To the Point
Edition 6 · February 2016

ISMPP EU highlights

More than 200 delegates from industry, medical communications agencies, and publishing, gathered on 19–20 January at St. Paul's, Aldersgate, London for the 2016 European Meeting of the International Society for Medical Publication Professionals (ISMPP).

This 2-day meeting, entitled 'Overcoming Challenges in the Age of Transparency' addressed the latest trends and developments in medical publishing, with a focus on the practical skills that drive successful publication delivery. Ashfield Healthcare Communications brings you some of the meeting's highlights!

ISMPP International Society for Medical Publication Professionals™

www.ismpp.org

Ashfield Healthcare Communications' stand, ISMPP, London

2015: A year in review

A retrospective of key events and emerging issues in the medical publications industry in 2015: moderated by John Gonzalez (Publications Director with AstraZeneca UK) who then handed over to Iain Hrynaszkiewicz (Head of Data and Health and Social Services Publishing, Nature Publishing Group/ Palgrave Macmillan UK)

Recurring themes in 2015 were transparency, trust (especially in peer reviews), patient involvement, Asia, and predatory journals.

Jan: Was the 350th anniversary of *Philosophical Transactions*, the world's first science journal

Feb: The rise of interdisciplinary research

Mar: More evidence of publication bias

Apr: OpenTrials announced (registry data for clinical trials)

May: BMJ extends requirement for data sharing to apply to all submitted clinical trials to aid transparency

Jun: Have conflicts of interest gone too far? Patient involvement and engagement in research and journals

Jul: Peer-review fraud becomes a trend; fake email addresses and fabricated researcher reports in various journal articles retracted as a result

Aug: The birth of GPP3 – additions included more information on authorship and data sharing

Sep: More data transparency – restoring study 329

Oct: Checklist developed for recognising, preventing and protecting against illegal predatory publishing

Nov: Altmetrics for trial registration records at ClinicalTrials.gov giving insight into data utilisation

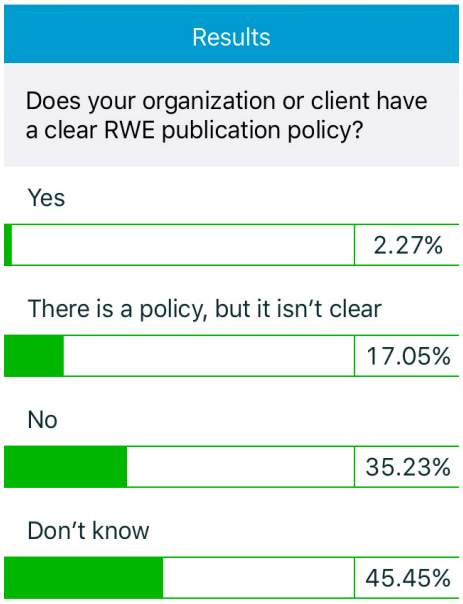
Dec: International Committee of Medical Journal Editors (ICMJE) guidelines updated. More warnings about predator journals. The Ingelfinger rule gets the elbow, in public health emergencies. Open Researcher and Contributor IDs (ORCIDs) are encouraged

Real World Evidence (RWE) and publication

Where publications on randomised clinical trials (RCT) are upheld as the shining light of medical publications, RWE publications, based on observational analyses, are viewed with uncertainty. Nonetheless, steps can be taken to mitigate poor public perception and develop valuable publications to a high standard. RWE data are important and complement RCT data in a real-world setting. As such, RWE publications can be influential in informing and bolstering reimbursements, for example.

To adequately address the concerns around RWE publications, the barriers to credibility need to be considered. These include an increased risk of bias due to lack of randomisation, questions around the representativeness of the selected datasets, concerns about cherry-picking the 'best' data from numerous analyses, and conflicting results from different studies. These issues can be addressed through the cohesive multidisciplinary collaboration of key experts to generate robust data, by following appropriate guidelines and by the transparent, accurate and clear (no technical jargon!) representation of the study methodology and outcomes. As always, transparency is key.

In short, the same rigorous approach should be applied to the development of RWE publications as to those reporting RCTs – plan, reform and publish.



Audience poll results during the ISMPP meeting

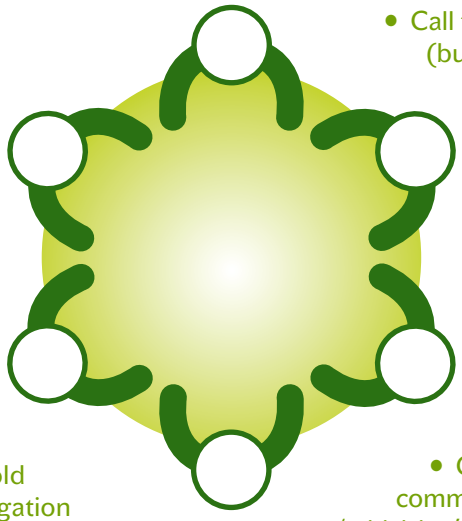
Discussion from the roundtables

Best practice on authorship

Many challenges arise when working with authors on publications of industry-sponsored studies. The ISMPP Best Practice on Authorship roundtable focused on two case studies where delegates were asked to share their opinions and advice.

The first case study described a situation where half of the authors of a tight-schedule publication failed to provide comments on drafts prepared by a medical writer. The participants suggested several approaches to address or avoid such issues:

- Be specific in the author agreement regarding level of required contribution and potential consequences (removal as author) if substantial contribution is not provided
- Have an internal policy on what threshold of inadequate input would result in relegation of an author to the Acknowledgements section
- Include open questions to the authors in the manuscript outline and drafts, ideally with some questions directed to individual authors
- Leave gaps in the manuscript for the authors to address questions
- Make clear in the accompanying email that the manuscript contains questions (to ensure the author opens the document)
- Call the authors – do not just rely on email (but document the discussions)
- Involve local affiliates or Medical Scientific Liaisons (MSLs) to engage with authors (request email summary of discussion), especially if there is an existing relationship
- Use the Publication Steering Committee or lead author
- Consider whether language barriers are an issue – might translation of the draft help authors to respond?
- Consider cultural issues – lack of comments may be due to views about 'criticising' others' written work
- Where there are a large number of authors, it may be acceptable for an author to simply agree with the comments of his/her co-authors, but they should explain why they agree.



Best practice on authorship (cont'd)

The second case study focused on how to decide order of authors on the publication byline. The participants suggested:

- The authors should discuss and reach mutual consensus – it is not the role of the sponsor to decide the order of authors
- Involve the internal clinical team and/or the Principal Investigator (PI) – their involvement in the study may allow them to comment on individual contribution
- Number of patients enrolled in the study may be one of the considerations
- Typically, the PI or Steering Committee members may be first or last authors, with industry contributors often in the middle
- After the decision on first and last author, a common suggested approach was to include all other authors in alphabetical order.

Devices/diagnostics publications

A roundtable interactive discussion was also held to share information on how device trials are run and the implications for publications. Nowadays device/diagnostic companies have a requirement for evidence-based medicine. There is an expectation for clinical trials to be published if the product is to be used and reimbursed, including post-marketing surveillance. It is not enough just to register the product. These clinical trials start at phase three (unlike pharmaceutical products). Therefore the communication strategy needs to be built before the clinical trial starts. Animal studies are vital to start the educational process. Regulatory, medical and economic studies are also useful for scientific communication.

There are no specific guidelines for devices and diagnostics (number of participants, length of trial etc.) as such, because of the broad range of products available. It is not possible to do a randomised controlled study either. The life cycle of a device/diagnostic generally is shorter, at 3–5 years. In terms of publications, it is possible to maximise opportunities to communicate data without the need for lots of trials, through for example, retrospective studies and patient case studies.

Patient lay summaries

Simplicity is key to patient lay summaries. Regardless of which disease they might suffer from, patients are a very mixed bunch with great variation in what's understandable to them. So, aim to keep it clear and simple. Writing about clinical research shouldn't be viewed as rocket science. Materials will likely exist to help guide you – how was the research described to patients in the consent form? Consider involving patients in the writing process too. If you're developing patient lay summaries, ask yourself this question at the outset – how would I explain the research to family, relatives and friends?

Multidisciplinary working

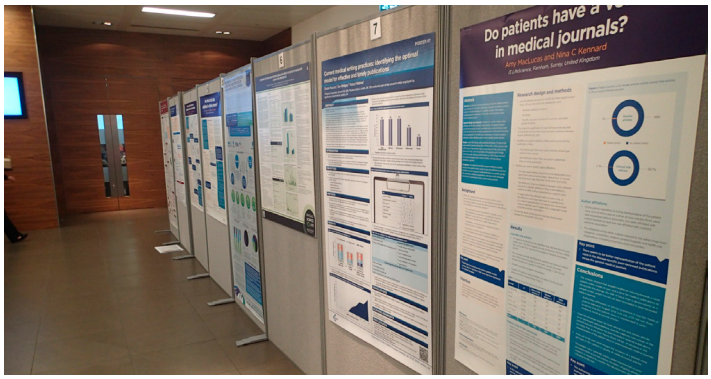
There are a wide variety of stakeholders involved in publication planning and development, many of whom have different needs. Effective multidisciplinary working is one way to drive efficient publication planning and development – but how can this be achieved in reality? Get early agreement on roles and responsibilities, and buy-in from all individuals involved in the partnership; foster open communication and exchange of ideas; be proactive with regard to management and delivery of publications and relationships, and aim to build a culture based on trust and confidence.

Industry–agency relationships

'The key to a successful client and agency relationship is partnership and communication.'

Speed research oral presentations

From the abstracts submitted for peer review to the 2016 European Meeting of ISMPP, five authors were invited to present a summary of their research in 8 minutes. The following presentations were selected and were followed by questions from the moderator Ryan Woodrow:



Posters displayed at the ISMPP meeting

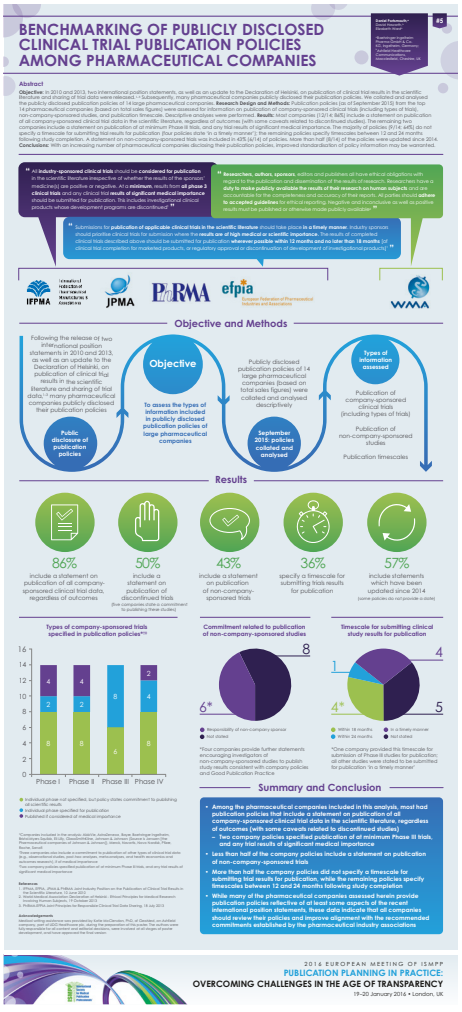
Eljamel S, et al. **Are we there yet? Does current practice in acknowledging professional medical writing support meet the requirements of GPP3?** Since the GPP2 guidelines were published, professional medical writing support has been acknowledged with increased transparency in industry-sponsored publications, however, recent findings suggest that changes are still needed in order to meet the recommendations of the latest GPP3 guidelines.

Gattrell W, et al. **Does professional medical writing support increase the impact of articles reporting randomised controlled trials?** The increased quality in the reporting of RCTs seen in articles prepared with medical writing support is reflected in the acceptance in higher impact journals than articles written without this support. This may be explained by: enhanced article quality, improved compliance with journal submission criteria, and provision of guidance to authors on target journal selection.

Kerr B, et al. **Reporting of positive and negative clinical trial results in the age of mandatory clinical trial registration.** Dissemination of primary data from negative trials appears generally comparable with that from positive trials. More widespread reporting of registry identifiers in abstracts would improve the speed, especially when searching for publications.

O'Regan NL, et al. **Journal choice: which factors do you value when submitting a manuscript?** Of the 186 publication professionals assessed, more than 90% felt that a listing on PubMed was the most important factor influencing choice of a journal for manuscript submission. They also felt it was important to have access to specific journal information, such as: reputation and prestige, speed of publication, rejection/acceptance rate and readership/audience.

Portsmouth D, et al. **Benchmarking of publicly disclosed clinical trial publication policies among pharmaceutical companies.*** Most pharmaceutical companies included in this analysis had publication policies that include a statement on publication of all company-sponsored clinical trial data in the scientific literature, regardless of outcomes. More than half the company policies did not specify a timescale for submitting trial results for publication, while the remaining policies specify timescales between 12–24 months following study completion.


BENCHMARKING OF PUBLICLY DISCLOSED CLINICAL TRIAL PUBLICATION POLICIES AMONG PHARMACEUTICAL COMPANIES

Abstract

Objective and Methods

Results

Summary and Conclusion

2016 EUROPEAN MEETING OF ISMPP
PUBLICATION PLANNING IN PRACTICE:
OVERCOMING CHALLENGES IN THE AGE OF TRANSPARENCY

Ashfield-sponsored poster presentation, with kind permission from Daniel Portsmouth, Boehringer Ingelheim Pharma GmbH & Co KG, Germany

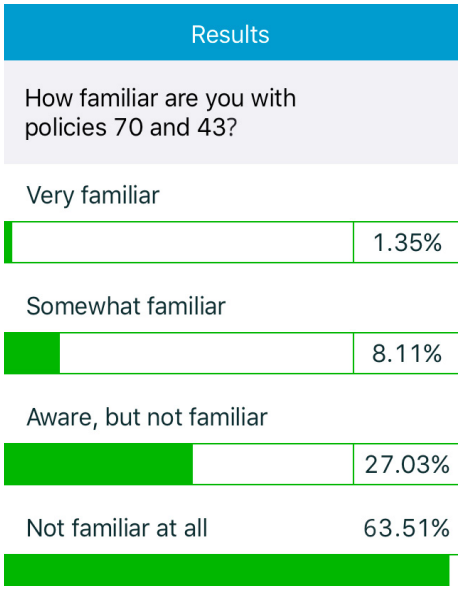
Data transparency and consistency

Data transparency and consistency are vital in ensuring public access to credible, scientifically rigorous publications. The desire to rapidly disseminate important information in the public domain, e.g. through late-breaking abstracts, often results in the development of publications without availability of a clinical study report. This may be a contributory factor, along with the rise of multiple public sources of clinical trial data, of data inconsistency, which in turn raises public uncertainty. More stringent guidelines may be desirable to ensure a higher degree of consistency in the age of improved data transparency.

Data and financial transparency reporting

Over the last few years, requirements for transparency and data reporting have become more widespread, with potentially substantial consequences for those responsible for scientific publication planning. The data and financial transparency reporting session featured an in-depth discussion of the European Medicines Association (EMA) and European Federation of Pharmaceutical Industries and Associations (EFPIA) changes to existing rules and directives and how they affect publication planning; representatives from EMA, EFPIA and industry provided an holistic perspective. Transparency is key to build trust, confidence, and ultimately empowers people, including patients. Fergus Sweeney (EMA) urged all to view the two policies 70 and 43 as these were complementary to publications. He stated that more and more people are reviewing data disclosure on websites (e.g. ClinicalTrials.gov is still the largest) prior to embarking on editorial support for publications. Finally, people are starting to look and compare data disclosed in various places and highlight discrepancies making it imperative for those involved in data disclosure to have robust processes for ensuring consistency on all data release. Laurence Rouxhet, Head of Publications Management & Web Disclosures, GlaxoSmithKline Biologicals, described their internal restructuring where Head of Publications and Head of Data Disclosure now report into the same Head of Medical Governance and use the same software. Thereby through systematic team processes, including regular monthly meetings, they prepare and review disclosure plans together.

The second area discussed by Andrew Powrie-Smith, Director of Communications, EFPIA, was around the availability of sharing individual patient-level data for non-commercial purposes, for example out of 190 requests in the EU, 130 were approved. One website that supports the collaborative sharing of data is www.clinicalstudydatarequest.com and there are many partnership examples now of sharing data such as Janssen and Yale University. Finally, with regard to transparency of financial reporting, companies are embracing this and setting their rules around recompense and collecting of data. Although medical writing per se is still not seen as a transfer of value by most parties.



Audience poll results during the ISMPP meeting

Keynote address – Vitek Tracz Publications: Where do we go from here?

This interesting and dynamic conference wrapped up with a thought-provoking talk from Vitek Tracz, founder of BioMed Central (BMC) and Faculty of 1000 (F1000). The latter was established to move away from the traditional journal editor-led paradigm and peer-review process, to establish a fully transparent and rapid publication medium for research. This novel approach aims to enhance scientific rigour and data availability, and its agreement with PubMed to index publications, once approval has been attained, makes these data broadly accessible.

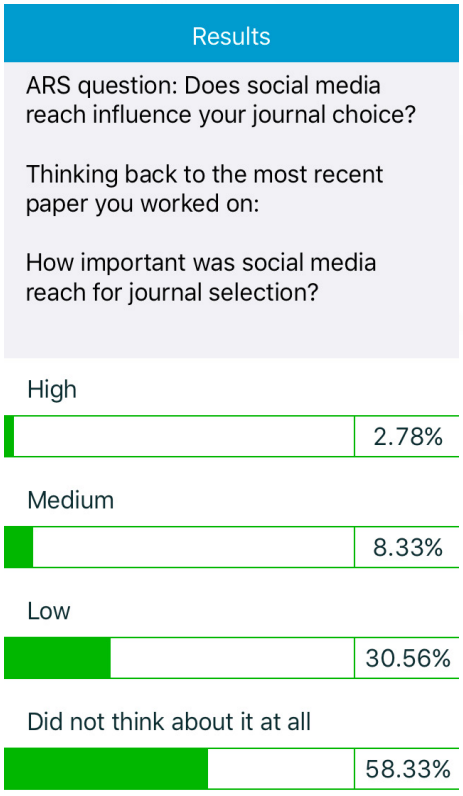
Publishing and journals: Practical considerations for medical publication professionals in 2016

A panel of experts comprising two medical publishers, a medical communications agency and a publication consultancy, provided ISMPP delegates with considerations to be aware of when selecting and submitting articles for publication.

Covering a 'hot topic' on the role and impact of social media in medical publishing, statistics were shared demonstrating the huge disparity between the levels of social media following across medical journals. Although some use social media alerts to promote publications the evidence suggested this had little impact on direct article downloads. However, the use of supplementary content (e.g. video and multimedia) does increase HCP engagement – leaving the ISMPP audience to ponder 'What can you do to make publication content more shareable?'.

Considerations were shared on how to ensure you are submitting ethical publications to journals; understanding when a journal or body may consider content fabricated, falsified or plagiarised. With 2,047 retractions from PubMed in 2014, and the numbers increasing, attempts to detect and address issues are improving. We should also be careful in the use of pre-published content, as it does vary between publishers as to what will be considered a duplication of publication. If you are unsure please check with the journal publisher. Other general tips were: to agree authorship early; register the trial pre first participants; and follow reporting guidelines.

The session briefly touched on the changing attitude towards open-access journals, seeing a decline in the perception that open-access journals were of a lower quality. This was also demonstrated by the statistic that 63% of scientists have published in an open-access journal in the last 3 years. It was highlighted that caution should be taken in fully understanding the model of open access for any publisher; gold being immediately open content; green being open after a period of time of publication. The session closed on the merits and issues faced with each of the peer-review options employed.



Audience poll results during the ISMPP meeting

Delegates in the Exhibition Hall during the ISMPP meeting

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If we can help with any additional insights, please contact
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Look out for future editions of *To the Point* in 2016, with insights from upcoming industry meetings and key areas of relevance to the healthcare community
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