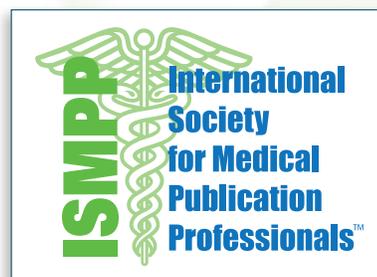


# To the Point

Edition 7 – May 2016

## ISMPP US highlights

*More than 400 delegates from industry, healthcare communications agencies, and publishing gathered on April 11-13, 2016, at the Gaylord National Resort and Convention Center in National Harbor, MD, for the 12th Annual Meeting of the International Society for Medical Publication Professionals (ISMPP).*



The 3-day meeting, entitled “Medical Publications in a Data-Rich World: Enhancing Quality and Transparency,” highlighted methods of ensuring quality of data and reporting amid increasing demands for transparency from patients, investors, and clinical colleagues, and Ashfield Healthcare Communications brings you some of the meeting’s highlights!

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## Keynote address - Jennie Sykes

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### *Truths, myths & misperceptions in the journey to transparency*

Increasing societal and patient expectations are the driving force behind the increased calls for data transparency. Although many myths and misconceptions of data sharing abound, particularly that the pharmaceutical industry is unwilling to share data to avoid releasing negative results, the pharmaceutical industry is making an effort to track and research data transparency, as demonstrated by the founding of the Medical Publishing Insights and Practices Initiative (MPIP) in 2008. Data gathered at GSK, an AllTrials member organization, demonstrated that 15% of 1058 GSK trials (conducted from 2010-2015) resulted in negative outcomes and 82% of these had been published as articles or congress abstract, with 10% pending publication and 8% not published. A similar trend was observed for trials with positive results. Dr. Sykes noted that calls for data sharing are likely to increase in coming years and invited other industry leaders to make commitments to full transparency.

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### *Data-sharing expectations in an age of transparency*

An expert panel representing the viewpoints of industry, academia, and medical journals discussed their expectations for how a new data-sharing proposal will effect clinical trial publication and data sharing plans.

In response to the increasing data transparency requirements from regulators and funding agencies, the International Committee of Medical Journal Editors (ICMJE) has proposed new requirements for authors to share de-identified individual-patient data underlying the results presented in an article within 6 months of publication. At the start of the session, only 22% of audience members reported being “very familiar” with this data-sharing proposal.

Patient confidentiality is a key concern for investigators and study sponsors. Particularly in the rare disease setting, it is possible that the de-identified data could still be linked to individual patients. Delaying implementation of this requirement may be necessary so that consent can be obtained from study participants, and data sharing plans will need to be incorporated into a consent statement for future studies.

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*“The only direction for transparency is: More Transparent.” Andy Powrie-Smith, Director of Communications, European Federation of Pharmaceutical Industries and Associations, Keynote*

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From a practical standpoint, it would be nice to have a single, standardized repository. However, as has been the case for clinical trial registration, getting the global community to agree on a single location and enforcing its use can be difficult.

Overall, the sentiments of the panel, which were echoed throughout the ISMPP 2016 meeting, were that data transparency is only going to increase, and publication professionals should consider how this will affect publication practices.

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## The CONVEY system

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Identification of conflicts of interest is a key part of transparency in industry-sponsored publications; however, completing disclosures is time consuming, hampered by lack of standardization, and fraught with errors such as unintentionally leaving out potential conflicts or misunderstanding what a journal considers a conflict of interest.

In recognizing the need for a global, standardized system for disclosure, the Association of American Medical Colleges has developed Convey, a web-based repository for author disclosures which can be accessed through subscription by organizations such as journal publishers. With Convey, a journal can decide which disclosures they want authors to provide, starting with standard fields but with the flexibility to add more fields/questions ad hoc. As part of each journal's submission process, authors will be prompted to sign into the Convey system (free for those inputting disclosures) and complete the online questionnaire. The Convey system will then store the author's information which can be retrieved and updated as necessary. Other journals or organizations that use Convey and also work with an author with disclosures in Convey will be provided real-time updates to disclosure information. Convey is still in late stage development and testing, but aims to launch with its first subscriber in Summer 2016.

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## The future of medical publishing

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In his keynote address entitled "Medical journals: time for something different," Richard Smith, former Editor of *British Medical Journal*, posited that medical journals have played an important role in spreading medical knowledge, but they now face a number of problems. Journals currently perform poorly in many of their key roles, such as selecting what's right for the audience, ensuring quality, promoting science, providing a reference, serving as a forum, and remaining entertaining. Dr. Smith argues that as a result, many journals will transform or disappear in the next 5-10 years. The medical journals that survive will focus on the function they perform well: campaigning for reform, investigating science and malpractice, and legitimizing issues.

Dr. Smith's view of the future has medical publishing as a process, taking full advantage of current information technology. Ideally, research would begin with a systematic review of the literature, leading to submission of a research grant (in the case of non-industry studies). The grant would include a commitment to publish all data; the systematic review and the grant, as well as the study proposal and any changes made to it, would all be made available in online databases. The final study would be published online, along with the full data set. This would allow others to use the data and reproduce the results, and eventually the public will decide what is important. In the new models of medical publishing, Dr. Smith sees a role for medical professionals as organizers, coordinators, and communicators.

## Enhanced content: pros, cons, processes, and trends

Evolving technology enables industry sponsors, authors, and journals to offer digital content and other enhancements to published material. Enhanced content can range from a simple video abstract embedded on a journal's website to digital animation of a drug's mechanism of action. Enhancements may provide multilingual translation or supplemental data presentations, but whatever the enhancement, there are caveats to consider.

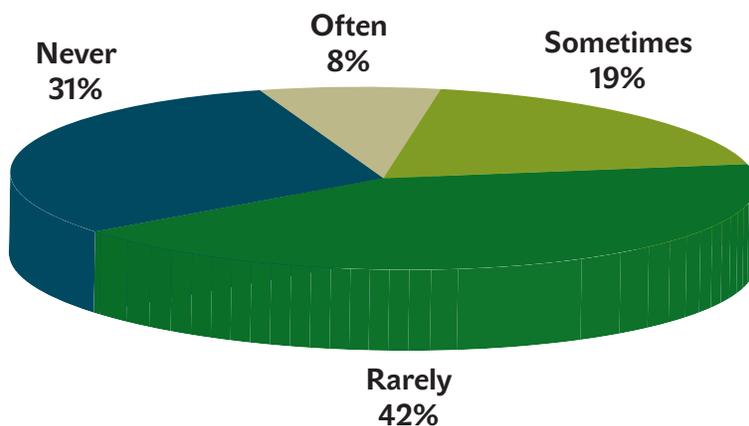
When used appropriately, enhanced content allows going beyond the printed page to provide more educational information. In the context of a congress presentation, this can allow more information to be provided than will fit in the extremely limited space permitted for a poster. For journal articles, readers may be able to access short summaries or interviews with the author explaining key results and their implications.

However, a poll of audience members showed that the majority (73%) rarely or never currently use

enhanced content in their publications. Top reasons given for why enhanced content had not been used were "not a priority" and "budget." In addition, the authors' interest in providing this additional content may be limited.

While enhanced content can improve the reader experience, scientific rigor and best publication practices need to be maintained. The speakers emphasized that enhanced content should "inform, not promote." Best practice recommendations include the following: the content must be within the scope of the underlying publication (no editorializing); no patients or patient information may be involved; relevant disclosures should be included; the Sunshine Act Transfer of Value should be considered in assessing agency support for content development; approvals should be obtained from the presenting author, the corresponding author, and the company; the product attorney should also be informed of the content.

### ARS question: How often do you use enhanced content in journals or poster presentations?



# Poster session

Dozens of abstracts were submitted for consideration for presentation at the 12th Annual Meeting of ISMPP. Some were selected for oral presentation in the general session, and many more as posters allowing in-depth conversation with those who conducted the research. A sample of these is summarized here.

## **Truss N et al. Choose your target journal carefully: quantification of delay to acceptance caused by each manuscript resubmission**

Data derived from industry-sponsored manuscript submissions were analyzed for time from submission to decision to resubmission, and for change in impact factor. Half of the manuscripts (21/41) were accepted at 1st submission, 13/41 at 2nd, 6/41 at 3rd, and 1/41 at 4th. With each resubmission, the cumulative time to acceptance increased and the average impact decreased. For manuscripts rejected at 1st submission, the mean time from submission to decision was 25 days; time from decision to resubmission to the 2nd journal was a further 54 days. By quantifying the potential delay to acceptance, these data demonstrate a way to raise author awareness of the implications of target-journal choice and reduce resubmission rates.

## **Nastase SA et al. survey of external authors to improve publication development processes**

Authors at BMS conducted a survey to determine external authors' experience with BMS publication development processes and use of their chosen web-based tool for documentation. Survey results highlighted the importance of setting expectations early on (i.e., during author kickoff) regarding review & approval process requirements and timelines, as well as a reduction in the number of automated reminder emails and elimination of frequent password changes when using the publication management tool.



## Publication planning for biosimilars

Biosimilars are biologic agents that are similar in composition and therapeutic effect to government-approved brand biologics. Development of biosimilars is intended to offer a more cost-effective alternative for treatment of disease states for which biologics are commonly prescribed (e.g., autoimmune disorders, cancer). In the US, FDA approval of biosimilars requires Phase 1 PK/PD data and one Phase 3 clinical trial, but developers may use these same datasets to seek all indications approved for the brand biologic.

When developing scientific statements and publication plans for biosimilars, the PK/PD data are considered the most relevant dataset, as it proves sufficient similarity to the brand agent. Emphasis should be placed on therapeutic equivalence, as well as cost. Cross-functional publication planning should be done in collaboration with health economic outcomes research (HEOR) teams.

It can be difficult to place the biosimilar trial data in mainstream, higher-tiered journals; consequently, congresses may

be the primary targets for the biosimilar portfolios. It was noted that it can be challenging to convince developers of the importance of publishing all data, including secondary and/or post-hoc analyses. In light of the fact that clinicians are often unfamiliar with the basics of biosimilars and their trade names, publication and/or presentation of the data will enhance their understanding of this relatively new entrant into the therapeutic landscapes.

## Scientific platform development best practice

Scientific platforms are valuable and often necessary tools not only for publication professionals but other company departments as well. Publication planners play an important role in bringing these other departments together, even if they do not have sole ownership of the platform. While the industry and medical communications panel stressed that it is never too late to start the platform development process, the majority of companies initiate the process at the phase 2 stage when there is generally enough data to predict the trajectory for a given product.

Involving colleagues across departments at early stages of the development can ensure that there is buy-in for the key aspects of the platform, including which communication points to prioritize and what scientific evidence supports clinical development. Because the

main goal of a platform is to maintain consistency across publications, it is often useful to consult with teams on the proper terminology to use in the platform; it may even be advisable to indicate any language that should not be utilized.

Development takes time, generally up to 5 months, so publication teams are advised to begin the process early. A literature review and interviews with stakeholders including those inside and outside the company (3 weeks) can provide the basis for mapping of unmet needs and areas where a shift in mind-set may need to be addressed (2 weeks). Over the course of a few weeks, key concepts can be workshopped with company stakeholders, followed by drafting and revising of the statements over a month or more. The panel suggested that the final step of development should include intensive vetting by experts in the field and even those

known to have dissenting opinions (~4 weeks).

During the process, departments should be consulted on how each intends to utilize the platform. Answering this question will help guide the final format of the platform, which can range from simple Word documents to hyperlinked, web-based portals.

Once developed, the platform should exist as a living document and can be revised as necessary when key data milestones, changes in the clinical program, or shifts in the clinical landscape occur. The publication team can help to implement use of the platform ensuring that new team members are being on-boarded and evaluating how the platform is being utilized company wide. Through this process, the scientific platform will retain its value to the publication team and company as a whole.

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## Roundtable sessions

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### *New models of peer review*

- Peer review in medical journals has a number of problems. It is time consuming, delays publication, and has not been effective at detecting fraud. Journal editors, authors, and study sponsors are all interested in finding new models of peer review, and a number of new models are now in use.
- Roundtable participants agreed that these new models are interesting, but do not satisfy many of the major issues, and room for improvement remains.

<i>Examples of newer, experimental models of peer review</i>	
<b>Double blind</b> (Nature journals)	Intended to overcome any personal biases and conflicts of interest
<b>Transparent</b> (EMBO Journal)	Reviewer reports are published online and are available to readers of the published article
<b>Open</b> (BMJ)	Reviewer reports are published online
<b>Collaborative</b> (Frontiers journals)	Interactive dialog between reviewers and authors, allowing authors to present their point of view to the reviewers
<b>Post-publication</b> (F1000, ScienceOpen)	Article is published online after only basic checks; peer reviewers are invited after the article is online
<b>Portable</b> (Axios, Peerage of Science)	Peer review report is independent of journals so the same article does not need to be reviewed multiple times by different journals

### *Best practice interacting with authors*

- Difficulty in getting some authors to fully participate in the review and approval process is common
- Authors in different cultures sometimes have different preferences for communication (e.g., telephone, face-to-face), and publication teams should consider the best way to solicit these authors' feedback
- For those who simply refuse to adhere to review timelines, a process should be in place for advising them that they can be removed from the author byline. Participants agreed that this type of discussion often prompts the authors to fulfill their obligations, although a diplomatic approach must be employed to maintain a collegial relationship with these authors
- It was stressed that in order to set realistic expectations, authors should be advised of their obligations prior to publication development during the author kickoff meeting, rather than simply in a written agreement or via email.

# Predatory journals

## *Protecting the integrity of scholarly literature*

Predatory publishing – the practice of soliciting manuscripts for non-indexed, non-peer-reviewed, disreputable journals – is on the rise. Fifty percent of session attendees indicated they were aware of having been approached by predatory journals. Shen and Björk (*BMC Medicine*. 2015;13:230) reported that, in 2014, there were 420,000 articles published across 8000 predatory journals from 966 alleged publishers. The predators publish fraudulent papers, as well as junk science, that would not survive peer review at an indexed journal. They also solicit articles from well-meaning scientists seeking to publish their data, by promising easy, rapid publication in exchange for a fee. Authors most commonly duped are those in developing countries, but others who work in a publish-or-perish environment fall prey as well.

Many of these disreputable journals have indiscernible locations and there is no institution or governing body with oversight of these predatory publishers, meaning no one can sanction them or shut them down.

### *Tips for recognizing predatory publishers*

- Spelling errors (broken English) in initial email
- Web-based email addresses (Yahoo, Gmail) for journal staff
- Journal/publisher emails and websites often mimic reputable journals with similar graphics, logos
- Journals promise rapid publication, accept submission within days
- Current issues not indexed in PubMed/National Library of Medicine

Predatory publishing is a global problem that requires vigilance on the part of multiple parties. Professional associations such as ISMPP can raise awareness of the problem and educate members about appropriate publication practices. Academic and research institutions operating with the publish-or-perish principle can educate their researchers about how to recognize predatory publishers. Academicians and medical experts should regularly conduct web searches on their own names to make sure they have not been added to editorial boards of fraudulent journals.

Medical publication professionals and editors have a responsibility to educate colleagues, using their authority and platforms to raise awareness about this burgeoning problem that threatens the integrity of scholarly literature.

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