry should interact with healthcare professionals in a more ethical, transparent manner.

These steps have had a tangible impact. However, Mr Powrie-Smith stated that there are still key issues to address. Meetings held between key figures within ABPI and other stakeholder groups have identified the following four main areas of priority for establishing trust and integrity:

- Industry support of medical education
- Clinical trial transparency
- Publications
- Declaration of payments

Each of these issues is being taken forward in partnership with stakeholders through the ESHLS Group. With regard to medical education, ABPI-sponsored research is ongoing to identify the areas valued by healthcare professionals, healthcare systems, and industry, while addressing any issues that affect the reputation of both healthcare professionals and industry. In relation to clinical trial transparency, the partners in the ESHLS group are agreeing and publishing a set of principles for clinical trial reporting in line with the IFPMS principles. ABPI will better communicate the steps that industry has taken over recent years to more openly share information about planned, ongoing, and completed studies, for example, through clinical trial registries.

Regarding publications, to bridge the gap between perception and reality, the ABPI will highlight in future communications that guidelines have been put in place by the industry (e.g. GPP2) to ensure ethical conduct. Finally, in terms of declaration of payments, considerable strides forward have been and are being made within the UK. In particular, Mr Powrie-Smith mentioned ongoing work to increase the transparency of financial relationships in partnership with stakeholders.

To conclude his presentation, Mr Powrie-Smith highlighted that building trust amongst healthcare professionals is not just about compliance. It is also not just about what ABPI can do. It should be about individuals. Each employee within the industry needs to carefully consider on an individual level what changes he or she can make to help establish trust and integrity with healthcare professionals and other stakeholders.



## *Publishing model diversity and online community judgment: what are we gaining?*

*Contributed by Martin Delahunty, Nature Publishing Group, London, UK*

Vitek Tracz, Chairman of Science Navigation Group, which includes Faculty of 1000 (F1000), focused on the future of journal publishing and in particular open access publishing and “post-publication” peer-review. Mr Tracz recounted his experience in developing BioMed Central (BMC) as the first open access publisher. Although challenging at the beginning, BMC has demonstrated to the more traditional STM (Scientific, Technical & Medical) publishers that open access publishing can be financially sustainable, and has enabled a shift from reader to author payment. He described F1000 as an iteration of the Current Opinion journals, with over 10,000 experts in biomedicine providing short post-publication evaluations of articles. F1000 has also launched an alternative way to measure the importance of a journal, the F1000 Journal Factor, or FFj, which differs significantly from the Impact Factor (derived from citations by the Science Citation Index [SCI]).

At the ISMPP meeting, he announced the launch of a new open access publishing initiative, “F1000 Research”, where articles will be published as separate (but linked) data sets, analyses and conclusions, and made public immediately, followed by ‘open’ post-publication peer review. This model will enable immediate and transparent sharing of research, with open post-publication peer review—reviewers named alongside their comments—giving the authors the opportunity to respond and improve their articles. When asked whether F1000 Research would be indexed by PubMed and SCI, he said he has approached PubMed regarding their requirements.

To finish, Mr Tracz said that with over 27,000 journals in the life sciences, all science findings are potentially publishable. Currently, however, small findings and negative findings are not always published and he now hopes to make these available. Controversially, he feels that journals and journal editors are now becoming generally irrelevant in terms of making findings visible. “Papers will live independently of a journal.” He feels that there may be a place for a few select journals that publish small numbers of “important” or “fashionable” research articles but that, otherwise, journals are substantially irrelevant in terms of making the broad flow of new findings visible.





## *Keynote presentation: What makes news?*

*Contributed By Andrea Cole,  
Gardiner-Caldwell Communications, Stockport UK*

During his presentation at the ISMPP EU meeting, Ben Goldacre, author of “Bad Science” in *The Guardian* newspaper and the pharmaceutical industry’s “sanest critic,” provided an overview of what he feels are the serious problems in how scientific data are obtained, processed, and disseminated plus some ideas about how to address these flaws to make future research activities more transparent and ethical.

Dr Goldacre pointed out that the problems in medical research begin at the level of trial design. Trials of new medications are carried out in “ideal” patients; ones who don’t have other comorbid conditions and are therefore more likely to recover quicker. The results from these trials of “ideal” patients may then be used to generate treatment guidelines, which are ultimately used to inform treatment decisions for the whole population. In one survey of asthma patients, only 6% met the eligibility criteria for inclusion in the randomized controlled trials that were cited in the global treatment guidelines (Travers J, et al. *Thorax* 2007;62:219–223.). The other way in which trials can be unhelpful or misleading is if the trial is comparing an active treatment against a placebo, when it should be compared against the current gold-standard treatment. One third of the new drugs approved by the US Food and Drug Administration (US FDA) were compared only against placebo in clinical trials. Using a dose of the gold-standard treatment that is too high or too low can also be potentially misleading. Overall, however, Dr Goldacre pointed out that industry-sponsored trials tend to be better designed than non-industry-sponsored trials, although they are also four times more likely to give a positive result for the drug under study.

***“Selective non-publication of unflattering data is unambiguously research fraud, and I think in some cases where it has resulted in serious loss of life then people should go to prison.”***

One of the potential explanations for this phenomenon is publication bias in which large-scale trials that give positive results are more likely to be published than smaller negative trials. Dr Goldacre recounted some of his personal experiences of publication bias, including that of reboxetin, the antidepressant. He prescribed this drug to one of his patients after reviewing the available literature, but only 24% of the clinical trials carried out using this drug were published. When the other 76% were made available, the drug was shown to be ineffective and possibly harmful, leaving Dr Goldacre feeling deceived.

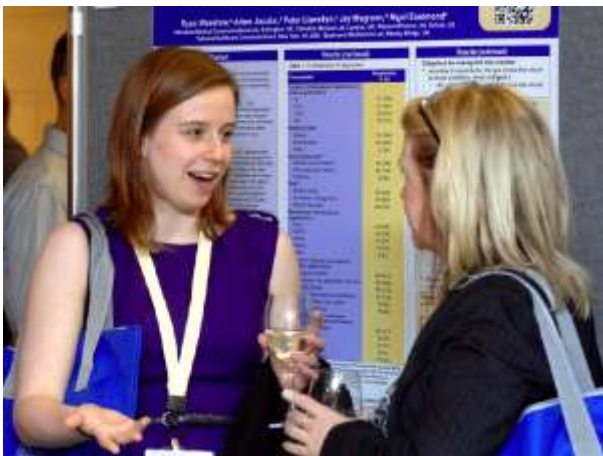
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But publication bias is not the only problem Dr Goldacre perceives with publication of medical research. Positive trials can be reported multiple times giving the impression of an accumulation of many different sets of data, when in fact it is the same data presented in different publications. Ghost authorship is now viewed as an unethical practice, but it is something that we still hear about as the media pick up on cases that are discussed in court, generally 5 to 8 years after it has happened.

***“I felt gravely deceived. I prescribed [reboxetin] to a patient in front of me on the belief that this was a safe and effective medicine, but in fact I was misled by a group of people, a system which permitted and which even incentivized this kind of publication practice.”***

So what should be done to increase transparency? Dr Goldacre was very clear on his recommendation, which is to publish all trials in humans with no exceptions. And he also feels that each trial should be published three times: once in a standard tabulated format, once as the clinical study report in full with any individual patient level data removed, and once in an academic journal as a polished essay. He would also like to see better industry regulation with enforcement of the rules involving the justice system, if necessary.

**Attendees at the European Meeting visit poster presentations**





## *EudraCT updated and EudraCT for publication planners: the good, the bad and the ugly*

*Contributed by Geraldine Thompson,  
UBC-Envision Group, Horsham, West Sussex, UK*

EudraCT, the once-confidential European clinical trials database, used to be chiefly the domain of our colleagues in compliance and only of broader interest to publications teams. All of that has changed over the past couple of years. Most notably, March 2011 saw the launch of the EU Clinical Trials Register (CTR), providing public access to protocol-related information for selected trials from EudraCT. During her session, Dr Ana Rodriguez, Head of Clinical and Non-clinical Compliance, Compliance and Inspection from the European Medicines Agency (EMA), described improvements that have occurred with the recent EU CTR upgrade to version 1.1 and the EudraCT upgrade to version 8 (see table on next page). The addition of clinical trial results is planned, with an estimated launch to occur in late 2012, subject to the finalization by the European Commission of the technical guidance on the publication of results. EMA is also involved in international activities and working closely with [clinicaltrials.gov](http://clinicaltrials.gov) to standardize requirements as far as possible. Dr Rodriguez confirmed that for clinical trials ending more than 6 or 12 months (as applicable according to the required deadline for submission for the trial type in question) prior to the coming into operation of the system for the submission of results, an alternative submission is possible, such as the provision of an authorized copy of a medical journal article.

What do these changes mean for publication professionals? Susan Scott, Director of Publications and Communications at Ipsen BioPharm, highlighted the key short-term implications: protocol-related information will be available on the EU CTR when the protocol is authorized, typically several months ahead of registration on [clinicaltrials.gov](http://clinicaltrials.gov). Information will be updated whenever the protocol is substantially revised, and trial identifiers should be included on all trial communications.

Considering the broader environment, Dr Scott suggested that publication plans might be replaced by “disclosure” plans, with teams considering all public disclosures of a trial. At the very least, publication teams should include trial registry officers to help plan data dissemination and ensure publications are consistent with registries. Dr Scott also floated the idea that protocols should be considered public documents since, notwithstanding industry concerns, demand for full protocol publication seems likely in the future.

*Continued on following page...*

EudraCT and the EU CTR: what's the difference?	
EudraCT	EU CTR
<ul style="list-style-type: none"> <li>• Confidential database</li> </ul>	<ul style="list-style-type: none"> <li>• Public website</li> </ul>
<ul style="list-style-type: none"> <li>• Clinical trial applications for all interventional clinical trials of medicinal products, where the trial has ≥1 EU investigator site</li> </ul>	<ul style="list-style-type: none"> <li>• Protocol-related information for a subset of trials within the EudraCT database:                             <ul style="list-style-type: none"> <li>○ Phase II-IV adult clinical trials with ≥1 EU investigator site</li> <li>○ All pediatric clinical trials with ≥1 EU investigator site and any trials that are part of a PIP including those where the investigator sites are ex-EU</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• Launched May 2004</li> </ul>	<ul style="list-style-type: none"> <li>• Launched March 2011, with staggered release of historical data</li> </ul>
<ul style="list-style-type: none"> <li>• Improvements in version 8 included processes to improve data quality, such as more extensive validation rules, and greater use of controlled terms lists rather than free text</li> </ul>	<ul style="list-style-type: none"> <li>• Improvements in version 1.1 included the facility to export searches (although with fewer options than in clinicaltrials.gov) and RSS feeds for searches of interest</li> </ul>
<ul style="list-style-type: none"> <li>• Results posting expected from late 2012</li> </ul>	<ul style="list-style-type: none"> <li>• Results posting expected from late 2012</li> </ul>
<p>EudraCT = European Union Drug Regulating Authorities Clinical Trials, EU CTR = EU Clinical Trials Register, PIP =pediatric investigation plan. More about the EU clinical trials register can be found at <a href="https://www.clinicaltrialsregister.eu/">https://www.clinicaltrialsregister.eu/</a>.</p>	

## *2011 ISMPP EU Poster Award Winner: Best Original Research*

*Contributed by Amy Zannikos, Peloton Advantage, Parsippany, NJ*

### **Publication of past and future clinical trial data: perspectives and opinions from a survey of 607 medical publication professionals.**

Ryan Woodrow,<sup>a</sup> Adam Jacobs,<sup>b</sup> Peter Llewellyn,<sup>c</sup> Jay Magrann,<sup>d</sup> Nigel Eastmond<sup>e</sup>

<sup>a</sup>Woodrow Medical Communications Ltd, Bollington, UK, <sup>b</sup>Dianthus Medical Ltd, London, UK,

<sup>c</sup>NetworkPharma Ltd, Oxford, UK, <sup>d</sup>Informa Healthcare Communications, New York, NY, USA,

<sup>e</sup>Eastmond Medicom Ltd, Whaley Bridge, UK.

Ryan Woodrow and colleagues conducted a survey between August 2-21, 2011 of over 600 publication professionals to determine their opinions regarding clinical trial data reported by pharmaceutical companies, specifically how much pharmaceutical data should be made public, where these data should be published, and the limitations of publishing negative data. Members of ISMPP, the American Medical Writers Association (AMWA), the NetworkPharma community, and other groups identified on LinkedIn were invited to participate. Over 600 professionals involved in the publication of medical research responded. Woodrow and colleagues concluded that the view of medical publication professionals should be taken into account when guidelines and legislation relating to medical publications are drafted. The poster was well received at the EU ISMPP meeting and was judged to contain the best original research of those posters in the meeting poster session. Results of the survey will be published in the May 2012 issue of *Current Medical Research and Opinion*.





## *Advancing and communicating publication practice in Europe*

*Contributed by Chris Winchester, Oxford PharmaGenesis™, Oxford, UK*

ISMPP can play a leading role in the success of the medical publications industry in Europe, concluded an expert panel moderated by Sarah Feeny, Head of Scientific Direction at Complete Medical Communications. Our critics present historical bad practice as current practice, with ghostwriting remaining a hot topic.

“The value of professional medical writing is still poorly understood”, Sarah noted, “and we have limited evidence in our defense”.

The panel recommended responding to our critics by continuing to improve our practice, as well as communicating how much we have improved. Ryan Woodrow, Scientific Director at Woodrow Medical Communications, challenged the audience to correct anything we are doing wrong, and an audience poll showed that almost half were playing an active role in shaping the publication practice of colleagues and collaborators. Adam Jacobs, Director at Dianthus Medical, highlighted the need for more data to show how practice has improved. One option would be to publish the results of audits of adherence to internal publication policies. However, only a minority of the audience had a publicly available publications policy in place.

When multiple stakeholders are pulling in different directions, as Tom Grant, Publications Director at AstraZeneca pointed out, ISMPP can play a role in informing and aligning their views. Stephanie Tortell, Client Services Director at Complete Medical Communications, and Ryan Woodrow suggested that collaborations with the European and American Medical Writers Associations could include joint statements and potentially joint meetings.



### 8<sup>th</sup> Annual Meeting of ISMPP

Practical Solutions for a Complex Medical Publications World

April 23-25, 2012

Hyatt Regency Baltimore Inner Harbor  
Baltimore, MD, USA

## *The editor's panel: a peek behind the editor's door*

*Contributed by Fiona Nitche, PhD, CMPP, Evidence Scientific Solutions, London, UK*

Keith Veitch, PhD, Head of Global Publications, Novartis Vaccines, moderated this session, which included panellists from various journals. The group discussed potential problems with authorship in the biomedical literature. Prof Finbar Cotter, Editor-in-Chief, *British Journal of Haematology*, stressed that authorship should be established before the development of a manuscript and that every single author is responsible for the integrity of the paper. He expressed concern that there were still many people who accepted “free rides.” The suggestion was made by Dr Stuart Spencer, Executive Editor, *The Lancet*, to determine authorship in the protocol, although not everyone agreed that this was feasible. Mr Francis Crawley, from the audience, suggested that editors should be more engaged in the publication planning process.

Then Dr Veitch asked about the panellists' perceptions regarding papers with industry-affiliated authors. The panellists agreed that for research papers, honesty and transparency were more important than an author's affiliation and that no distinction was being made between industry-sponsored articles and those from academia. However, review articles by industry-affiliated authors (past or present) were considered a “no-no.” Not all members of the panel or of the audience agreed with this position.

The panel emphasized the importance of a cover letter as part of a submission. This letter should not be a “rehash of results” but should outline the relevance of the article for the journal's readership. This is important to journal editors because citations and impact factors matter not only to journals but also to academic authors. Academic careers of authors are still dependent on the number of publications in their CVs and the impact factors of the corresponding journals.



The panel also debated new publishing models. Dr Jigisha Patel, Series Editor – Medicine, BioMed Central described the open peer-review system at BioMedCentral in which peer reviewers sign their reports, and all peer-review comments and previous drafts are published along with the final version of the paper. However, an audience member cautioned that industry people would not use the post-publication comments facility, as this opened “a can of worms.”

Jay Magrann, VP & Director, Product Solutions, Informa Healthcare, commented that the traditional journal article would continue to play an important role in putting data into context for the readership they serve. Online clinical trial registries and supplementary data publication serve as additional reference sources for those requiring more detailed information.



## *Publishing data on OTC and consumer products: providing evidence and expelling the myths*

*Contributed by Amy Zannikos,  
Peloton Advantage, Parsippany, NJ*

David Mays, Director of Global Strategic Engagement at Johnson & Johnson, discussed why disseminating scientific information on OTC and consumer products

is critical to allow clinicians and consumers to make informed decisions regarding the use of these products. Literature searches come up with relatively few peer-reviewed publications on OTC and consumer products. Whereas consumers generally trust expert opinions when they receive information, the wealth of information available on the internet regarding OTC and consumer products can confuse and even mislead them. Dr Mays discussed several examples of conflicting information available publicly, including the use of “trace” amounts of chemicals, the actual contents of so-called “natural” ingredients, and the inclusion of preservatives in cosmetics. Dr. Mays concluded by emphasizing the importance of providing clear and accurate scientific information on OTC and consumer products to the public, in particular, avoiding underestimating the public’s ability to comprehend scientific information and make informed decisions

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To get started, click on the following link:

<http://www.ismpp.org/members/newmbrs.html>



### ***Quarterly Quick Quiz Winner!***

Congratulations to Linda V. Wychowski, PhD, CMPP, UBC-Envision, Philadelphia, PA, USA for correctly answering the quiz. As the contest winner, Linda will soon receive a Visa® gift card.



## *Consumption of articles in the digital age*

*Contributed by Tim Collinson,  
Fishawack Communications, Knutsford, UK*

Introducing his presentation on how consumption of articles is rapidly evolving in an ever-increasing digital environment, Chris Surridge, Chief Editor and Associate Publisher with the Nature Publishing Group, emphasized that in scientific publishing, the medium is not the message; the message is the scientific data, while the medium is becoming increasingly irrelevant.

To date, a 400-year history of journals has seen various experiments on “the article of the future”, and while the familiar format of introduction, methods and results has been retained, recent digital advances mean we have tools at our disposal to decorate an article with the likes of video, commentary and document links, to help to communicate its message. Such advancements are undoubtedly changing the way in which we access and digest articles, and although scientists still lag behind in engagement in social media, the commentary, ratings and rankings that accompany data disclosure are increasingly integral to the published article.

Dr Surridge commented that an unread paper may as well not exist. There is no single measure to determine how articles are consumed, but in this digital era, we have the opportunity to determine so much more about how, when and by whom an article is being accessed. He described the limitations, and challenged the value of traditional measures such as the impact factor, index immediacy, and cited half-life. Our inability to determine which journal pages the reader is accessing from a journal taken from a library is being overcome by the insight brought by article-level metrics such as downloads, citations, news coverage and mentions (blogs, Twitter). However, as yet, such metrics are by no means precise. Citation measures can vary greatly between the likes of PubMed, Crossref, Scopus, and Web of Science. At this stage there are no standards for counting, no independent auditing, no standardized definition of a “hit” or a “download”, and of course no “mention” is the same.

Is it true that an unread paper may as well not exist? Perhaps, but every paper begins unread; and is a paper read by 10,000 people any more important than one read by only two people? Sometimes the future decides which published papers were the most important. The role of the publisher is still deemed important. Are print journals dead yet? No, but perhaps their days are numbered!

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## *Event Photos*



**ISMPP and Advocacy  
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**Very special thanks to those who contributed and edited articles for this issue:**

Andrea Cole	Tim Collinson
Martin Delahunty	Meenakshi Kashyap
Fiona Nitsche	Linda Rice
Geraldine Thompson	Kristina Wasson-Blader
Chris Winchester	Ryan Woodrow
Amy Zannikos	

**The International Society for  
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PO Box 2523  
Briarcliff Manor, NY 10510  
+1 914 618 4453  
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International Society for Medical  
Publication Professionals

Newsletter created by: Tim Collinson, Meenakshi  
Kashyap, Kristina Wasson-Blader, Sadie  
Whittaker, and Amy Zannikos



*Quarterly Quick Quiz*

**Question:**

The EU Clinical Trials Register (EU-CTR):

- a) is a confidential database listing all interventional clinical trials of medicinal products
- b) is a public website that includes protocol-related information for a subset of trials within EudraCT
- c) includes only phase III and phase IV adult clinical trials
- d) B and C

Submit your response to [newsletter@ismpp.org](mailto:newsletter@ismpp.org) by April 15, 2012. A winner will be selected at random from the correct responses and will receive a \$25 (or equivalent local currency) Visa® gift card. The winner will be announced in next quarter's issue.



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