Conference Insights

The International Publication Planning Association’s 7th Annual Meeting

in-depth report from a meeting held in San Francisco, CA, USA, 15–16 June 2009

by Elizabeth Wager
KeywordPharma – inspiring best industry practice

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FDAAA Legislation: Global Implications for Clinical Trial Reporting and Publication Planning
A KeywordPharma Expert Review by Elizabeth Wager
Published November 2008
ThePharmYard product code kwp024

This report describes the new requirements for trial registration and the reporting of results, and explains what companies need to do now.

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Executive summary

The reputation of publication planners continues to require defence against accusations of ghost writing and ghost management. Demands for increased transparency remain prevalent, while the age-old issue of industry sponsorship still provokes unwarranted prejudice. Companies are responding positively, with the introduction of new policies on the disclosure of results and an increased focus on compliance. However, this has, in turn, led to a diverse range of guidelines and new challenges for publication planners in interpreting them. The emergence of online communication channels such as blogs, which can often contain misinformation or imbalanced commentary, lends new complications for company communication strategies.

The International Publication Planning Association’s 7th Annual Meeting, covered in depth in this Conference Insights review, looked at the regulatory, ethical and operational challenges in publication planning, and presented an industry in transition. Beginning with an overview of the evolving regulatory frameworks for trial registration and results disclosure, and their impact on publication planning, professionals shared insights into how the industry is responding and what more can be done to enhance its reputation among health professionals and journal editors.

The meeting also explored critical issues such as risk mitigation, budget management and the issues of authorship and developments in health economic and outcomes research from the perspectives of journal editors, publication planning professionals and medical communications experts.
The International Publication Planning Association’s 7th Annual Meeting – Programme
Organised by The International Publication Planning Association, San Francisco, CA, USA, 15–16 June 2009

**Chair:**
Dan Donovan, President, Envision Pharma, Senior Vice President, United BioSource Corporation

**Day one**

FDAAA, Efficiency & Accelerated Time Lines: How Does it All Add Up?
Panellists:
Catherine Arnaudeau-Bégard, Lead Manager Publication Planning, Global Medical Affairs, UCB Pharma S.A.
Tricia Deja, Manager, Medical Publications, Astellas Pharma Global Development, Inc.

**Moderator:**
Maureen F Garrity, Director, Medical Publications, Astellas Pharma Global Development, Inc.

Risk Mitigation in Publication Planning: How to Proactively Face the Industry’s Newest Challenges
Dan Donovan, President, Envision Pharma, Senior Vice President, United BioSource Corporation

Elizabeth Crane, Senior Manager, Medical Publications, Astellas Pharma Global Development, Inc.

Coping with a Global Organization: The Pros & Cons of the Most Popular Models
Panellists:
Mark Molenda, Associate Director, Medical Affairs Strategic Trials Team, Centocor Ortho-Biotech Services LLC
Matt Monberg, Senior Scientific Communications Associate, Lilly USA LLC

**Moderator:**
Maureen F Garrity, Director, Publications, Astellas Pharma Global Development, Inc.

The Changing Healthcare Environment: Generating & Communicating Economic & Humanistic Value to Payers & Decision Makers
Christopher Leibman, Senior Director – Pharmacoeconomics, Elan Pharmaceuticals
Michael R Pollock, President, Reynolds Pollock & Associates

Clinical Trial Disclosures: Hot Button Issues & the Latest Updates
Scott Lassman, Partner, Wilmerhale

The Editors’ Perspective: Promoting a More Effective Partnership between Publication Planners and Journals
Panellists:
Michael Callaham, Editor, Annals of Emergency Medicine
Mikel Gray, University of Virginia, Department of Urology and School of Nursing, Editor in Chief, Journal of Wound, Ostomy and Continence Nursing
Charon Pierson, Editor-in-Chief, Journal of the Academy of Nurse Practitioners

**Moderator:**
Elizabeth Loder, Clinical Editor (Secondary Care), BMJ

**Day two**

Senate Finance Program for Medical Publication Professionals
**Discussion Leader:**
Dan Donovan, President, Envision Pharma, Senior Vice President, United BioSource Corporation

**What You Need to Know About GPP2: Updates and Implications for Publication Planners**
Catherine Arnaudeau-Bégard, Lead Manager Publication Planning, Global Medical Affairs, UCB Pharma S.A.
Art Gertel, VP Strategic Regulatory Consulting, Medical Writing & QA, Beadsworth Consulting Group, Inc.
Liz Wagner, Managing Director, Sideview

Tackling the Authorship Debate: A Practical Discussion on Disclosure, Transparency & Positive Steps You Can Take to Move Beyond the Guidelines
Panellists:
Nancy Bormann, Associate Director, Medical Communications, Biogen Idec
James T Magrann, Publisher, Current Medical Research and Opinion

**Moderator:**
Kirby Lee, Assistant Professor of Clinical Pharmacy at the School of Pharmacy and Institute of Health Policy Studies, School of Medicine, University of California, San Francisco

Reviews, Reprints & Supplements: Demystifying the Current Environment
Panellists:
Catherine Arnaudeau-Bégard, Lead Manager Publication Planning, Global Medical Affairs, UCB Pharma S.A.
Mikel Gray, University of Virginia, Department of Urology and School of Nursing, Editor in Chief, Journal of Wound, Ostomy and Continence Nursing
James T Magrann, Publisher, Current Medical Research and Opinion
Craig Smith, Senior Editor and Manager, Supplement Division, Elsevier

**Moderator:**
Elizabeth Crane, Senior Manager, Medical Publications, Astellas Pharma Global Development, Inc.

Publication and Reporting Bias of Clinical Trials Submitted to the FDA
Kirby Lee, Assistant Professor of Clinical Pharmacy at the School of Pharmacy and Institute of Health Policy Studies, School of Medicine, University of California, San Francisco

Firewalls: How do we Reorganize and Conduct Business to Respond to the Current Environment?
Joseph B Laudano, Senior Director, Medical Affairs, Forest Research Institute
Ansgar Conrad, Senior Manager, Medical Communications, Actelion Pharmaceuticals US, Inc.
Leslie Meltzer, Manager, Medical Communications, Actelion Pharmaceuticals US, Inc.
The International Publication Planning Association (TIPPA) is an industry-run association. Our mission is to foster excellence in medical publications and communications within the biopharmaceutical industry by providing a foundation from which the industry can stand together to organize thoughts and present recommendations and ethical guidance.

In addition TIPPA provides practical strategies for developing, implementing and executing an effective publication and communication plan as a critical component of the clinical biopharmaceutical development process. Our aim is to help biopharmaceutical communication executives and their agencies produce ethical and targeted publications and clinical data throughout the product lifecycle.

Benefits of Membership
TIPPA brings together professionals from pharmaceutical companies, medical journals, academia and medical communication agencies to tackle the challenges of publication planning. There is no fee for membership and some of the benefits include:

- An annual meeting that offers fresh insight on the most pressing issues facing publication planning professionals and networking time to exchange ideas with your peers.
- Regional events that provide additional educational resources and networking opportunities during the months between the annual meeting.
- Online web meetings that provide the latest information and guidance from industry experts on pressing industry topics.

As a member of TIPPA, you will join a network of peers from the pharmaceutical industry including:

- Procter and Gamble Pharmaceuticals
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- Wyeth Pharmaceuticals
- TAP Pharmaceutical Products Inc.
- Amgen Inc.
- Genentech, Inc.
- Genzyme Oncology
- Medseas Health Communications, LLC
- Roche Laboratories
- Teva Neuroscience
- Pfizer, Inc.
- Talecris Biotherapeutics
- Boehringer Ingelheim
- Envision Pharma, Inc.
- Altana Pharma AG
- Schering Plough
- Novartis Pharmaceuticals
- MedThink Communications
- Apothecom Associates LLC
- 3M Pharmaceutical
- Eli Lilly Pharmaceuticals
- Guidant Corporation
- Eli Lilly and Company
- Takeda Pharmaceuticals NA
- Prescott Medical Communications
- Elsevier
- PPSI
- MGI PHARMA
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- Rx Communications, LTD
- Merck & Co., Inc.
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- GlaxoSmithKline
- And many more!

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About the author

Elizabeth (Liz) Wager is the author of books on ‘Getting Research Published: An A to Z of Publication Strategy’ and ‘How to Survive Peer Review’. She is a co-author of ‘Good Publication Practice For Pharmaceutical Companies’ and the European Medical Writers Association guidelines on the role of medical writers.

After obtaining a first-class zoology degree from Oxford in 1983, she worked for Blackwell Scientific Publications, Janssen-Cilag then Glaxo-Wellcome. In 2001, she set up her own company, Sideview, which provides training, writing, editing and publication consultancy services. Since going freelance, Liz has run courses on publication strategy, medical writing and publication ethics on five continents.

She is the Chair of COPE (the Committee on Publication Ethics) and a member of: the BMJ’s Ethics Committee, the World Association of Medical Editors Ethics Committee, and the World Health Organization Scientific Advisory Group on trial registration. She is also a Visiting Fellow at the UK Cochrane Centre.

She can be contacted at: liz@sideview.demon.co.uk or via www.lizwager.com

Free Webcasts at www.NetworkPharma.tv

WEBCAST: Headlines and deadlines
Recorded 25 June 2009, London

In this webcast Elizabeth (Liz) Wager, Publications Consultant, Sideview, focuses on what the world thinks of publication planners and how have journal editors responded to FDAAA.

WEBCAST: Guidelines update
Recorded 25 June 2009, London

In this webcast Elizabeth (Liz) Wager, Publications Consultant, Sideview, focuses on the forthcoming Good Publication Practice Guidelines (GPP2), developments in declaring competing interests and journal transparency polices.

Video Discussion

An informal discussion between Liz Wager and Chris Graf
Recorded 14 May 2009, Oxford

Liz Wager (Publications Consultant and Co-author of the original Good Publication Practice Guidelines(GPP)) and Chris Graf (Associate Editorial Director, Wiley - Blackwell and leader of the Steering Committee of ISMPP responsible for developing the forthcoming GPP2 Guidelines) reflect on the origins of GPP and why an update was felt to be needed.

For more news, views and information about all aspects of publication planning please visit www.ThePublicationPlan.com
Current challenges in publication planning

Opening The International Publication Planning Association (TIPPA)’s 7th Annual Meeting, Dan Donovan (Envision) invited participants to “think, discuss, and take action”. He noted that the reputation of publication planners continued to require defence against accusations of ghost writing and ghost management. He challenged attendees to do something, both within their own companies and externally, to correct the many misconceptions about the profession.

Donovan went on to acknowledge the incredibly complex environment faced by publication professionals who must be aware not only of journal requirements but also of the increasingly restrictive policies of academic institutions governing relations with pharmaceutical companies (Figure 1).

While many journal editors now recognise the legitimate roles of professional writers and planners, and the high quality of industry-sponsored research, a good deal of prejudice remains. Donovan cited a recent editorial in Blood, describing how the journal had rejected a manuscript because it had industry sponsorship. He likened this to “scientific profiling” and urged editors to judge submissions objectively, on their science, and not solely on their funding source.

Another trend is the demand for increasing transparency in publications. Many companies have embraced this and now have helpful policies on the disclosure of results. A more worrying trend, said Donovan, is the dwindling of industry-side resources, which has led to redundancies in some companies. However, the demand placed upon companies via the FDAAA requires them to deliver more publications in a tighter framework, so many people are faced with the challenge of doing more with less.

Companies and publication planners need to keep abreast of the rapidly evolving world of blogs. These often contain misinformation or unbalanced commentaries but, Donovan noted, “because they are written, people think they are true”. These uncontrolled and rapidly evolving discussions can be difficult to deal with but should not be ignored.

Companies are now placing an increasing focus on compliance. This represents a challenge to publication planners because there are so many relevant guidelines and different interpretations of what they mean. Responding to tighter regulation of continuing medical education (CME) activities in the USA and to criticisms of the use of ghost writers, some companies are considering the appropriate role of medical writing agencies. A few have decided to bring medical writing and publication planning activities in-house and stopped using agencies while, in contrast, other companies are increasing their use of agencies to ensure compliance with professional standards and to act as a ‘third eye’ on publication activities.

Concerns about risk limitation are increasing the role of legal rather than scientific considerations in shaping publication planning. This can lead to what Donovan views as an “overly conservative approach” and to “restrictive publication policies”. Companies have to strike a balance between avoiding undue influence on the one hand and, on the other, having unrealistic expectations that academics and investigators can be responsible for all aspects of publication.

Despite the challenging times, Donovan concluded that most companies are heading in the right direction, and
there have been encouraging moves towards greater transparency. There is, he said, a strong organisational commitment to improving medical publications. Companies should continue to strive to publish all clinically relevant material, and publication planners should work towards adding value to the medical literature.

The FDA Amendments Act

The first session comprised a panel discussion of requirements of the US Food and Drug Administration (FDA) Amendments Act (FDAAA) for trial registration and disclosure, and how these affect publication planning. The session was moderated by Maureen Garrity (Astellas); the panelists were Catherine Arnaudeau-Bébard (UCB Pharma), Tricia Deja (Astellas) and Liz Wager (Sideview).

The FDAAA is being implemented in three phases, starting in September 2008. The first phase introduced mandatory registration for phase II–IV studies and a requirement to post a tabular summary of efficacy findings on ClinicalTrials.gov. The second phase, which will come into force in late September 2009, will require disclosure of adverse events. The third phase, from September 2010, is termed “expansion by rule making”. Although this phase has not yet been fully defined, it may require posting of lay summaries, posting of full protocols (not just a summary of trial designs) and an expansion of the scope of the regulations to cover unapproved products.

A further complication for companies operating in the USA is that, alongside the federal law, individual states have introduced their own legislation. In particular, the state of Maine requires public disclosure of the results of all trials conducted since 2002 of any drug sold in the state. Another problem is that, while the FDAAA requires companies to post only a tabular summary of key findings (with virtually no text), the state of Maine originally required companies to post summaries in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)-E3 format on websites such as clinicaltrialresults.org. The state is now proposing to require companies to post on ClinicalTrials.gov (despite the fact that it does not accommodate the longer ICH-E3 format summaries). Companies that had complied with the original requirements and posted ICH-E3 summaries have been forced to go back and re-register older studies on ClinicalTrials.gov and post the results in the tabular format.

Maine also requires adverse event data to be posted, although this is currently voluntary under the FDAAA and the format to be used by ClinicalTrials.gov has not yet been established. Companies are therefore concerned that they must post information in one format now (to comply with Maine legislation) but may then have to go back and supply it in a different format when the FDAAA requirements for adverse event reporting come into force in September 2009.

Despite the lack of clarity over legislation, companies cannot afford to ignore the new laws. Penalties of up to $10,000 per day, per violation may be imposed under the FDAAA and, in addition, the state of Maine can impose fines of $5000 per day for late posting. As well as stiff financial penalties, non-compliant companies may be identified on ClinicalTrials.gov and it is not clear if or when such notices will be removed after the violation has been corrected. So far, no companies have been fined or “named and shamed”.

The requirements keep changing!

As well as federal and state laws, various organisations make demands on companies for disclosure. In many cases, these requirements go beyond those of the FDAAA. For example, the International Committee of Medical Journal Editors (ICMJE) will publish studies only if they have been registered before patients were enrolled (wheras, under the FDAAA, registration must occur within 21 days of the first patient entering the study) and this requirement applies to all trials (not just phase II–IV trials of applicable products). The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) will soon be encouraging companies to disclose the results of all confirmatory and exploratory trials of products marketed anywhere (not just in the USA).

The FDAAA requirements have created a considerable workload for drug and device manufacturers. Regulatory affairs departments are required to certify to the FDA that the requirements have been met. Trial registration entries must be kept current (e.g. with details of all trial sites). The new requirements have implications for developing protocols, since the choice of endpoints and study end-dates may affect which results must be posted and when.

Requirements for clinical trial disclosure have created a new industry

Registering trials on ClinicalTrials.gov has also become increasingly complex. Since the register was established, over 50 new fields have been added, and incomplete posting is not accepted.
Requirements for clinical trial disclosure have created a new industry. Responding to the difficulties associated with the ClinicalTrials.gov website, a number of web-based databases have been developed so that users can gather the data gradually (e.g. the Veritas Clinical Trial Register). There are also websites listing global requirements for trial registration (e.g. TransparentCT.com).

The need to disclose results has also created new challenges for publication planners. Since the summaries posted on ClinicalTrials.gov include only data tables presented without clinical context or interpretation, many companies try to publish results in peer-reviewed journals at or before the FDAAA deadline for the posting of results. This timescale means that publications must be started as soon as data tables are available and before clinical study reports are finalised. One of the panellists, Tricia Deja, explained how publication planners at Astellas have risen to this challenge (Figure 2).

To achieve publication at the time of results posting, Deja said that writing must be initiated sooner than previously, and authors must be involved from the earliest possible stage – preferably from the initial investigators’ meeting (to ensure fulfillment of ICMJE authorship). At Astellas in the USA, a publication steering committee is proposed, which considers all potential authors (both within the company and externally) and identifies individuals who are likely to meet the journals’ authorship criteria. The intent is to start to talk about how data will be published and establish timelines. Written authorship agreements set out the timelines and responsibilities of all authors and also what support they can expect from the company. Telephone conferences or meetings involving all members of the steering committee and potential writing group are held as the trial progresses. Some manuscript sections, such as the Methods, can be drafted before the data analysis is available, with the aim being to “move publication along much more quickly than before”, in order to achieve publication within 12 months of the study end (defined as the last patient’s last visit). Deja commented that “it’s a case of doing as much as you can ahead of time”.

Catherine Arnaudeau-Bégard echoed these sentiments as she described the processes at UCB Pharma. UCB is implementing this promising model, aiming to set up a publications steering committee early and to agree authorship before the results are available. They use the Consolidated Standards of Reporting Trials (CONSORT) checklist to prepare the Methods section of manuscripts, which can be drafted before data analysis. Liz Wager (Sideview) then discussed the response of journal editors, in particular the ICMJE, to the FDAAA. She noted that whereas the ICMJE had been in the forefront in demanding trial registration, their position on results disclosure was quite different. The ICMJE appears to have accepted, rather grudgingly, that companies are now required to post results summaries on ClinicalTrials.gov, but, instead of welcoming this as a major advance in transparency, their guidelines stress the potential dangers of posting non-peer-reviewed data. However, while peer review is undoubtedly useful for ensuring a balanced interpretation and toning down
unjustified conclusions, there is no evidence that it can detect incorrect or fraudulent data. The tabular summaries of key efficacy findings are far more limited than those published in journal articles, yet they serve a useful purpose, especially when they disclose results that would otherwise never have been published. The ICMJE accepts that posting basic tables on ClinicalTrials.gov does not constitute prior publication and, therefore, will not affect the chance of publishing findings in a peer-reviewed journal. However, they have stated that disclosure of more detailed information might jeopardise future publication, and this has led to several companies taking down longer summaries (such as those in ICH-E3 format) which had earlier been posted on public websites.

Posting basic tables on ClinicalTrials.gov does not constitute prior publication and, therefore, will not affect the publication of findings in a peer-reviewed journal

Of course, while trial registration may benefit journals by helping peer reviewers and enabling editors to detect redundant publications, disclosure of trial results has, until recently, been a profitable monopoly for journal publishers. Journal editors therefore have a considerable competing interest in this debate. Journals might suffer if new systems for the disclosure of results became accepted that were easier or cheaper for companies than traditional publications (e.g. posting ICH-E3 summaries on websites).

However, with the current requirements for limited posting on ClinicalTrials.gov, and companies’ preference to publish their findings more fully, accompanied by introductions and discussions to provide explanation and interpretation, there may actually be an increase in the number of papers submitted to journals.

Companies also need to be aware of what is being said about their products on websites and blogs

So why is all this important to publication planners? Increasing disclosure has created opportunities for unauthorised data analyses, and companies need to anticipate these and be prepared to validate their position rapidly. The consequences of being ‘caught off guard’ can be serious, and were demonstrated by the impact of the independent meta-analysis published in 2007 in the NEJM on GlaxoSmithKline’s anti-diabetic drug rosiglitazone.3

Companies also need to be aware of what is being said about their products on websites and blogs. Many websites, such as worstpills.org and the websites of the Public Citizen Health Research Group (citizen.org) and the Institute for Safe Medication Practices (ismp.org), include drug safety information.

Solid science published in peer-reviewed publications forms the best defence to junk science on the internet

The FDA’s Risk Management Framework principles can be applied to publication planning. They include risk assessment, risk minimisation, risk communication and an evaluation of the risk management processes. Companies should be more proactive on safety issues, for example, by publishing safety reviews and meta-analyses, especially if concerns have been raised. Publications in journals may be a component of risk evaluation and mitigation systems, and should be considered within the context of the broader communications package (including patient brochures and websites). Since references are helpful, peer-

Risk mitigation in publication planning

The meeting next considered risk management. Dan Donovan described the negative image of the pharmaceutical industry, which some commentators view as a “big, bad industry, only concerned with profits”. This image has not been helped by adverse publicity surrounding drug safety issues, some of which has been fuelled by lawyers seeking litigation.

Donovan went on to describe the safety environment and suggested that publication planners need to understand the FDA’s Risk Evaluation and Mitigation System (REMS) and the Adverse Events Reporting System (AERS) database. If the FDA perceives a ‘signal’ suggesting a possible safety problem, for example, from AERS (which collects information from a variety of sources and includes unvalidated cases), it could launch an enquiry. There has been a rapid increase in the investigation of safety problems (with 48 new programmes launched since 2008). According to a recent editorial in the New England Journal of Medicine (NEJM), the new FDA Commissioner, Margaret Hamburg, is positioning the FDA around safety. Companies are increasingly required to do post-approval safety monitoring and to contribute adverse event data to registries.

Several high-profile law suits against companies have hinged on product safety, but Donovan suggested that the courts are not the right place to determine the complex science of adverse event causality. Such cases, he said, often become battles between so-called experts rather than a dispassionate and objective analysis of all available data.
reviewed publications should underlie other types of communication. Good publications may also counteract unauthorised analyses. Donovan suggested a new golden rule in this age of widely available data: “do your own analysis before it is done unto you!” He also advised companies that solid science published in peer-reviewed publications forms the best defence to junk science on the internet.

**Doing more with less**

Elizabeth Crane (Astellas) explained that the key to success in defending and negotiating publication budgets is to manage expectations. She started by reviewing the different models for financing publications. These fall into four groups:

1. **Outsourcing-dependent**: when writing and publication planning is carried out exclusively by agencies or freelancers; the role of the publication staff is to manage these relationships. Such departments tend to have a relatively flat structure.

2. **In-house writing**: such departments tend to have more vertical ‘depth’ in their structure and the primary cost is staffing.

3. **‘Do-it-all’**: in small companies, one person may be responsible for writing and other functions; there may be no specific publications budget.

4. **Mixed model**: when companies use a mixture of in-house writers and agencies; costs are divided between staffing and outsourcing.

The key to success in defending and negotiating publication budgets is to manage expectations

When planning your budget, Crane said that while it is helpful to get information from agencies about charges, it is not fair to request detailed quotes if you have no intention of outsourcing the work. As well as the direct costs of writing publications, you should remember to include costs for steering committee meetings, postage, shipping, travel, obtaining literature, publication fees and copyright permissions.

Several management tools are available to help manage budgets and the publication process. When assessing such packages, you need to consider whether you will have to pay for training, and the cost implications for any additional IT requirements needed to run the software. In terms of staff costs, you need to consider whether you will enter legacy data (i.e. information on completed publications and previous projects) and, if so, who will do this.

Unfortunately for budget planners, there is no simple formula that can be used to calculate how many people you need to produce a certain number of publications.

When planning for publication requirements it is vital to understand the company’s product pipeline.

The organisation of publication professionals within the company will affect their utilisation. Centralised publication teams offer greater flexibility, since workload can be shared. Centralisation also brings benefits in terms of training and sharing best practices. Writers and publication planners embedded in specific product teams can develop useful knowledge of a particular therapy area but the structure is less flexible if workload is variable. Companies using in-house staff should consider recruitment costs, which may also involve relocation costs.

It’s one thing to produce a realistic budget, but it requires different skills to persuade senior management to agree to your proposals. Crane’s recommendation is to “know your audience”. Before presenting your budget plan, try to discover whether individuals want the ‘big picture’ or lots of detail. Find out their preferred styles of learning and receiving data (e.g. bullet points, graphs or spreadsheets). Understanding managers’ pet peeves or identifying areas of the budget that always receive extra scrutiny (such as travel costs) can be helpful. Similarly, it is important to know about current budget constraints and to understand likely budget thresholds. In some cases, so long as your total figure is below a certain threshold, it matters less how you have reached that figure. In other cases, your budget will be scrutinised line-by-line and you will be expected to justify every item.

As well as working out how much it costs to run a publications department, it is important to demonstrate the value it provides. One of the effects of recent changes in US legislation, which makes some forms of results disclosure compulsory, has been to shift companies’ view of publications as a ‘nice to have’ function to something that is an essential part of compliance. This may make it easier to argue for budgets. If your company has corporate values that refer to disclosure or transparency, this may also help to demonstrate that publications are essential.

Presenting a robust publication plan with detailed timelines and clear deliverables is more likely to obtain a budget than vague ideas.

It is important to demonstrate the value a publications department provides
If a development programme is cancelled, resources tend to be transferred to other areas. However, if a company has committed to publishing all its trials, a publication budget may still be required, regardless of whether the product reaches the marketplace. In such cases it may be necessary to explain the implications of the company policy and recent disclosure laws to those taking the financial decisions. Agencies also appreciate being given as much warning as possible if a budget is going to be cut or work on a product stopped.

Coping with a global organisation

Opening the session on globalisation, the moderator, Maureen Garrity, commented that whilst it feels as if the world has got ‘flatter’, global working still poses many challenges. Mark Molenda (Centocor) suggested that companies should consider both internal and external global features. Internal globalisation may affect company policies, processes, relationships and systems. External globalisation affects the perceptions of companies and best practices. Relationships are hugely important. For example, when working with investigators from different countries, the local culture and etiquette must be understood. Face-to-face meetings may be needed before other communication methods such as telephone conferences can be used productively. Workers have to be adaptable, especially when working across different time zones. Time differences can cause problems when trying to arrange phone calls, but can also be used to advantage (e.g. by making the ‘overnight’ review of documents possible).

Global working still poses many challenges

According to Matt Monberg (Lilly), publication professionals need to be aware of different local conventions and investigators’ understanding of issues such as authorship and the role of medical writers. It may be necessary to educate overseas colleagues and investigators about local legal requirements and marketing restrictions such as the FDAAA and rules governing off-label promotion. Global planners also need to understand the local requirements of different markets.

Global planners need to understand the local requirements of different markets

While a corporate publication policy may be applied globally, it may be necessary to have different local operating guidelines. When outsourcing work, companies also have to decide whether to have global or local contracts. Working with local vendors requires careful coordination but may offer advantages.

Several participants mentioned the challenges of developing publications under co-marketing agreements. If both companies have their own, detailed publication policies, it can be hard to decide which takes precedence. Developing a truly global publication strategy can also be tough. The strategy needs to meet the needs of different markets but to avoid central and local publications competing with each other for space in the best journals.

Clinical trial disclosure requirements

The latest developments in US requirements on trial results disclosure were set out by Scott Lassman (WilmerHale). He pointed out that “it’s not just federal government playing in this space” any more: there are now state regulators and state enforcement officials. As the FDA withdrew from enforcement activities in recent years, the states stepped in. But while the FDA’s enforcement role is set to increase under the Obama administration, according to Lassman, the states “are not going away”.

The FDAAA legislation contained little detail when it was passed, but left it up to the FDA and National Institutes of Health to “figure out how to do it”. This means that detailed regulations will not be available until September 2010. Issues currently causing controversy include the lay summaries and the format for adverse event reporting. The current tables required to be posted on ClinicalTrials.gov do not contain much information and, in particular, virtually no text, so there is little room for interpretation. However, there are concerns that lay summaries might be misleading or promotional. Since many studies examine unlicensed indications, there are also concerns about off-label promotion. Since ClinicalTrials.gov is an official US government database, some people are worried that including off-label information could be viewed as official endorsement of these uses.

Another area of controversy is whether the results of trials of products that are not approved should be posted. The Pharmaceutical Research and Manufacturers Association of the USA now recommends that findings from trials of discontinued drugs should be made publicly available. This move has been welcomed by researchers, who expect such studies will provide useful information about safety issues and the possible class effects of drugs.

The pharmaceutical industry has not, however, endorsed calls for the disclosure of full trial protocols (rather than the summaries currently included in registers). Companies feel this might reveal too much information including off-label information could be viewed as official endorsement of these uses.

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The latest developments in US requirements on trial results disclosure were set out by Scott Lassman (WilmerHale). He pointed out that “it’s not just federal government playing in this space” any more: there are now state regulators and state enforcement officials. As the FDA withdrew from enforcement activities in recent years, the states stepped in. But while the FDA’s enforcement role is set to increase under the Obama administration, according to Lassman, the states “are not going away”.

The FDAAA legislation contained little detail when it was passed, but left it up to the FDA and National Institutes of Health to “figure out how to do it”. This means that detailed regulations will not be available until September 2010. Issues currently causing controversy include the lay summaries and the format for adverse event reporting. The current tables required to be posted on ClinicalTrials.gov do not contain much information and, in particular, virtually no text, so there is little room for interpretation. However, there are concerns that lay summaries might be misleading or promotional. Since many studies examine unlicensed indications, there are also concerns about off-label promotion. Since ClinicalTrials.gov is an official US government database, some people are worried that including off-label information could be viewed as official endorsement of these uses.

Another area of controversy is whether the results of trials of products that are not approved should be posted. The Pharmaceutical Research and Manufacturers Association of the USA now recommends that findings from trials of discontinued drugs should be made publicly available. This move has been welcomed by researchers, who expect such studies will provide useful information about safety issues and the possible class effects of drugs.

The pharmaceutical industry has not, however, endorsed calls for the disclosure of full trial protocols (rather than the summaries currently included in registers). Companies feel this might reveal too much information useful to competitors, especially in the early stages of product development.

Until the federal regulations are adopted (most likely in September 2010), individual state legislation must be followed. However, once national systems are in place,
these will pre-empt state laws. The state of Maine has been among the most active in passing legislation on trial disclosure. However, the state requirements keep changing and are not always consistent with developments in federal legislation.

Until the federal regulations on trial disclosure are adopted, individual state legislation must be followed

Not only are individual states making demands on pharmaceutical and device companies, but states appear to be collaborating more. Lassman likened such multi-state groups to "wolf packs" and cited as examples the 29 states involved in suits against Merck under consumer fraud statutes over Vioxx®, and the 32 states bringing cases against Eli Lilly about Zyprexa®. Publication activities have been highlighted in these law suits. Merck's settlement included an undertaking to follow the ICMJE authorship criteria in all publications (although this was widely reported in the press as agreeing not to engage in 'ghost writing') and the Lilly consent decree covered reprint distribution. Companies affected by such law suits therefore have to abide by the terms of their settlements as well as complying with legislation such as the FDAAA.

Another area in which both federal and state legislation is being discussed is the requirement for financial disclosures by trial investigators and authors on industry-sponsored publications. A Physician Payments Sunshine Act (2009) is currently being considered. This might require companies to disclose all payments to physicians on a federal register. However, whereas early drafts of the Act suggested that it would pre-empt any state initiatives, more recent versions have been less clear, so even if the Act becomes national law, companies may also have to abide by individual state requirements.

Generating and communicating economic and humanistic value to payers and decision makers

Developments in the fields of health economics and outcomes research (HEOR) were addressed by Christopher Leibman (Elan) and Michael Pollock (Reynolds Pollock & Associates). The speakers stressed that this was "an evolving arena" in which the requirements are constantly shifting. Effective communication of HEOR messages requires a fully integrated, long-term communication strategy.

Companies now realise that, as well as demonstrating their product's efficacy, safety and quality, they need to provide evidence of value for money, which is sometimes termed the '4th hurdle'. With ever-increasing pressure on health budgets, a '5th hurdle' of affordability may develop. New products will be launched in an increasingly complex and challenging marketplace, and this increases the demand for information. Therefore, research designed to demonstrate economic and humanistic values needs to be performed. Sometimes this will take the form of specific HEOR projects, but economic and patient-centred endpoints can be included in clinical trials if given sufficient forethought.

Effective communication of HEOR messages requires a fully integrated, long-term communication strategy

The audience for such research is broad and not easy to compartmentalise (Figure 3).

While clinical trial results are usually aimed at prescribers, outcomes research needs to reach payers, policy makers and even patients. Selecting a target journal can therefore be difficult, but some HEOR studies are published in the top clinical journals such as JAMA and the Annals of Internal Medicine, and are not restricted to specialist health economic titles.

Many US companies now compile a dossier following American Managed Care Pharmacy guidelines. These dossiers are influential in formulary decisions and are similar to those used to support reimbursement applications in some European countries. Publications in peer-reviewed journals are a critical component of these dossiers, and findings referenced in good journals are likely to be more impressive than citations to ‘data on file’.

Michael Pollock pointed out that if you can’t get someone to pay for your product, then you won’t sell it, and if you can’t sell it, there’s not much point making it. The key to getting reimbursement is therefore to carry out good research and to communicate the results well. Formulary and reimbursement decisions are not ‘impulse purchases’ but must be evidence-based. An effective communication strategy will build up a story in a logical sequence. HEOR should be integrated into the clinical...
The target product profile is developed by considering “what do you want to say about your product?” and developing specific ‘value messages’. Since messages must be supported by scientific evidence they may have to be reviewed and revised as data accumulate. This requires close collaboration between HEOR and colleagues working in clinical, marketing and medical departments, as well as with publication planners. Therefore, communication is the key to success.

The first HEOR publications should set the scene (e.g. by analysing the cost of illness or a needs assessment). Even if studies have already been published by competitors on similar topics, economic data go out of date quickly, so an update may be needed, or the messages can be focused on your company’s product. The story is then developed by demonstrating the impact of a new product on patients’ quality of life, satisfaction or preference. To support reimbursement and inclusion in formularies, evidence about cost-effectiveness or cost-utility will be needed, sometimes based on modelling in the early stages, but later supplemented with ‘real-world studies’.

Communication is the key to success

Companies should have a definite strategy for developing and publishing HEOR projects. HEOR messages should align with and support product positioning. A well thought-out ‘HEOR story’ follows a logical progression without any gaps. For example, it is always important to define the problem (such as an unmet medical need) before you offer the solution. If payers (and prescribers) do not accept that the problem exists, they will not be interested in discussing solutions. HEOR professionals therefore need to understand the market and be able to anticipate the needs of external audiences.

Companies should have a definite strategy for developing and publishing HEOR projects

While creative messaging plays a role in product differentiation, HEOR messages must be credible, and therefore must be based on robust science. This requires close liaison between clinical, HEOR and marketing departments. HEOR teams also have to understand the needs of local, as well as global, marketing teams.

Pollock suggested that, like any good tale, an HEOR story needs a beginning, a middle and an end. In the beginning, the scene is set and you define the problem. In the middle, you offer a solution to the problem, and at the end, you show how economic and humanistic data help solve the problem. Ideally, there is a happy ending and no nasty surprises. The benefits will be positive product differentiation, competitive advantage, market access and commercial success.

One participant asked where HEOR fits within a company. The panel advised that if HEOR is part of marketing there may be legal and compliance problems; therefore, in most companies, HEOR falls within Research & Development (R&D). It is important to establish that HEOR is a legitimate form of scientific research, and to challenge perceptions that it is simply a marketing tool.

Editors’ panel

The highlight of TIPPA’s annual meeting for many participants was a lively session involving four journal editors. Michael Callaham (Annals of Emergency Medicine), Mikel Gray (Journal of Wound, Ostomy and Continence Nursing [JWOCN]) and Charon Pierson (Journal of the American Academy of Nurse Practitioners [JAANP]) were ably moderated by Elizabeth Loder (Editor, Headache and Pain and Clinical Editor, BMJ).

Dr Loder started by asking the panellists whether their journal had a mission statement and to describe what they publish.

• JAANP is aimed at nurse practitioners, mainly working in primary care. It publishes a wide range of papers including reviews and case studies, but to be accepted, papers must have broad appeal and be appropriate to the audience. However, authors often ignore the journal’s mission statement and submit articles that are relevant only to a highly specialised readership, and are therefore not suitable for the journal.

• JWOCN publishes about 60% original research papers and 40% of what Mikel Gray describes as “clinical bits”. It is owned by an academic society, about 70% of whose members work in acute medicine and 30% in long-term care. It is aimed at healthcare professionals using a wide range of wound dressings, ostomy and continence devices, and drugs. It aims to publish research that is likely to influence practice, and therefore welcomes HEOR papers, which are popular with readers.

• The Annals of Emergency Medicine is another society journal, in this case belonging to the American College of Emergency Physicians. It aims to publish articles of interest to its readers and, since emergency medicine is “a specialty in breadth”, according to Michael Callaham, this covers a wide range of topics. The journal publishes both clinical and basic research papers.

• The BMJ’s mission statement is to “help doctors make better decisions” and the editors try to bear this in mind when considering papers.
Asked if their journals had specific policies relating to industry-sponsored research, Dr Callaham commented that bias is not limited to industry. He is particularly concerned by unfunded studies, which are often poorly designed and reported. He advised companies to “keep the science clean” and to resist the temptation of including too much interpretation or “spin”. Dr Pierson noted that her journal found the Committee on Publication Ethics (COPE) guidelines helpful (http://publicationethics.org).

Commenting on the new impetus that “everything must be published”, following the recent legal requirements for disclosing trial results, Dr Loder commented that “not all the ramifications have been thought through”. She agreed that while a timeline of 1 year may sound generous, it is actually not long to get a study analysed and published. If companies adopt a strategy of publishing a full paper in a peer-reviewed journal at around the same time as posting summary tables on ClinicalTrials.gov this may affect their choice of target journals to those with lower rejection rates or faster turnaround times.

Dr Pierson commented that negative results and even failed trials can make interesting publications, but the reasons for failure must be explained; simply reporting the findings is not enough. At the BMJ, the editors consider that the research question is more important than the answer. But Dr Callaham noted that equipoise is a critical feature of clinical research and that, unless there is uncertainty about the effects of treatment, the trial will not be ethical.

The editors were asked whether it was essential for papers reporting industry-funded research to have one or more external authors. The questioner highlighted the fact that postings on trial registers and in results databases are done by company staff and do not list authors, so perhaps external authors were no longer needed. The editors felt that clinicians can bring a useful perspective to publications, in particular an understanding of the clinical relevance of findings, but agreed that named authors must be involved from an early stage in the publication process and not brought in “just to add a name”. If company personnel are truly the only people qualifying for authorship, then it is fine to have a paper with no external authors. Journal requirements to declare individuals’ contributions to a study and its publication (rather than just listing names on the byline) may expose guest authors who have not contributed sufficiently to merit authorship.

When it comes to presenting the results of secondary analyses (rather than primary publications), the principal investigator may be reluctant to be named as an author unless he/she has been fully involved in the analysis. Once again, if company employees are the only people who meet the journal’s authorship criteria, these are the ones who should be named.

Questioned about the use of professional medical writers, Dr Gray emphasised that clear disclosure of their involvement and funding was the primary issue. If writers can interact with the journal it can be a productive partnership. Dr Pierson commented that most clinicians don’t have time to write, and even if they do, they may not be good writers. She believed that investigators often benefited from a partnership with a medical writer but that full disclosure was essential. She had experienced a big change in this, and felt that people were more forthcoming and willing to disclose writers’ involvement than before. Dr Loder agreed that a good writer can bring value and “make our lives easier”.

Discussing how medical writers should be acknowledged, Dr Loder emphasised that the BMJ seeks an honest description of exactly what has been done. The acknowledgement should include funding information and should distinguish between medical writing and medical editing.

The question of who should submit the final version to the journal provoked a lively debate. A few journals now insist that articles must be submitted by the lead author and will not accept submissions from writers or agencies. However, the panel members did not necessarily share this view. One editor commented that the submission process is purely administrative and agreed that principal investigators often don’t have enough time for this. They admitted that many journals’ electronic submission systems required a considerable amount of ‘legwork’. However, they stressed that editors want reassurance that the authors have approved the final version.

The editors were then challenged over whether journal word limits encouraged ‘salami publication’ – producing several articles from the same data set. Dr Loder explained that the BMJ no longer has word limits for its online articles (the online version of the journal is considered the official publication), whereas shorter versions appear in the printed journal. She believes this will become the standard, and that word limits could disappear, perhaps in the next 10 years. JAANP does not impose strict limits but gives authors suggested guidelines on appropriate length. Like the BMJ, this journal allows authors to publish supporting material online. JWOCN also publishes longer online versions and shorter print versions of articles. Dr Callaham agreed that editors now expect more and more of authors, but warned that very long articles were often unreadable. The Annals of Emergency Medicine therefore strives to balance full reporting with economy of communication.

The discussion then focused on the issue of raw data posting. Dr Pierson expressed concern that practising clinicians wouldn’t know what to do with raw data and are therefore unlikely to be interested in them. She agreed that it was helpful to provide additional online information, such as data tables to support articles, but did not feel that providing raw data would be helpful. Dr Gray agreed, and suggested that JWOCN readers would find it “a bit overwhelming” while only a “tiny group” of researchers would want this amount of data. Dr Callaham expressed concerns that data might be distorted or misinterpreted through inappropriate analyses.
While primary care clinicians might not appreciate raw data, they do want practical guidelines, and the panel was asked for their views on the role of commercial companies in developing these. The BMJ avoids publishing industry-funded consensus statements and prefers different methods for developing guidelines. However, Dr Loder felt that such guidelines might be acceptable in specialist journals in areas where high-level evidence is lacking and opinion is the only thing available. She also commented that opinion-based guidelines may provide a useful starting point, since peer review is good at detecting bias, and later publications can improve and criticise the statements made. Dr Gray agreed that in his field of ostomy management only about 20% of practices were properly evidence-based and therefore opinion was useful. In the field of emergency medicine, Dr Callaham concurred that there was a “crying need to fill the evidence gap”, but expressed concerns that the methodology of consensus statements was often “suspect” and that there was always a risk of bias with self-selected groups, whether funded by industry or not. He called for more rigour in developing clinical guidelines and warned that there was evidence that peer review did not always solve the problems.

**Senate Finance Committee inquiries**

Dan Donovan opened the second day of the meeting with a presentation given on behalf of Gene Snyder (who was unable to attend). In the USA, the Senate Finance Committee, in particular Senator Charles Grassley, has been investigating publication processes in pharmaceutical and device companies. Donovan warned the audience “If Senator Grassley comes calling, are you ready?” and told them that every US Pharma, biotech and device company needs to be prepared.

The Committee has extensive powers and can demand huge amounts of information. For example, in one case it demanded all documentation about every publication on the product under investigation going back 13 years, plus documentation for publications relating to all the company’s other drugs for a period of 8 years: all this had to be produced within 30 days. The inquiry demanded details of any payments to authors, detailed accounts of author participation in publications, evidence of all payments to agencies and information about the role of marketing, legal and medical departments in developing publications.

Unlike clinical trials, for which the agreed standards have been accepted for some time and codified in Good Clinical Practice (GCP), publication planning is a relatively new field and there are many different guidelines. Most of the relevant guidelines, such as Good Publication Practice (GPP), were developed less than 10 years ago and few companies had fully defined policies or standard operating procedures (SOPs) 5 years ago, much less 13 years ago.

In order to satisfy the Committee, companies must have robust policies and SOPs, and be able to prove that these are followed. Policies should cover authorship criteria, the acknowledgement of medical writers and conflict resolution. Processes should ensure early author engagement, the appropriate involvement of professional writers and adequate review and approval mechanisms. Just having documentation is not enough. Organisations need to ensure that practices are consistent across divisions, should ensure that staff (including those working in agencies) are properly trained and should do periodic audits to check that guidelines are being followed.

Information about publication development will be found in emails, publication planning software or databases, and with third-party vendors. Company policies and SOPs may also be posted on internal websites (or intranets). In addition to these written documents, it is important to note telephone calls and meetings, especially those involving authors. A mock audit can be helpful to identify issues. Using an external auditor may also provide useful insights into company procedures. Company publication teams need to be proactive and to keep abreast of all relevant policies and guidelines – as Donovan put it: “get your house in order! That’s your job!”

**GPP and GPP2**

The next session developed the theme of guidelines by focusing on GPP. Liz Wager (a member of the working group that developed GPP) outlined the history of the guidelines, which began with a meeting in 1998 under the auspices of the Council of Biology Editors. This meeting brought together journal editors, academic investigators and publication professionals from the pharmaceutical industry. It revealed the editors’ and investigators’ concerns about industry-developed publications and also some misconceptions about the ways in which companies operated. After the meeting, a group of participants from the industry got together to draft some guidelines which were eventually published in 2003.

A thorough review of the GPP guidelines has been coordinated by the International Society for Medical Publication Professionals (ISMPP) under the leadership of Chris Graf (Wiley-Blackwell). Catherine Arnaudeau-Bégard (a participant in the GPP2 global consultation) outlined the development of GPP2. This has involved much wider consultation than was possible for the original GPP document, and the GPP2 working group has received around 120 comments, not just from pharmaceutical companies but also from journal editors, communications agencies and professional organisations.

The scope of GPP2 will be broader than that of the original guidelines, and this is reflected in the title, which
now mentions biotech and medical device companies as well as the pharmaceutical industry. The guidelines have also shifted their emphasis from medical writing to include publication planning.

The final version of GPP2 has not yet been published (as of August 2009) but has been submitted to a peer-reviewed journal. The new guidelines will recommend that:

- companies should draw up written publication agreements with investigators
- there should be no payment for authorship
- all authors should have full access to the study data.

The scope of GPP2 will be broader than that of GPP and will focus more on publication planning.

It is hoped that GPP2 will provide an updated standard for publication, while still recognising the importance of other guidelines such as those from the ICMJE. Dr Arnaudeau-Bégard called on participants to promote GPP2 and become advocates for its standards, commenting that “you are the drivers for the successful implementation of GPP2”.

Providing a medical writer’s perspective on GPP2, Art Gertel (Beardsworth Consulting Group), one of the ISMPP GPP2 reviewers, commented that the new guidelines address different stakeholders such as authors and writers in a more targeted way. But he noted that misunderstandings about ghost writing persist, and that publication professionals need to endorse the view that transparent collaboration that is properly attributed does not constitute ghost writing. He then presented a checklist developed by an international group of medical writers. The checklist is designed to help journal editors avoid ghost authorship and ensure proper acknowledgements; it asks authors to describe any writing assistance and prompts them to acknowledge this. The checklist also asks whether guidelines such as GPP have been followed.

While welcoming GPP2, Dr Gertel expressed concern about the proliferation of guidelines, although he commented that there was not much difference between them and that most agreed on the fundamental principles. He challenged the audience to work towards a “unified theory of good publication practice” to create a single standard, and warned that lack of clarity could harm the profession. In his view, publication professionals “should be in the vanguard of ensuring ethical behaviour”.

Tackling the authorship debate

The challenging issues of disclosure and transparency were addressed by a panel representing a wide range of backgrounds: Nancy Bormann is Associate Director of Medical Communications at Biogen Idec, but has previously worked for a communications agency, James Magrann is the publisher of Current Medical Research and Opinion (CMRO) and Kirby Lee is Assistant Professor at the School of Pharmacy and Institute of Health Policy Studies at the University of California, San Francisco (UCSF).

According to Dr Lee, “publication planners are in the middle of everything” and face a challenging role trying to meet the requirements of academics, editors and companies. He noted that the ICMJE authorship criteria do not help determine the order in which authors are listed. Therefore, his colleagues at UCSF have developed a contributorship grid. The grid is used to record what each contributor did and how much time they spent on each activity, so the results can be discussed among the group. However, decisions about authorship order still require judgements about authors’ contributions and whether some tasks are more important than others; for example, whether 1 hour’s statistical analysis is comparable to 1 hour’s data acquisition.

Publication planners face a challenging role trying to meet the requirements of academics, editors and companies

At Biogen Idec, an authorship committee is set up for every study. The principal investigator is usually the first author but all authors must contribute intellectually to developing the publication (simply being on the committee does not guarantee authorship). Principles for agreeing the order of authors are determined when the study is set up.

CMRO has recently launched a transparency policy. It now requires details of research sponsorship, authors’ financial relationships that are relevant to the publication and acknowledgements of writing assistance. Magrann emphasised that having financial relationships is not inherently bad, but that such relationships should be disclosed in the paper so that readers can consider them when assessing the article’s conclusions. His journal now uses the term ‘financial relationships’ rather than ‘conflicts of interest’ and publishes such information for its editorial board, editorial staff, authors and peer reviewers. Information about reviewers’ financial relationships is not disclosed to authors during the peer-review process, but it is included in articles – without disclosing the reviewers’ names.

Reprints and supplements

Moderator Elizabeth Crane (Astellas) commented that the current environment was confusing and urged participants to talk to their legal departments to...
understand the full implications of recent FDA guidelines about reprints. James Magrann (publisher of CMRO) said that the biggest challenge was the “perception of supplements” which he felt had “taken several hits” in the past few years. Unfortunately, some people now viewed supplements as vehicles for promotion rather than for science, but the key to restoring the image of supplements was transparency.

Mikel Gray (whose journal JWOCN publishes about two supplements per year alongside six regular issues) stated that the key challenge was positioning supplements. He also commented that he appreciated “the hoops [that publication professionals] have to jump through” and that he was impressed by individuals’ desire to “do the right thing”.

Craig Smith (a Senior Editor at Elsevier, with responsibility for supplements) wondered what publishers could do to make internal regulators more comfortable. He recounted a recent experience of a company that got an FDA warning about off-label promotion concerning one supplement and promptly abandoned another planned supplement, despite their being no problems with its content. He felt publishers should provide guidance and should be careful to distinguish legitimate writing assistance from ghost writing. He also commented that electronic media offered exciting opportunities, such as including video components and webcasts, but that companies (and regulators) were not sure how to scrutinise and approve these.

Asked when it was appropriate to produce a supplement, Dr Gray suggested they were useful for linked manuscripts, to avoid salami science. According to its publisher, the ideal supplement for CMRO would comprise:

- an introduction to set the scene and outline the supplement’s aims
- some original research
- reviews of existing treatments
- a risk analysis of therapeutic options
- a paper on HEOR aspects.

A supplement such as this gives readers a broad perspective and the advantage of grouping related papers together.

All panel members agreed that it was a good idea to call the editorial office of the chosen journal to discuss a proposed supplement. Although the Editor-in-Chief will take the final decision, a preliminary discussion with the Managing Editor or publisher responsible for supplements (such as Craig Smith at Elsevier) was normally helpful. This approach should be made early in the planning process as ‘last-minute supplements’ can cause problems, and enough time needs to be allowed for peer review and production. Both Elsevier and CMRO welcome approaches from agencies or sponsors as well as from potential authors.

The panel was asked whether supplements undergo the same level of peer review as the rest of the journal. At CMRO, supplements and journal articles are subjected to exactly the same review process and have the same rejection rates. At JWOCN, the rejection rate for articles in supplements is actually slightly higher than that for the main journal because the tight deadlines mean that if authors cannot revise an article within the timeframe it will be rejected. All supplements published by Elsevier are peer reviewed, but the process may be slightly different; for example, one reviewer might review all papers in a supplement to ensure consistency as well as quality.

Another participant asked whether you should publish original research in a supplement. The panelists agreed that there was no rule against this; however, given the reputation of supplements, and recent FDA limitations on distributing company-sponsored supplements, many companies prefer not to.

Publication planners need to be aware of restrictions on the distribution of company-supported supplements. Unlike articles in regular peer-reviewed journals, these may be considered as promotional material and therefore require different forms of approval.

### Publication and reporting bias

Kirby Lee, Assistant Professor of Clinical Pharmacy at UCSF, presented evidence that the medical literature is skewed towards positive or favourable results. The non-publication of negative studies and over-publication of positive trials is termed publication bias, but bias can also be caused by selective reporting of favourable outcomes within a study or by framing data and thus creating ‘spin’. He reassured the audience that publication bias is not just an industry problem but appears to be systemic. It is, nonetheless, serious because it affects the evidence on which medical decisions are made. Publication bias may therefore lead to increased healthcare costs, wasted research funds and, ultimately, harm to patients.

**Publication bias is serious because it affects the evidence on which medical decisions are made**

Four studies (all published within the past year) have demonstrated publication bias. In his own study, Lee and colleagues examined trials included in licensing applications to the FDA for drugs approved between 1998 and 2000. Of the 909 trials identified, only 43% were published according to a search of PubMed and other databases, despite a follow-up of 5–8 years after the drug was approved (Figure 4). A higher proportion of pivotal trials (76%) were published. Further analyses showed that trials with significant results were more likely...
to be published than those with results that did not reach statistical significance.5

In another study, Rising et al. considered drugs approved between 2001 and 2002, and compared how study outcomes were reported in regulatory reports and journal articles.6 They found that 78% of the efficacy trials were published, but, like Lee et al.’s study, showed that those with favourable outcomes were more likely to be published.

Turner and co-workers carried out a meta-analysis on the efficacy rates in antidepressant trials published between 1987 and 2004, comparing reports in journals with those submitted to the FDA.7 Of the 74 trials identified, 69% had been published, but the publication rate for positive studies was 97%. The meta-analysis showed greater efficacy rates in the journal articles than in the FDA documents that described the same studies. This is a cause for concern since clinicians rely on publications rather than regulatory documents, and most meta-analyses are based on published data and are therefore likely to be biased. (Differences between regulatory reports and journal articles may reflect changes requested by editors or peer reviewers.)

A group led by Decullier examined studies approved by French research ethics committees in 1994.8 They contacted principal investigators and sponsors for details of publications and obtained a 67% response rate. They found that while the publication rate for phase II–IV studies was 43%, it was only 17% for phase I studies. Even positive phase I studies were often not published, and publications of phase I studies tended to appear after those for other types of trial.

While these four studies clearly demonstrate that publication bias exists, there are only limited data on its causes. In some cases, authors may not bother to submit negative findings in the belief that they are uninteresting and likely to be rejected. However, there is also evidence that some drug companies’ publication strategies have effectively suppressed unfavourable results. Chan and Altman9 surveyed authors, who suggested that reasons for selective reporting included journal space constraints and considering some findings not to be clinically important.

Solutions to publication bias include trial registration, which should highlight non-publication of entire studies and the selective reporting of outcomes. If journals are unwilling to publish reports of failed studies, these could be posted on company websites.

Firewalls: responding to the current regulatory environment

Scrutiny of CME activities and concerns about the involvement of marketing in publications have led many companies to erect ‘firewalls’ to separate departments. Leslie Meltzer (Actelion) commented that there are many misconceptions about how industry develops publications. Some commentators perceive that the main drivers for publications are commercial rather than scientific and are concerned that the publication process is not being led by those with an interest in scientific integrity. However, initiatives such as GPP have helped to explain companies’ procedures.

Ansgar Conrad (Actelion) outlined the many players involved with publications, including internal and external authors, statisticians, medical writers, project managers, reviewers and journal editors. In most companies, publication strategy is driven by the medical affairs department, with input from clinical science, regulatory and legal departments. The role of the marketing department varies. The aim of firewalls is to prevent undue commercial influence on publication activities. Firewalls may be set up internally (i.e. between departments) or externally (between sponsors and
investigators). If the sponsor’s internal firewalls are effective, this reduces the need for external barriers. However, in small companies, where a few people cover many roles, this may be difficult.

There is very little guidance about firewalls, and the topic is not covered by GPP or journal instructions. Firewalls will affect reporting structures, budget responsibilities, participation in strategic and tactical meetings, and publication approval. Policies vary from preventing any involvement of marketing in publications to allowing marketing to review manuscripts. Many companies adopt a midway approach, involving marketing in developing high-level publication strategies but not permitting them to comment on individual publications.

According to Joseph Laudano (Forest Research Institute), companies need to pay attention to the language used to describe activities. Editors and investigators may be concerned about commercial-sounding terms even if they describe innocuous activities. Companies should aim for a transparent publication process that is clearly documented and auditable. Internal procedures should be based on external guidelines. Companies also need to be able to demonstrate how they foster compliance (e.g. through documentation, training and internal communication). Any instances of non-compliance, together with the remedies taken to avoid future problems, should be documented. Publication planning software can increase transparency and improve documentation of processes.

**Companies should aim for a transparent publication process that is clearly documented and auditable**

**The TIPPA member survey**

Shortly before the annual meeting, TIPPA surveyed its members. Although the response rate was low, the findings should be of interest to anybody aiming to benchmark publication processes in their own organisation.

Of the 23 responders, 78% worked in companies that had a separate, dedicated publications department. Most of these departments (65%) were located within medical affairs, with 13% in R&D and 4% in marketing. Virtually all the publications departments (91%) administered their own budget.

Writing abstracts, posters and papers was handled solely by in-house writers in 9% and entirely outsourced in 35% of companies, but 56% of companies used a mixture of agency and in-house writers. The departments most likely to approve publications were R&D (65%) and medical (52%), but in 13% of companies, the marketing department could sign off. However, a trend towards decreasing the influence of marketing in publications was evident. Many companies (83%) had reorganised their publications function in the past 2 years, and of these, 52% had reduced the influence of marketing and 38% had moved the publications team away from the marketing department.

**Conclusions**

Publication planners face many challenges. They have to balance the needs of journal editors, reviewers, authors, research sponsors and regulators. The number of federal and state laws (in the USA) and guidelines affecting publications is growing, and publication professionals need to keep abreast of these. This is not a simple task, since some of the requirements are inconsistent and the rules regarding results posting are evolving rapidly. However, the penalties for non-compliance are serious, so companies are increasingly scrutinising their publication processes. Reacting to requirements to post results summaries onto ClinicalTrials.gov within 12 months of the end of studies, many companies are now aiming to publish full papers in peer-reviewed journals at around the same time, thus adding to the pressure on publications teams. TIPPA’s 7th Annual Meeting provided an opportunity to hear about the impact of the latest regulations and to learn from many experienced publication planners how to meet these challenges.

**References**


2. For more information visit www.consort-statement.org


Drug reviews:

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ThePharmYard product code: core052

Exforge® (amlodipine/valsartan combination) in hypertension: the evidence of its therapeutic impact
ThePharmYard product code: core051

Agomelatine: the evidence for its place in the treatment of depression
ThePharmYard product code: core050

Eptifibatide: the evidence for its role in the management of acute coronary syndromes
ThePharmYard product code: core049

Temozolomide: the evidence for its therapeutic efficacy in malignant astrocytomas
ThePharmYard product code: core048

Omalizumab: the evidence for its place in the treatment of allergic asthma
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Tolvaptan: the evidence for its therapeutic value in acute heart failure syndrome
ThePharmYard product code: core046

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