ISMPP 2017 Report

Global Publications Practices: Advancing Ethics and Scientific Integrity in an Era of Data-Sharing

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ISMPP 13th Annual Meeting, National Harbor, MD, USA

The 13th Annual Meeting of the International Society for Medical Publication Professionals (ISMPP) brought together over 560 delegates from around the world representing industry, academia, publishing and independent communications agencies. The conference featured a broad spectrum of symposia and interactive discussions around the theme of "**Global Publications Practices: Advancing Ethics and Scientific Integrity in an Era of Data-Sharing**".

The following key themes of the conference are detailed in this report:

Data Sharing and Transparency

Dr Deborah Zarin, the director of ClinicalTrials.gov (CT.gov), provided an overview of the role of the CT.gov website in our modern era of data transparency and sharing. She summarised the requirements described in Section 801 of the Food and Drug Administration Amendments Act (FDAAA) that came into effect earlier this year, on 18th January 2017. In addition to mandating the availability of a minimal data set of study results for applicable clinical trials, FDAAA now also requires the collection of study protocols and statistical analysis plans. The legislation specifies the timeframe in which study data must be submitted to the website – within 12 months of study completion – and specifies penalties of up to $10,000/day for late compliance.

Dr Zarin also participated in a discussion panel, along with industry representatives, called "Building a Roadmap for Responsible Data Sharing". Solutions to the ongoing challenges to data sharing identified by the panel were shifting academic culture to be more collaborative with industry, and publicising or disseminating the availability of relevant data sets to facilitate these collaborations, thereby avoiding unnecessary clinical trials.

Recently, the International Committee of Medical Journal Editors (ICMJE) released their highly-anticipated requirements for data sharing.[1] While they do not yet mandate the sharing of study data, as of 1st July 2018, publications reporting the results of clinical trials submitted to ICMJE member journals will require a statement indicating:

- Whether individual deidentified participant data (including data dictionaries) will be shared
- What data in particular will be shared, and whether additional, related documents (such as study protocols, statistical analysis plans, etc.) will be available
- When the data will become available and for how long
- By what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism)

Some examples of data sharing statements meeting ICMJE requirements can be found in their editorial.[1]

In addition to FDAAA now in effect in the United States, legislative updates to the regulation of clinical trials in the EU will soon come into effect by October 2018, with Regulation 536/2014 replacing the existing EU Clinical Trial Directive 2001/20/EC. The regulation will harmonise the submission and assessment process for clinical trials conducted in multiple EU Member States, and also create a website through which the information submitted to the EMA will be made publicly available, though protection of personal data and commercially confidential information is still stipulated.

While challenges and concerns with data sharing still remain, the industry and its regulators are moving toward a vision where transparency and sharing deidentified patient data becomes the norm, so that maximum knowledge can be gained from the efforts and risks borne by each clinical trial.

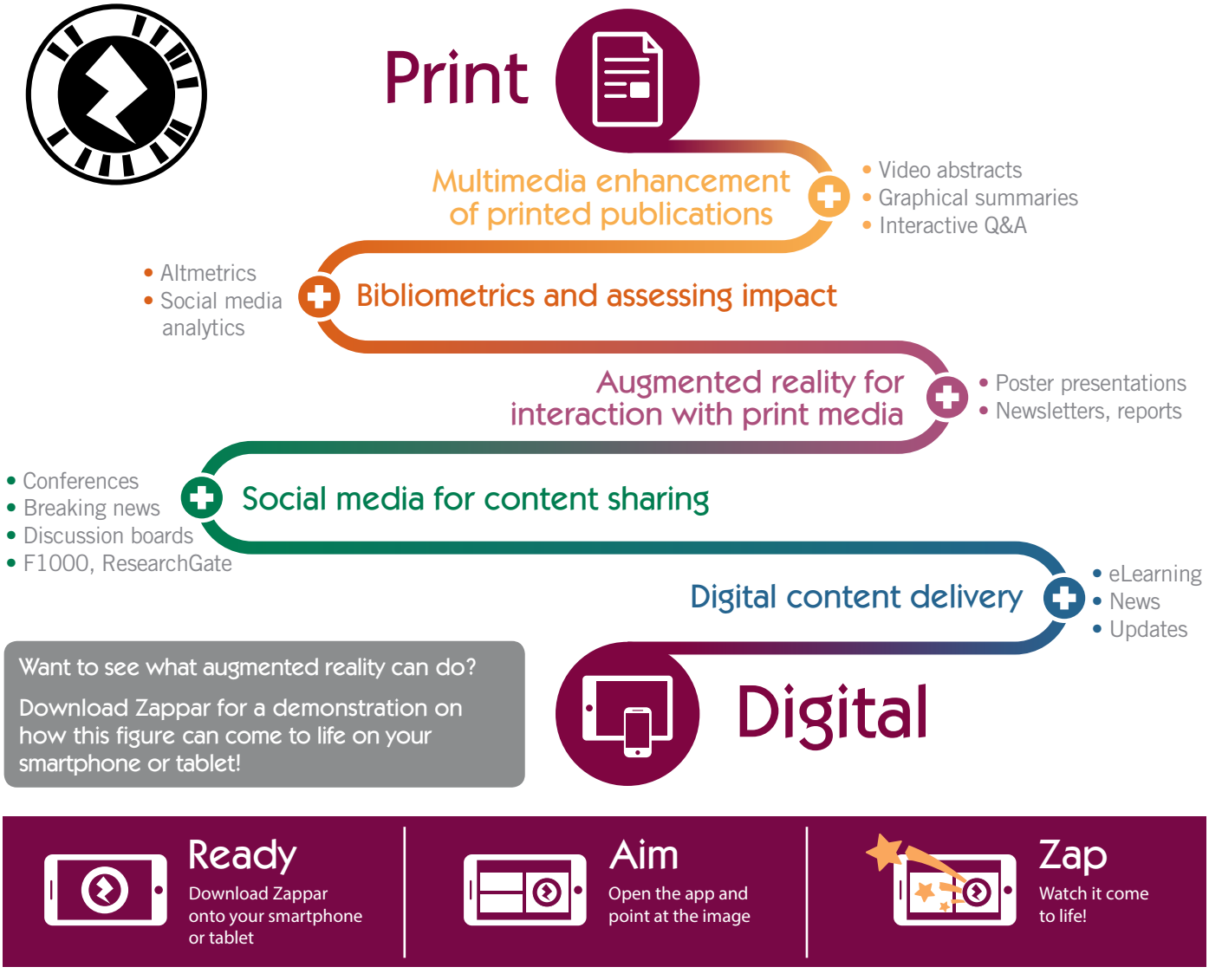
The Role of Digital and Social Media in Medical Publications

In today's era of diminishing print consumption and the rise of digital information saturation, how do you deliver targeted content to the appropriate audience, be they healthcare professionals (HCPs) or patients? This question was posed in the pre-conference workshop, "How to Integrate Digital Advances into your Publication Strategy". Solutions to the ongoing challenges of content delivery, in an environment of constant bombardment by emails, notifications and newsflashes, included understanding the consumption profile of the target audience by examining their preferred device or platform (e.g. desktop computers, tablets, smartphones), and ensuring portability of information between digital devices, or between print and digital content. Many journals now also offer digital enhancements such as video or graphical abstracts that provide quick summaries of manuscripts, which can be advantageous to audiences who may not have much free time, such as clinicians or HCPs.

As the use of social media platforms grows, messages from trusted colleagues or breaking news delivered by reputable conferences is becoming a vehicle for the dissemination and discussion of new information. Many journal publishers offer social media posts to increase the attention given to published articles, as social media is now a notable portion of the measurable impact of a publication taken into account by services such as Altmetric.

Innovative enhancements such as augmented reality can also help bridge the divide between the two seemingly disparate realms of digital and print, and help congress posters stand out in a crowded conference **(Figure 1)**.

Figure 1. Bridging the gap between digital and print media in medical publications



Publications Planning

During the pre-conference workshop on "Advanced Publications Planning", participants shared advice and best practice on how to develop a strategic publications plan, and translate strategy into a tactical plan.

The development of an effective publications plan should be a cross-functional exercise, to ensure that all key stakeholders are involved in the process and committed to the delivery of the plan. It is helpful to conduct a gap analysis to identify how new publications will add to the current medical literature, and to consider factors such as launch timing, author recommendations, and any FDA or EMA timing requirements for reporting or publishing.

Publications strategies should also take into account the new challenges to effective data communication, which include greater scrutiny and regulation of data, and the new ways to access data. A useful place to start when developing a meaningful strategy is the preparation of scientific communication points or key messages. These evidence-based statements may help to explain the disease state, contextualise the product, and effectively summarise the information that needs to be communicated; they may change as the product moves through the development lifecycle and the communication needs evolve. They should be tailored to each type of audience and be supported by scientific evidence.

Concentrating on the differentiated benefit of the product, rather than all of the potential benefits, will ensure that the resulting plan focuses on publication quality, not quantity. To establish the key differentiators, a useful exercise can be the forecasting of competitor publications. To accomplish this, the team should try to think as though they were working for the competitor company; based on the information available in the public domain, what would it make sense to publish, at which congresses, and when? Although this information is unlikely to be completely accurate, it adds to the body of intelligence available from which to build a successful plan.

A common challenge for publications professionals is working with limited data. This can arise when working on products occupying the rare disease space, or when a product is reaching the final stages of the drug lifecycle and there are fewer ongoing studies. In this scenario, maximising the impact of the data that are available is key, which might involve encore publications targeting different audiences, ensuring that manuscripts are published with open access, or using digital options to enhance publication value and aid readers' understanding. It may also be appropriate to publish review articles, but it is always preferable to ensure these are based on sound methodology. Systematic literature reviews and meta-analyses combine the results from multiple studies to obtain an overall estimate of the treatment effect, and the Delphi method[2] is useful for establishing expert consensus, which can then be developed into a publication.

Practical Tips for the Medical Publication Professional

Expedited Congress Publications

In a session on how to comply with best practice while maintaining ethics, Maura McGrail (Senior Account Director; Peloton Advantage) and Kim Tran (Director, I-O Lung Global Publications and Scientific Content; Bristol-Myers Squibb) used case studies to demonstrate how to overcome the challenges presented by developing congress presentations under compressed timelines.

A strong collaboration between publication managers, statisticians, and medical writers is required in these circumstances, and preparation is key. Ensuring that all non-data dependent decisions have been made at the earliest opportunity is helpful; medical writers can provide support by setting up a mock submission for an abstract to determine congress requirements, and engaging authors early by communicating the timelines and ensuring that any author absences are known in advance. The session leaders emphasised that tight deadlines should not impact transparency, and agencies should not start drafting an abstract without the input of all authors. Organising a call with all authors once the data are available can be an effective approach – all data should be reviewed and discussed, in order to decide on the key messages, and an outline of the abstract can be drafted there and then with the participation of all authors.

The Publisher Perspective

This section of the meeting brought together representatives from three publishers (Adis, Elsevier and Taylor & Francis) to discuss how they are working more closely with medical publication professionals and authors to improve quality. The publishers identified four key 'pain points': journal selection, formatting of manuscripts for submission, conflict of interest forms, and the peer-review process. They provided information about ways their journals are streamlining these protocols to assist authors with submission **(Table 1)**.

Table 1. Process improvements introduced by publishers to assist medical publications professionals

Publisher	Improvements
Adis	• Encourages the pharmaceutical industry to approach publication managers to discuss potential submissions; if deemed relevant for their journals, draft manuscripts are then taken to the editors for consideration. • True metrics are provided on their journal websites about the speed of their peer-review process. • Rapid+ journals do not require authors to follow journal style. • Standard submission forms are used across all journals, which assists the manuscript cascading process.
Elsevier	• A journal selector, which makes suggestions based on the manuscript title and abstract. • The "Your Paper Your Way" system allows submission of unformatted manuscripts. Formatting is required only if the manuscript is accepted. • A web-based publishing campus, covering topics such as how to write a manuscript and the peer-review process.
Taylor & Francis	• Medical writers can oversee the whole submission process on behalf of authors, and medical writers are automatically copied into email communications. • The eCopyright system allows authors to sign forms online. • Unedited versions of manuscripts are published online as soon as possible following acceptance, before proceeding with copy-editing.

On the topic of selecting the right journal, the publishers all recommended discussing realistic expectations with the authors, as specialist journals are often more appropriate than high-impact generalist journals. In addition, their website metrics demonstrate that most readers access their content through PubMed and Google; readers use basic keywords to conduct searches and if the topic is of interest, readers will find the publication, no matter where it is published.

The publishers also encouraged regular communication with the editorial office, and offered help if there is uncertainty around the completion of conflict of interest forms. Similarly, if authors or medical writers have questions about peer-review comments, or disagree with some of the comments received, editors are usually happy to discuss these. If you are resubmitting a manuscript following a rejection, the publishers stated that the authors should acknowledge this in the cover letter and outline any changes made to address any peer-review comments received, as it is not uncommon for a reviewer to receive the same manuscript in subsequent submissions.

References

1. Taichmann D. *et al.* Ann Intern Med 2017; doi:10.7326/M17-1028
2. Dalkey N. and Helmer O. Manag Sci 1963; 9(3): 458–467

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Costello Medical provides scientific support to the healthcare industry in the analysis, interpretation and communication of clinical and health economic data. Due to growing demand across an increasing range of service offerings and geographies, Costello Medical has grown organically since foundation in 2008 to a team of over 100 based in Cambridge, London and Singapore.

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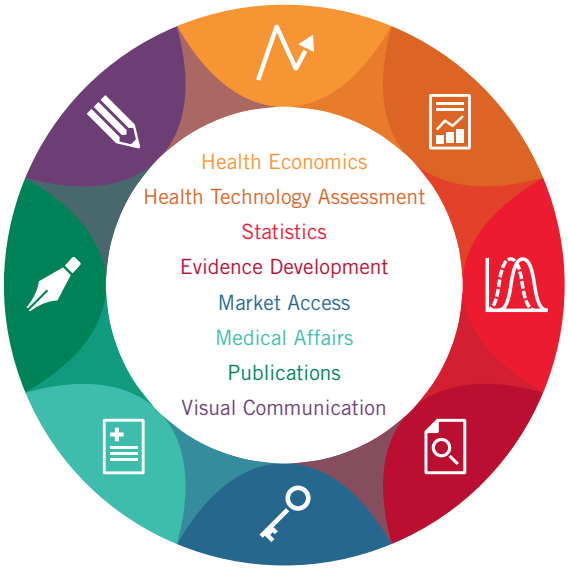

Costello Medical will also be attending the ISPOR 20th Annual European Meeting 4th–8th November 2017, Glasgow, UK

Further Assistance

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.