ISMPP European Meeting 2017

Conference Report

The 2017 European meeting of the International Society for Medical Publication Professionals (ISMPP) was held from 17–18 January in London, UK, with the theme of:

"The Evolving Role of Publication Professionals in a Multi-Stakeholder Environment".

The sessions and topics were varied, but discussions and symposia revolved around incorporating industry, research, publishing and patient perspectives in the evolution of medical publications and communications.

This report provides a summary of the main themes from the meeting:

- Data Sharing
- Data Transparency
- Extending the Reach of Publications

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Conference attendees...

250+ Delegates

13+ Countries

Delegates representing...

Industry

Publishing

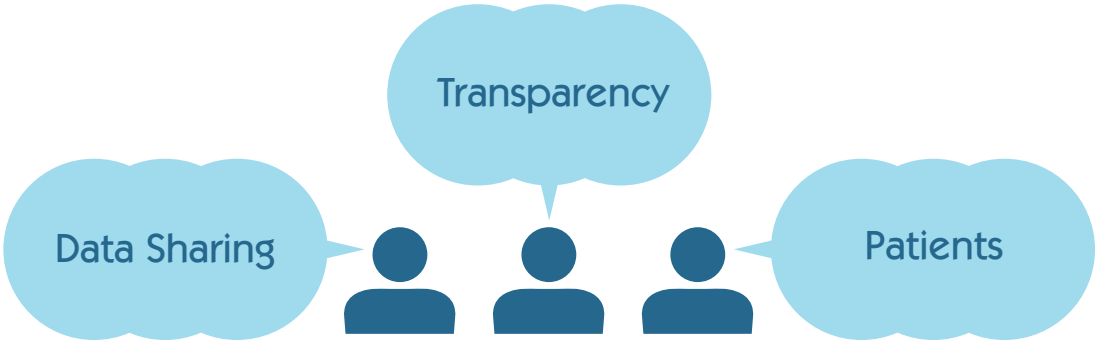
Independent agencies

Academia

The conference included...

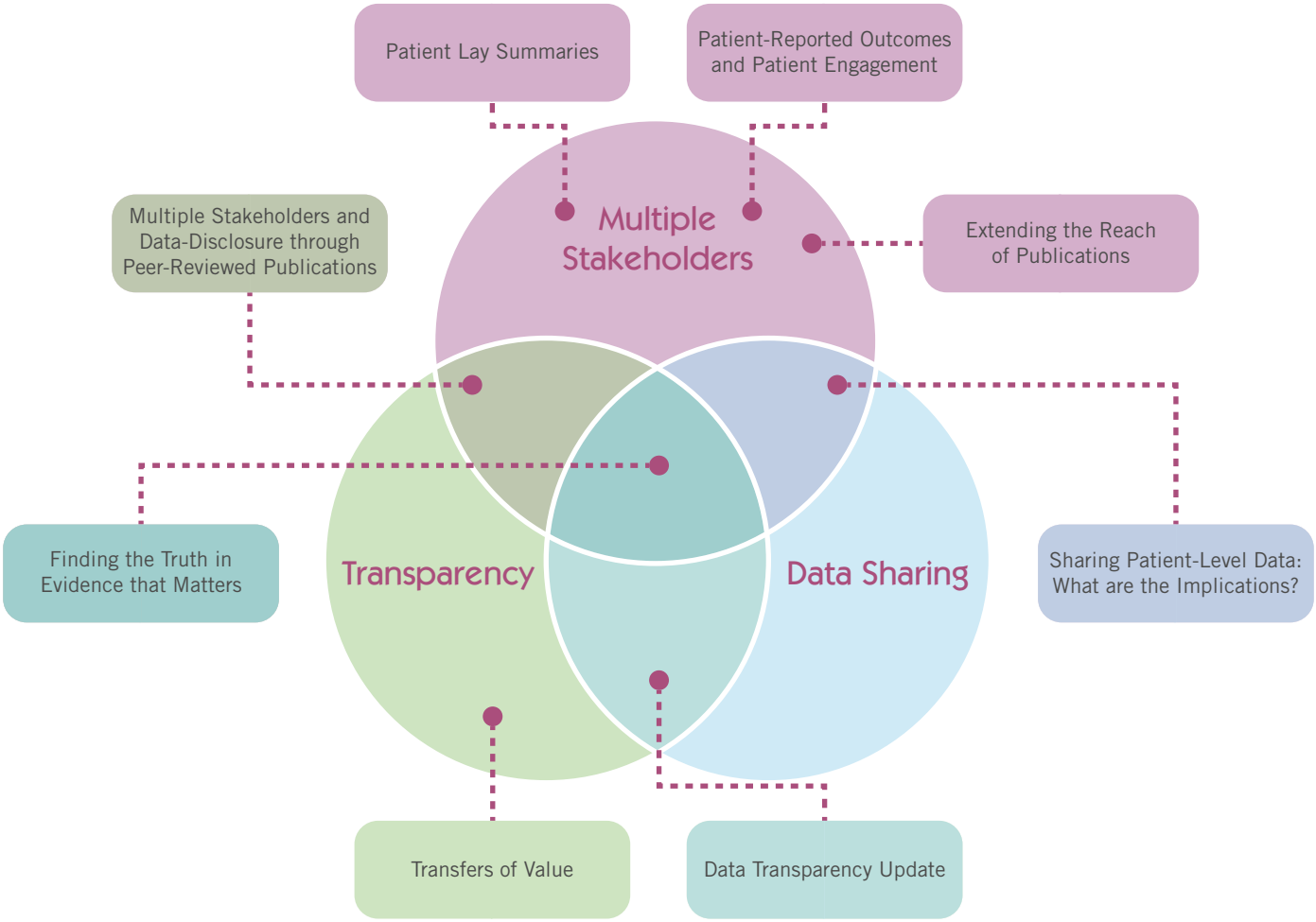
11 Talks and Seminars

Conference highlights and themes...



The 2017 European meeting of the International Society for Medical Publication Professionals (ISMPP) brought together delegates from industry, academia, publishing and independent communications agencies. The meeting featured a broad spectrum of symposia and interactive discussions around the theme of "The Evolving Role of Publication Professionals in a Multi-Stakeholder Environment". Recent controversies and ongoing debates ensured that data sharing and transparency continued to be major topics of discourse at the meeting **(Figure 1)**.

Figure 1. Themes and Sessions at ISMPP-EU 2017



Sharing Data and Patient-Level Data

The institutionalisation of data sharing policies by major funders of scientific research (i.e. European Research Council, Research Councils UK, Wellcome Trust) has led to increased awareness of Open Science and Open Data movements. The potential benefits of open data include increased reproducibility, improvements in public trust, better scientific innovation and research, and reductions in the burden and cost of disease on society. A number of initiatives to widen the breadth of data sharing to also encompass the pharmaceutical industry have been proposed.

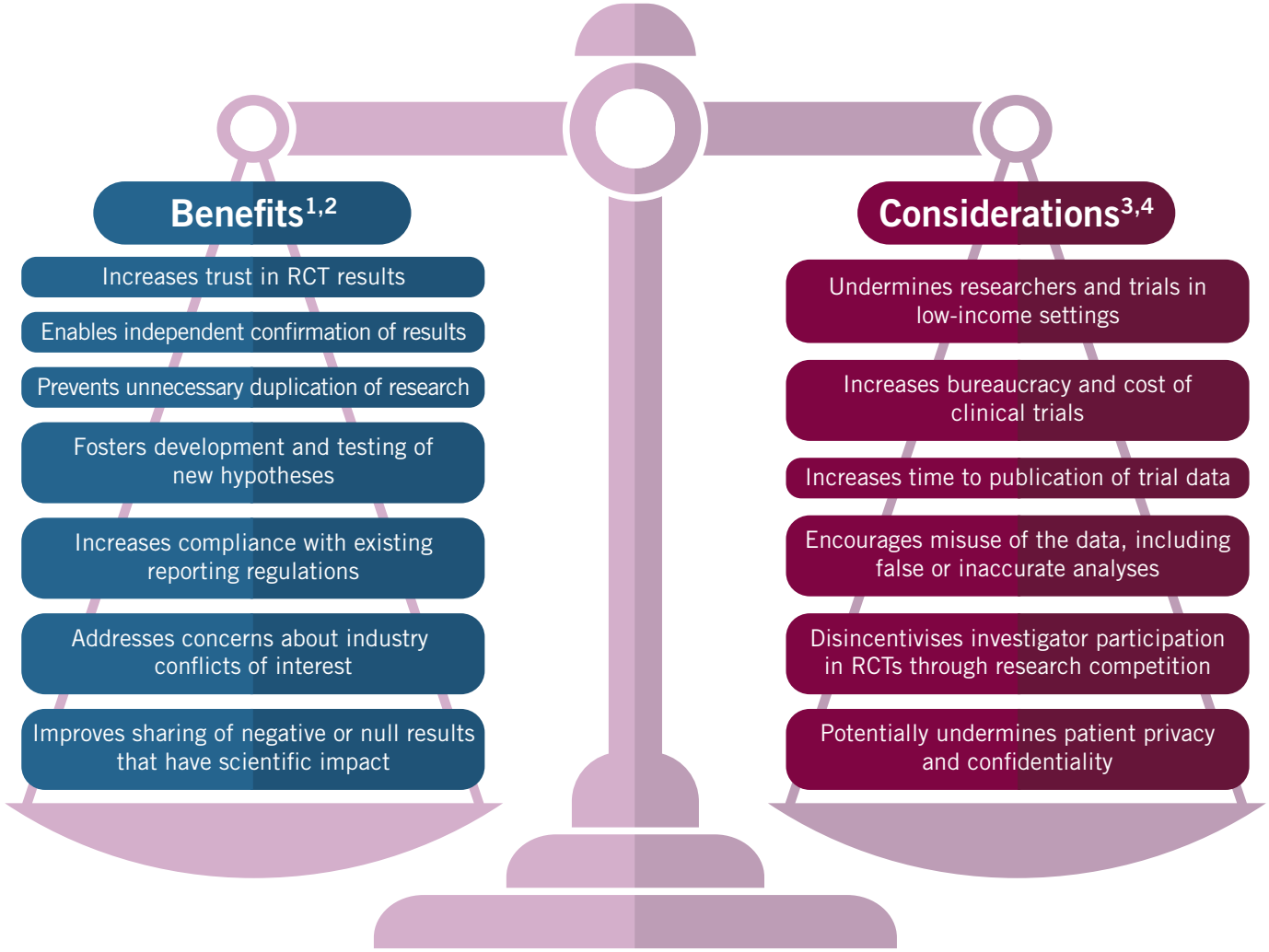
Early 2016 heralded the publication of an editorial by the International Committee of Medical Journal Editors (ICMJE) proposing that future clinical trial reports must make the individual patient data presented in the manuscript available for public sharing. A lively debate took place during the session, with Dr Fiona Godlee (*The BMJ*) defending the proposal, citing the need for transparency as a result of the Tamiflu® and reboxetine scandals. The most vocal opponents were Dr Stuart Spencer (*The Lancet*) and Professor Philip J. Devereaux (McMaster University), who were concerned that the proposal may lead to an increase in cost and development time for new drugs, that competitors and those unfamiliar with the trial may perform spurious analyses, and that there would be reduced opportunities for career starters to publish, thus negatively impacting research careers. Other panellists were more cautious, raising patient privacy as an issue, and also suggested that data sharing reforms should be discussed with all stakeholders – including the public – and should not be imposed by the ICMJE.

Ms Marie-Claire Pickaert, Deputy Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA), also raised the point that the public release of individual patient data is already covered by the second phase of the EMA's Policy 0070, though it has yet to come into force. In a separate session, Dr Slavka Baronikova (Shire International) and Ms Manon Boisclair (Celgene) shared their experiences with the first phase of Policy 0070, heavily emphasising the need for cross-collaboration across departments, increased resource allocation, and early preparation in order to comply with these procedures.

Carl Heneghan, Professor of Evidence-Based Medicine at Oxford University and the cofounder of the All Trials campaign, contributed to the subject of clinical trial data transparency and disclosure with his keynote address, titled *Finding the Truth in Evidence that Matters*. He highlighted the current perception of the problems with medical research, focussing on issues with external validity (e.g. non-representativeness of the trial population), internal validity (e.g. study design bias), and a lack of real-world significance for most endpoints evaluated. In addition, Professor Heneghan raised concerns about the reporting of clinical research data, such as hidden data (i.e. cherry-picking outcomes, unpublished negative data), and the exchange of pre-specified primary and secondary outcomes when publishing results. Throughout his talk, he advocated strongly for smart trial design, stating that optimal sample size, the choice of appropriate outcomes and the minimisation of bias would lead to better evidence-based medical research. Professor Heneghan was in favour of increasing data sharing, suggesting that reporting all data would result in benefits and new discoveries for the field. He did acknowledge that data sharing posed challenges such as patient privacy and an increased burden on the resources of small pharmaceutical companies, but remained optimistic that these were ultimately resolvable.

Figure 2 provides a summary of the main arguments for and against data sharing.

Figure 2. Sharing Patient-Level Data when Reporting Randomised Clinical Trial (RCT) Results



Data Transparency

Transparency was also a hot topic at this year's meeting. In a session about publication practices and disclosure, industry representatives from Merck, Boehringer Ingelheim, AstraZeneca and GSK Vaccines shared their experiences in complying with the publication of all clinical trial data. The discussion revealed many differences in company publication standard operating policies, including timelines, the clinical trial phase they publish and the number of submission attempts. However, all involved in the debate agreed that wherever possible, trial data should be reported in peer-reviewed journals, and publications should be developed independently of commercial interests.

Ms Marie-Claire Pickaert (EFPIA) also led a session clarifying the reporting of Transfers of Value (ToVs) from a European perspective, and acknowledged that improvements and clarifications were necessary, especially in cases where ToVs must be reported for a clinician receiving medical writing support from an independent agency. She emphasised that the EFPIA code allowed detailed explanations for reporting ToVs in a separate Methodological Notes document.

Extending the Reach of Publications

Increasing publication visibility in the digital realm was the subject of a session led by representatives from Envision Pharma, John Wiley & Sons and Shire International. Targeting search and content consumption habits was noted as being particularly effective for communicating results, and it was also suggested that social media participation by key opinion leaders, particularly on Twitter, could increase the reach of publications to a lay audience.

Patient Lay Summaries were a topic of discourse during the roundtable sessions. Participants discussed the variability in the availability of lay summaries of journal articles and the lack of guidance about the format that these should take. The majority of participants felt that patients themselves should be involved in the preparation or review of lay summaries to ensure that these would be useful and relevant to readers without a clinical background. Generally, it was thought that such summaries should describe the question that the research was seeking to answer and explain whether this question was answered by the study. In addition, it was suggested that a text summary may not be the most useful format for lay summaries; an infographic or more visual approach may be more effective and aid understanding of the topic.

Patient Lay Summaries

Lay Summaries was also prominently recognised at the meeting. Tom Rees *et al.* won the poster award for most reflective of the meeting's theme with "Development of a Framework for Publishing Patient Lay Summaries in Medical Journals", while Maria Haughton and Danielle Machin from Costello Medical Consulting received the Best in Original Research award for their poster, "The Prevalence and Characteristics of Lay Summaries in Published Journal Articles". This research highlighted that relatively few journals currently publish summaries for lay readers, but the positive discussions during the roundtable session suggested that these may become more commonplace in the future.

AMWA, EMWA, ISMPP Joint Position Statement

The first international joint position statement between the American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA), and the ISMPP was released at the meeting. The statement outlines the roles and responsibilities of medical writers, and provides guidelines reflecting current recommendations such as the Good Publications Practice (GPP3) and ICMJE recommendations.

References

1. Taichman D. *et al.* Ann Intern Med. 2016; 164(7):505–6; **2.** Warren E. N Engl J Med. 2016;375(5):401–3; **3.** Horton R. The Lancet. 2016;388(10050):1143; **4.** International Consortium of Investigators for Fairness in Trial Data Sharing. N Engl J Med. 2016;375(5):405–7.

Costello Medical Consulting

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If you would like any further information on the themes or research presented above, please do not hesitate to contact Danielle Machin at: danielle.machin@costellomedical.com.