



Preface

Dear Colleagues,

The 9th Annual Meeting of the International Society for Medical Publication Professionals (ISMPP) is titled “Empowering the Medical Publication Community to Advance the Profession.” The program presents an opportunity for education and open exchange among diverse stakeholders to provide knowledge and practical tools to work globally, build better relationships, and find commonalities. As science advances, the way in which information is analyzed and transmitted to end users continues to evolve. Ongoing examination and improvement of the standards that guide scientific and medical data dissemination are crucial.

Medical Publication Professionals have both the opportunity and the obligation to lead the way in ensuring scientific integrity, clinical relevance, and transparency of medical publications. In addition, we are in the unique position to examine the issues and shape the future for managing the increasing array of data and the need for sharing between the pharmaceutical industry, academic researchers, and organizations representing a variety of interests, with the ultimate goal of improved patient care.

The abstracts presented at the April 2013 meeting demonstrate the commitment of ISMPP to building a strong

evidence base to support the work we do, to identify solutions to the issues we face, and to identify and address the challenges that lie ahead. Through well-designed research, we demonstrate the high standards and values that we embody.

This issue of CMRO marks our fifth collaborative journal publication effort, showcasing the research conducted over this past year by members of ISMPP. In addition, this issue includes the abstracts that were accepted for poster presentation at the 2013 European Meeting of ISMPP that took place on January 22–23, 2013, in London, UK.

On behalf of ISMPP, we would like to express our sincere appreciation to the publishers of CMRO for their continued support of ISMPP’s initiatives.

Sincerely,

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*Oral presentation at the 9th annual meeting of ISMPP

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*Oral presentation at the 9th annual meeting of ISMPP

†Encored poster at the 9th Annual Meeting of ISMPP

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†Encored poster at the 9th Annual Meeting of ISMPP

‡Poster Winner, Best Original Research, 2013 European Meeting of ISMPP

Editorial

ISMPP: All grown up

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When the International Society for Publication Professionals (ISMPP) was founded in 2005 it was with the intention that the society would become the pre-eminent voice and authority in the field of medical publishing. As we just hosted our 9th Annual Meeting and look to convene for our 10th next year, we have moved beyond our formative years and now find ourselves in a position – and with the responsibility – to take a leadership stand on current issues surrounding medical data publishing and ensuring best practices throughout the global research community.

ISMPP recently took a pioneering step by passing a resolution for reduced membership and certification exam fees for publication professionals from the Asia-Pacific region and/or World-Bank designated lower income countries. This has already resulted in a record-high number of ISMPP Certified Medical Publication Professional applicants for the Spring 2013 exam cycle. Further, the Society also held its first-ever Asia-Pacific ISMPP University webinar, focused on ethical publication practices and applying GPP2 in the Asia-Pacific region. ISMPP's efforts to make membership, professional certification, and regionally relevant educational opportunities more accessible across the globe are an important step forward in leading efforts to build and maintain professional standards in these regions.

But there is much more to be done. Recent months have brought major developments impacting the world of medical publishing – clinical data-sharing decrees on the part of some industry, journal and regulatory constituents; a final ruling on The Physician Payment Sunshine Act; and launch of the AllTrials campaign, to name a few. While progress has certainly been made, there remains for some stakeholders a lingering mistrust of medical research; some with good reason and some based on inaccuracies perpetuated by ill-informed third parties. As a consequence, the perceived clinical utility of research findings is sometimes questioned by clinicians and other stakeholders, including patients.

Taking a stand

As a society that has matured and grown, ISMPP will be making a greater and more visible commitment to the professional space by taking a proactive stance on many of the issues and challenges facing our profession. Whether alone or in partnership with other like-minded groups, ISMPP has a responsibility to set standards. We need to speak up, articulate the 'how to' and uphold our core purpose – transparent and ethical scientific exchange.

For the future, perhaps we can look to positively influence other areas such as health literacy. Opportunity abounds. ISMPP needs to lead the way.

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Lorna Fay, Chair, ISMPP Board of Trustees (2013–2014), Director/Team Leader, Publishing, Pfizer.
Jennifer Ciafullo, ISMPP Education Content Manager, contributed to the concept and provided writing assistance for this editorial.

Abstracts

A medical writing survey to develop a certification examination

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Objective: We surveyed medical writing professionals regarding key knowledge, skills, and abilities (KSAs) to include in a medical writing certification examination.

Research design and methods: An online survey was conducted from April–July 2012 by the American Medical Writers Association. Respondents ($n = 1177$) rated which KSAs were most to least important in their work. Using text boxes, they could also add further comments.

Results: Underlying domains of competency were gathering, evaluating, organizing, interpreting, and presenting. The seven highest scores were all in the 'presenting' domain of KSAs (mean scores of 4.65 to 4.52; 5 = extremely important)¹. In subgroup analyses, the greatest number of significant differences in item ranking occurred between those who primarily write (or write and edit), and those who primarily edit. In addition, respondents suggested additional items not included in the survey, but that they felt were important in their work; these included subject matter knowledge, software and multimedia skills, people skills (especially with diverse stakeholders), working as a team (team and process management), and contract negotiations.

Conclusions: While some KSAs are broadly applicable, a meaningful medical writing certification examination must reflect the profession's diversity in the types of questions asked. Differences seen between writers and editors in item rankings indicate that an eventual examination will be able to test KSAs that are more specific to medical writing, as opposed to other communication skills such as editing.

Reference

- Gegeny TP, Klein KP. AMWA's medical writing certification initiative: where are we now? *AMWA J* 2012;27:184-7

A review of manuscript cycle times from 2009 to 2012: results from a major pharmaceutical sponsor*

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Objective: This study reviewed development and cycle times for clinical trial manuscript submissions from a single, major pharmaceutical sponsor.

Research design and methods: We evaluated cycle times for all the sponsor's clinical trials for which a manuscript submission was identified between 2009–2012 by conducting a descriptive analysis calculating time from last subject last visit (LSLV) to submission (LSLV–Sub), and time from submission to publication (Sub–Pub).

Results: There were 463 clinical trials with LSLV in 2009–2012 with valid manuscript submission dates. Mean LSLV–Sub time over this period was 81.2 weeks (wk). For each individual year, mean LSLV–Sub times were 2009: 104.4 wk; 2010: 75.9 wk; 2011: 62.1 wk; and 2012: 23.4 wk. Among the 691 primary manuscripts submitted from 2009–2012 with valid submission and publication dates, mean Sub–Pub time was 30.9 weeks. For each individual year, mean Sub–Pub times were 2009: 35.5 wk; 2010: 33.4 wk; 2011: 29.7 wk; and 2012: 21.2 wk. A similar trend in timing was observed for secondary publications.

Conclusions: We observed a marked decrease in time from LSLV to submission between 2009–2012. Likely drivers include: changes in our corporate policies to

reinforce commitment to transparency and expedite dissemination of data to further scientific advancement and patient care, use of internal tracking systems, and internal communication of these metrics. We also observed a similar but smaller decrease in time from submission to publication. Potential reasons include: improved targeting of appropriate journals, improved manuscript quality, and/or more efficient practices by journals.

An automated literature analysis tool to enhance literature searches for publication subcommittees (PSCs) and publication planning

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Objective: In order to provide publication subcommittees (PSCs) with literature searches to assist with meeting business goals, we piloted an automated literature analysis tool to enable access to searches that are comprehensive, provided in multiple formats, linked directly to publications/document delivery, and delivered on demand.

Research design and methods: A Lean Six Sigma methodology was utilized to identify the tool. We defined the problem, measured and analyzed to find the root cause, made improvements, and put controls in place to ensure searches continue to meet the PSCs' needs.

Results: PSCs are provided with search results that: 1) are comprehensive due to searching multiple bibliographic databases that utilize search strategies developed by experienced library science professionals; 2) have greater functionality due to the mining of key concepts and integration with the full text via library subscriptions and document delivery; 3) can be output in multiple formats, including Word, Excel, EndNote, RSS feeds and interactive charts; 4) are intuitively organized within the tool to enable rapid assimilation into users' workflow; 5) are delivered automatically; and 6) save money.

Conclusions: Implementation of this tool has resulted in the ability to automate searches. The results are delivered on demand, comprehensive, intuitively organized and output in multiple formats. PSCs can use the tool to keep updated on current literature, analyze publication topics aiding in publication planning, save time in reviewing searches due to formatting, timing and dedicated functionality, and cut costs.

Attitudes of healthcare professionals towards medical writers and pharmaceutical company involvement in publications[†]

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Objective: The aim of this study was to understand the attitudes of healthcare professionals towards the involvement of professional medical writers in peer-reviewed publications.

Research design and methods: An opt-in, non-incentivized, Internet-based survey of medically qualified, registered users of EPG Online (www.epgonline.org), a disease and medicines knowledge site for healthcare professionals, was conducted.

*Oral Presentation.

[†]Portions of data from this abstract were previously presented at the 2013 European Meeting of ISMPP by S Smith et al.

Results: In total, 295 individuals (30% women; 62% aged 31–50 years) from 54 countries responded. Some 66% reported concern about pharmaceutical employee involvement in manuscript preparation as authors or reviewers, even if disclosed. Furthermore, 30% said they would trust a peer-reviewed publication less if medical writers were involved and only 14% would trust it more (among US respondents this was 33% and 14%, respectively). A positive opinion on publications prepared with medical writing support was more common among those aware of GPP (17% vs. 8%). A total of 11% reported that their institution had rules in place to restrict collaboration with professional medical writers when developing manuscripts. However, among those with previous publications ($n=204$), 68% said that they would agree to be an author or co-author of a publication developed with the assistance of a professional medical writer.

Conclusions: There are high levels of concern among healthcare professionals about the involvement of the pharmaceutical industry and professional medical writers in the production of peer-reviewed manuscripts. However, most express openness towards such collaborations, suggesting that positive engagement could lead to more positive opinions.

Augmented reality: bringing another dimension to scientific publications

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Objective: This initiative aims to: (1) define the concept of augmented reality (AR); (2) examine potential uses in medical publications; (3) evaluate existing journal/congress guidelines; and (4) propose strategies for future use of AR in medical publications.

Research design and methods: AR represents the interface between the digital and physical worlds. Similar to quick response codes, AR places markers in a print-based environment that link to digital enhancements (video, animations, interactive graphs), which are accessed via tablet or smartphone. AR can increase the educational value of peer-reviewed publications, poster presentations, and supportive educational materials by creating interactivity, which in turn may increase both access and retention of information within a poster or journal article. It can also be used for elaboration of a complex topic or provision of supplementary materials.

In order to assess the potential use of AR, guidelines for 18 congresses and 29 journals in major therapy areas were examined.

Results: Although five of the congresses have guidelines on interactive e-posters, none of the congress guidelines for printed posters discuss AR technology. None of the journals surveyed have guidelines on AR, but 17/29 make some reference to allowing digital media, with a majority providing instructions for uploading interactive files.

Conclusions: AR can be valuable for both enhancing publications and extending their life span. In order to promote its use, it will be important to partner with journals and scientific associations to determine how best to incorporate this technology, including issues concerning copyright.

Celgene history books: an innovative and interactive key publication archiving tool

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Objective: Over the years, the number of clinical trials with Celgene products has increased drastically, leading to more requests for published material from various departments. Internally, there were several sites where abstracts, posters, oral presentations, and manuscripts were archived; however, there was no tool providing a chronological overview and quick access to all material.

Research design and methods: Various cross-functional teams from Global Medical & Scientific Communications collaborated to develop a History Book to

classify publications. Key clinical trials were identified and labeled with a consistent taxonomy in a bibliographic style. All publications were organized in an electronic PDF format, and hyperlinked to trial websites and internal databases.

Results: Six disease History Books were developed and published in 2012 detailing 24 trials and covering more than 627 citations. After 6 months of usage, a survey was sent to all users ($n=423$ from 30 countries), and demonstrated high utilization and satisfaction ratings across departments, including medical, clinical, legal, regulatory and drug safety. Awareness and availability of the tool was communicated via corporate e-mails and internal portal alerts.

Conclusions: The History Books successfully addressed a previously unmet need, and provided a permanent, up-to-date resource accessible to various cross-functional teams. In addition, this innovative tool has been very popular and frequently used when onboarding new colleagues. More information will be presented at the meeting.

Clinical trial data – reducing the time to submission

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Objective: For patients and physicians to avail of the latest clinical trial findings, peer-reviewed trial data must be made public quickly. Initial trial results are often presented at medical conferences, yet the peer-reviewed final data may not be published for several years. This Continuous Improvement project was undertaken to assess and minimize the time to submission for primary manuscripts for industry-sponsored clinical trials. The goal was to determine if a primary manuscript could be submitted within 52 weeks of primary completion date (PCD) per study protocol.

Research design and methods: To determine the baseline time from PCD to submission, all primary manuscripts in one therapeutic area with a PCD between 2009 and 2011, and with a journal submission date were identified. A process map was generated and analyzed.

Results: Of the 164 primary manuscripts identified, 18 had both a PCD and submission date. The median time to journal submission for these manuscripts was 71.4 (range: 15–93) weeks, suggesting need for improvement. Delays or inefficiencies in author selection, review process and methods of incorporating comments were identified. Methods to minimize delays were implemented. This streamlined process yielded a time to submission of 40 weeks, a 44% reduction compared to the baseline median.

Conclusions: The streamlined process resulted in significantly faster manuscript submission. This will allow trial data to be useful to more patients and clinicians. Overall these changes have the potential to improve the speed of the publication of clinical trial data.

Corporate integrity agreements 2012

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Objective: US Department of Health & Human Services (HHS) Office of the Inspector General (OIG) works with the Department of Justice (DOJ) investigating alleged Medicare and Medicaid service provider misconduct, imposing fines and issuing Corporate Integrity Agreements (CIAs) to pharmaceutical companies. We examined CIAs issued in 2012 with provisions specific to publications-related activities.

Research design and methods: Previous year public records of OIG and DOJ pertaining to pharmaceutical company CIAs were reviewed.

Results: Four CIAs met criteria. General provisions of the CIAs are similar to previous CIAs: strict authorship criteria, written authorship agreements, disclosure of funding/sponsorship, and needs assessment. Two CIAs went beyond this. Allegations of off-label promotion for one company specified years of dissemination of inaccurate and misleading publications and downplaying safety data, before eventually admitting no evidence of drug benefit. The CIA required that future publications not downplay safety, and be balanced and timely. In another,

specifications alleged improper conduct in manuscript development and submission, response to reviewer comments, and subsequent resubmission and publication that misrepresented clinical significance and product safety. The CIA required appropriateness, accuracy, and balance in presentation of clinical study results in future publications and educational activities.

Conclusions: DOJ and OIG continue to scrutinize publication activity and include publication-related sanctions in their 2012 CIAs. Two followed investigations that reviewed published articles for accuracy and appropriateness of content. They focus on important components of good publications practices beyond process, i.e., publications are responsible and timely, in accordance with established reporting standards.

Digital dissemination of scientific poster presentations via quick response (QR) codes: implementation and analytics

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Objective: Use of quick response (QR) codes is increasingly ubiquitous across multiple industries. Adoption of this technology to disseminate scientific data and presentations within Pharma has been slow, but its prevalence is increasing. Pfizer Oncology was interested in developing a consistent QR-code approach for congress posters. Results of a pilot followed by a large-scale rollout at major international congresses are described.

Research design and methods: A uniform approach and tracking system were developed to include creation, programming, testing, deployment, and tracking. Usage data were collected and analyzed via Google Analytics.

Results: A total of 50 posters, representing assets across the Pfizer Oncology portfolio, were tagged with QR codes at five congresses: 2011 European CanCer Organisation–European Society for Medical Oncology, and the 2012 meetings of the IMPAKT Breast Cancer Conference, American Society of Clinical Oncology, European Society for Medical Oncology, and American Society of Hematology. Overall, there were 1806 total visits by 1049 unique visitors. Geographic representation of users was broad. The iOS (iPhone and iPad) operating system was the predominant platform among users accessing posters at these congresses. These results suggest successful dissemination of scientific data via QR code technology. Limitations in data collection (particularly around geographic representation of users) and at the point-of-access, due to myriad available QR code readers, were noted.

Conclusions: As demonstrated here, QR codes are an effective tool to communicate scientific data at national and international congresses via an electronic platform. Despite limitations with data collection and variation among QR code readers, this technology has enhanced data dissemination at congresses.

'Got GPP skills?' Skill-building initiative for publication professionals in pharmaceutical industry setting

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Objective: An interdepartmental initiative 'Got GPP Skills?' was implemented as part of a global medical publications department's ongoing efforts to ensure proficiency in good publication practice (GPP) and commitment to ethical, transparent data dissemination. It was anticipated that this series might motivate participants to pursue the Certified Medical Publication Professional (CMPP) credential.

Research design and methods: The target audience was individuals involved in publication planning and execution within a pharmaceutical company globally. The curriculum was created based upon the International Society for Medical Publication Professionals' (ISMPP) domains for CMPP training (Publication Plan Development, Tactical Plan Development, Publication Plan Implementation, and Professional Responsibilities), as well as internal publication policies. Internal CMPP-credentialed staff served as session facilitators. Recommended resources were

provided. A number of modalities were leveraged to facilitate knowledge exchange, including Microsoft Live Meeting, Audience Response System, and case studies. A SharePoint site was created as a portal for session materials.

Results: Of the 85 medical professionals targeted, 35% participated, including individuals from the US, Australia, Europe, and Asia. Over a 4 month period (November–February), six 2 hour sessions were held. Results of a post-session survey, assessments, and number of participants choosing to pursue the CMPP credential will be presented.

Conclusions: The 'Got GPP Skills?' initiative served as an advocacy tool raising awareness of ISMPP and GPP within our organization. Based on the high level of interest globally, this series will be ongoing.

Guidelines for literature analyses: an agency perspective

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Objective: This study aimed to develop a uniform approach for the development of literature analyses, incorporating the best practices of professional organizations, scientific literature, and evidence-based medicine.

Research design and methods: A search of PubMed and EMBASE for protocols and methods in the literature, combined with a search for guidance documents from organizations, including the American Medical Writers Association, Cochrane Collaboration, the American Medical Association, government agencies, and universities, revealed a preliminary list of procedures for scientific literature analyses. These results were examined by medical information staff and distilled into a suite of guidelines distributed to medical writers for feedback and approval. A second round of review from scientific and medical experts preceded the final process guidelines, which were circulated to industry professionals.

Results: The result is a guidance document that provides all medical writing personnel with a step-by-step method for the organization and completion of a scientific literature analysis. The guidelines instruct staff on: 1) conducting preliminary MeSH searches; 2) focusing searches to a specific therapeutic area or audiences; 3) conducting qualitative analysis on publication type, frequency, and global distribution; 4) creating client specific deliverables, including slide decks, white papers, and manuscripts; 5) incorporating reviewer comments after multiple draft review; and 6) delivering a focused, scientifically sound product.

Conclusions: Guidelines for conducting scientific literature analyses vary between organizations, resulting in incomplete or inconsistent reports. Developing a standardized approach for internal and external stakeholders provides a template for literature analyses that is applicable to all parties.

Implementation of an educational program regarding best publication practices and the introduction of publication management software across a global organization

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Objective: A medical publications department in the global headquarters of a large biopharmaceutical company identified needs for improved access to publication capability in ex-US regions and to implement global standards of publication development and management.

Research design and methods: A cross-functional working group identified topics needed for best publication practices education, appropriate participants, and channels for training. Based on the level of involvement in publication development, participants were tiered to receive either web-based or live training on both best publication practices and publication planning and tracking software.

Results: Six core areas for best publication practices training (authorship, disclosures and acknowledgments, payment of honoraria, publication development processes, investigator-sponsored research, and encore presentations) were identified. Live trainings on best publication practices were undertaken in several venues over a 6 month period for more than 200

participants from ~35 countries. In one region, best publication practices training was coupled with live software training for more than 100 participants in three venues. The most common follow-up inquiries centered on publication development processes, authorship criteria, encore presentation standards, and publications arising from investigator-sponsored research. Post-training surveys were positive. Metrics from the publication management application and additional compliance initiatives will be used to assess compliance.

Conclusions: Training on best publication practices concepts and on publication management software was launched to apply uniform standards of publication development and to enhance regional and local publication planning capabilities. Follow-up initiatives for continued outreach are in development.

Improving data accessibility through innovations in regional publication planning, training, and implementation

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Objective: This study sought to maximize exposure to data among regional audiences, including physicians and other healthcare practitioners, by implementing targeted, regional publication planning education in alignment with a global strategy.

Research design and methods: To assess baseline awareness of publication planning, best practices, and guidelines across regions, the global scientific communications team of a multinational pharmaceutical company held a Publication Planning Team (PPT) meeting to review educational gaps as well as global/regional publication plans. A questionnaire was distributed to company representatives from various regions, which included Europe, Latin America, Japan, and the United States. Targeted regional training initiatives were implemented based on the results.

Results: Regional company representatives completed a questionnaire on planned publications, targeted congresses/journals/audiences, upcoming datasets, awareness of best publication practice, and interest in further education. Based on the results, interactive workshops were conducted to address region-specific educational gaps. Interactive training sessions included: publication mapping, development process, guidelines, and internal compliance. In breakout sessions, publications were mapped from database lock to submission while following proper publication process and milestones. Participants gained a comprehensive understanding of the company's global publication plan, learned how to align regional/global strategic plans, and gained awareness of accepted best practices to maximize compliance with company and industry publication guidelines.

Conclusions: Tailored, region-specific educational programs led to increased regional/global alignment and an increased awareness/accessibility of regional publications.

Incomplete conflict of interest (COI) disclosures – contribution of medical journal requirements[‡]

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Objective: The purpose of this study was to evaluate recent conflict of interest (COI) disclosures from authors in a specific therapy area, to determine whether COIs are reported accurately, and to explore whether COI policies and disclosure requirements may have contributed to observed inaccuracies.

Research design and methods: From a manuscript recently published in the *New England Journal of Medicine*, we identified all academic authors, searched PubMed for publications by these authors in the same therapy area over the 12 months prior to publication, and selected all relevant publications with freely available COI statements. For authors listed on ≥ 3 of these publications, we developed hypothetical complete COI disclosure statements, compiled from all explicitly stated COI disclosures, and organized these according to the standard categories in the International Committee of Medical Journal Editors Uniform

Disclosure Form for Potential Conflicts of Interest (http://www.icmje.org/coi_disclosure.pdf). Published COI statements were compared against hypothetical complete COI statements, and inconsistencies in authors' disclosures were summarized descriptively. In addition, we surveyed the format that journals requested for disclosures (i.e., form [available to download via manuscript/submission site] vs. no form) and whether journals provided specific guidance on categorizing disclosures.

Results: Eleven authors met the eligibility criteria, with 55 individual disclosures obtained from 43 unique manuscripts included in the analysis. Almost all (54/55; 98.2%) disclosures appeared to be inaccurate. Breaking these disclosures down by COI category, 154/171 (90.1%) separate statements were incomplete/inconsistent. 'Consultancies/Honoraria' was the most frequently inaccurate category (49/55; 89.1%). Of the surveyed journals, 13/27 (48%) used a form to collect COIs and only 6/27 (22%) requested provision of COIs by pre-defined category.

Conclusions: The apparent high level of incompleteness in disclosing potential COIs is concerning and may be in part attributable to inconsistent journal disclosure policies. Therefore, we recommend that authors develop and maintain a standard COI statement to ensure consistency and transparency in their disclosures, and that all journals adopt the ICMJE disclosure form.

Increasing and evolving use of smart technology to access congress posters^{*}

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Objective: After a successful pilot study of the use of quick response (QR) codes on scientific congress posters, we developed a central web-based platform to enable our medical communications agency partners to integrate QR technology into all posters supported by our company. We report the development and subsequent usage of this e-poster delivery system.

Research design and methods: Our system was launched in February 2012; it automatically generates a QR code for incorporation during the poster layout process and hosts an electronic copy of the final poster. Upon scanning the QR code with a mobile device, delegates may access the e-poster via a user-friendly interface. To enhance the understanding of the scientific content of posters by a wider audience, we also added multiple language options.

Results: As of January 2013, 13 partners have used the platform for 177 posters with QR codes. Posters appeared at 61 major congresses in 34 different countries; >1000 delegates have now accessed e-posters. Since the option to download translated posters was added in July 2012, English, French, German, Italian, Spanish and/or Japanese versions of 13 posters have also been available. A short message service (SMS) text facility has also been introduced.

Conclusions: The e-poster delivery system is an environmentally sound, efficient and flexible platform for providing access to congress presentations. As greater functionality is added, including translations for non-native English speakers and an SMS option, its value to delegates continues to grow.

Introducing good publications practices in China: a case study in nuance and know-how

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Objective: Chinese authors are eager to publish their research in top-tier medical journals to share their scientific experience and enhance their professional standing. However, the concept of good publications practices is relatively new in China and adherence to these guidelines may pose challenges due to cultural nuance and language barriers.

Research design and methods: The idea for this project came directly from our Chinese customers, who asked for support in improving their presentation and publication skills. We partnered with a local scientific publications organization to develop a comprehensive program, which provided an overview of uniform requirements for manuscript preparation, good publications practices, including

[‡]Portions of data from this abstract were previously presented at the 2013 European Meeting of ISMPP by C. Campbell et al.

^{*}Oral Presentation.

the need for full disclosure, and authorship criteria. We translated and shared the Good Publication Practice 2 (GPP2) guidelines and provided all attendees with a Chinese translation of the International Committee of Medical Journal Editors uniform disclosure form.

Results: We trained 40 clinicians, representing a range of therapeutic areas: metabolics (4%), cardiovascular (13%), infectious disease (29%), hepatology (38%), hematology (12%), and orthopedics (4%). Attendees completed a post-meeting survey: 91% of attendees indicated they would be directly involved in the preparation of a manuscript in the near future; of these, 41% requested writing assistance, 27% requested editorial support, 64% requested refresher training in statistical analysis, and 27% requested support in journal selection and manuscript submission.

Conclusions: Training in good publications practices is in high demand in China. Additional areas of focus include refresher training in statistical analysis.

Kicking off cost-efficient abstracts: factors influencing abstract development time

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Objective: We aimed to determine factors affecting abstract development time (ADT) in order to maximize efficiency and minimize cost.

Research design and methods: Data were collected from 27 (of 157 total) abstracts developed by Nucleus Global in conjunction with external clients for publication at scientific meetings. The mean number of hours spent on the project (editorial and management time) was calculated, and predictors were examined. Two-tailed *t* tests were used to determine the relationship between key predictors and ADT. For continuous predictors, a median split was performed prior to conducting the *t* test.

Results: Results are presented in Table 1.

Conclusions: Having data available, and holding a kick-off call at abstract initiation, significantly reduce the number of hours required for completion; more drafts were associated with longer ADT. Number of authors was not significantly related to ADT.

Perception of multimedia content by journal editors

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Objective: The purpose of this study was to assess journal editors' attitudes toward current and future trends regarding multimedia content (e.g., webcasts and resource centers).

Research design and methods: An e-mail was sent to 60 individuals (editors-in-chief, associate editors, and managing editors) representing 50 peer-reviewed journals published by Elsevier. The e-mail asked recipients to provide their thoughts on multimedia content regarding their journals via Survey Monkey, where a 10-question survey was posted.

Results: Of the 60 e-mails sent, 32 responses were received, and of those, 24 were from editors-in-chief.

- >50% of respondents reported posting video content that:
 - Supports print articles – 53%
 - Is independent of print articles – 67%
- Using a 7-point Likert scale ranging from 1 (*strongly oppose*) to 7 (*strongly favor*), 96% of respondents' answers ranged between *neutral* and *strongly favor* posting peer-reviewed multimedia activities with their journals.
- When presented with a real-life example of a journal 'Virtual Review Article' (peer reviewing a video roundtable, posting online with journal branding, and indexing in PubMed), using a 7-point Likert scale ranging from 1 (*no interest*) to 7 (*very interested*):
 - 94% responded between 4 (*neutral*) and 7
 - 41% responded 7 (*very interested*)
- When asked about major benefits of multimedia content (survey takers were given choices and asked to check all that applied), the predominant response was:
 - 'Providing content in an alternative format that readers are requesting' – 87%
- Using a 7-point Likert scale ranging from 1 (*no risk*) to 7 (*high risk*), survey takers were asked to rate the risk that posting purely online peer-reviewed editorial content might diminish the journal's credibility:
 - 3% perceived *high risk*
 - 87% ranged between 1 (*no risk*) and 4 (*neutral*)

Conclusions: Survey results suggest that journal editors recognize the desire of journal readers to receive content in multimedia formats; are generally not concerned about multimedia content undermining journal credibility; and are interested in peer reviewing, posting, and indexing multimedia content to their journal much like a print article.

Publication agreements or 'gag orders'? Compliance of publication restrictions with Good Publication Practice 2 (GPP2) for trials on ClinicalTrials.gov

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Objective: Good Publication Practice 2 (GPP2) recognizes the shared responsibility of authors and sponsors to publish clinical trial data and confirms authors' freedom to publish. We investigated publication restrictions for clinical trials registered on ClinicalTrials.gov.

Research design and methods: Record data from included trials (phase 2–4, interventional, recruitment closed, results available, first received after 11/11/2009, any sponsor type) were electronically imported. Publication agreement information was manually imported from the 'Certain Agreements' field. Two authors independently categorized publication restrictions regarding GPP2 compliance; discrepancies were resolved by consensus.

Table 1. Factors impacting ADT.

	Yes, Hours	No, Hours	<i>p</i> Value	
Data availability prior to initiation	24.1	45.5	<0.0001	
Kick-off call prior to initiation	28.7	41.2	0.017	
	Median (Range), Number/Rounds	≤Median, Hours	>Median, Hours	<i>p</i> Value
Number of external authors	7 (0–20)	30.1	36.3	0.240
Number of internal authors	3 (1–9)	36.2	26.1	0.060
Number of drafts	6 (3–15)	27.6	38.5	0.031
Rounds of review	6 (3–12)	29.5	39.6	0.061

Results: Of the 389 trials retrieved, 81% (314/389) had a publication restriction. Significantly more publication restrictions were GPP2 compliant than noncompliant (74% [233/314] vs. 26% [81/314], chi-square $p < 0.001$). Reasons for noncompliance were insufficient information (51%; 41/81), sponsor-required approval for publication (35%; 28/81), sponsor-required text changes (9%; 7/81), and sponsor bans on publication (6%; 5/81). Drug trials (181/256) were significantly less likely to have GPP2-compliant restrictions than other trials (52/58; relative risk 0.79, 95% CI 0.70–0.89, $p = 0.003$).

Conclusions: This is the first study to investigate publication restrictions using the largest, international, public-access database of publication agreements. Most publication restrictions for clinical trials are consistent with GPP2 and do not include 'gag orders' forbidding publication. Sponsors should ensure that publication agreements recorded on ClinicalTrials.gov confirm authors' freedom to publish data and are audited to ensure consistency with GPP2 and any other publication agreements (e.g., in protocols, contracts) between sponsors and investigators.

Publication experience in orphan diseases: case study with Cryopyrin-Associated Periodic Syndromes (CAPS)

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Objective: Few medical communication reports discuss the planning and execution of clinical publications that describe treatment options for rare or 'orphan' diseases. While orphan-designated drugs follow the same development pathway as other pharmaceutical products, key challenges are the limited resources and small patient pools available for research, thus often restricting the number of scientific studies and associated publications. Physician-driven disease-state/educational publications therefore increasingly become important in highlighting the unmet needs of such patient populations. This report describes publication activity in support of an orphan-designated drug for a rare disorder, Cryopyrin-Associated Periodic Syndromes (CAPS).

Research design and methods: We examined completed, ongoing and planned publication activities across several areas of research and development in CAPS. In addition, we assessed disease-state/educational publications highlighting unmet therapeutic needs for the CAPS population.

Results: About a dozen reports, including a number of clinical and disease-state/educational manuscripts have been published in peer-reviewed journals such as *Journal of Clinical Pharmacology* and *Arthritis and Rheumatism*. Importantly, we supported a publication on the development of a new patient-reported outcome instrument to measure disease activity in CAPS patients' baseline and treated states. Investigator-initiated studies have also yielded publications, and several such independently conducted studies are ongoing.

Conclusions: Our experience demonstrates that publications reporting pivotal trials and physician-driven disease-state/educational publications are integral to an orphan-disease publication plan.

Publication of health economics and outcomes research (HEOR) data in non-HEOR journals: a literature analysis*

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Objective: Health economics and outcomes research (HEOR) data may be relevant to both HEOR and clinical audiences. This analysis evaluated the top 20 journals publishing general quality of life measures and key cost-related analyses.

Research design and methods: Literature searches (PubMed; limits: English, 2012) were conducted for SF-36/SF-12, EQ-5D, HAQ, pharmacoeconomics, cost effectiveness, health utility, and direct/indirect costs. The top 20 journals represented in each search (by number of citations) were classified as HEOR or non-HEOR based on audience.

Results: Non-HEOR journals were among the top 20 for all searches (Table 1), representing >50% of journals for SF-36/SF-12, EQ-5D, HAQ, pharmacoeconomics, and direct/indirect costs. Similar results were observed for analyses based on the total number of articles.

Conclusions: Many HEOR topics and measures may be appropriate for publication in non-HEOR journals.

Relationship of citations received for published articles to a journal's impact factor at time of submission

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Objective: Authoring teams may emphasize measures such as impact factor (IF) when selecting target journals. Subsequent 'success' may be measured as the number of citations in the peer-reviewed literature. The utility of a journal's IF to predict citations for submitted articles is uncharacterized.

Research design and methods: All drug-related journal submissions ($n = 362$) for a pharmaceutical company for 1 year were assessed. The number of citations since publication was determined on a single date (July 26, 2012) using Google Scholar. Days elapsed from publication date to citation count date were calculated and used to normalize for days post-publication. Linear regression analyses were used to characterize the relationship between a journal's IF and subsequent number of peer-reviewed literature citations for individual articles.

Results: For 258 evaluable and published articles, the average journal IF at time of submission was 4.9 (range: 0.23–47.05). The average days elapsed since publication was 726.8 (range: 265–1094). Absolute citation counts ranged from 0 to 437 (average = 14.7). The absolute number of citations and a normalized quarterly citation rate were both positively correlated to a journal's IF ($R^2 = 0.44$ and 0.49, respectively). The number of days since publication was not a strong predictor of citation number ($R^2 = 0.05$).

Conclusions: Since less than half of citations received by published articles may be dependent upon the journal's IF, authoring teams should consider other possible factors besides IFs when choosing target journals.

Table 1. Analysis of top 20 journals publishing on selected HEOR topics by audience.

Concept	Total articles, <i>n</i>	Total unique journals, <i>n</i>	Analysis by journal (top 20 journals only)		Analysis by article (top 20 journals only)		
			HEOR journals, <i>n</i> (%)	Non-HEOR journals, <i>n</i> (%)	No. of articles in top 20 journals, <i>n</i>	Articles in HEOR journals, <i>n</i> (%)	Articles in non-HEOR journals, <i>n</i> (%)
SF-36/SF-12	1518	638	2 (10)	18 (90)	353	84 (24)	269 (76)
EQ-5D	453	239	7 (35)	13 (65)	169	98 (58)	71 (42)
HAQ	261	129	0	20 (100)	146	0	146 (100)
Health utility	2359	1254	11 (55)	9 (45)	324	185 (57)	139 (43)
Pharmacoeconomics	787	353	9 (45)	11 (55)	299	193 (65)	106 (35)
Cost effectiveness	4648	1682	11 (55)	9 (45)	811	408 (50)	403 (50)
Direct/indirect costs	1778	999	6 (30)	14 (70)	315	115 (36)	200 (63)

*Oral Presentation.

Table 1. Average time in months.

Published in	N (%)	1st Submission to Acceptance	1st Submission to Publication	Average Impact Factor
1st choice journal	249 (61%)	4.58	6.64	4.99
2nd choice journal	98 (24%)	9.74	11.99	3.09
3rd, 4th or 5th choice journal	63 (15%)	16.98	18.50	2.40
Total	410	7.83	9.79	4.14

Submitting prior reviews with a previously rejected manuscript when seeking publication in another journal: implications for closing the credibility gap in reporting industry-sponsored clinical research

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Objective: In an effort to close the credibility gap in reporting industry-sponsored clinical research, a Medical Publishing Insights and Practices roundtable recommends the sharing of prior reviews of a previously rejected manuscript when the author submits to a different journal¹. The objectives of this study are to confirm that this practice would increase the credibility of industry-sponsored clinical studies, and to assess the current situation in terms of journals making this possible, since there is currently no consensus among journal editors.

Research design and methods: We sent an anonymous online survey to approximately 30,000 recipients who registered to receive electronic Table of Contents alerts.

Results: The survey received 488 responses, including 122 editors and 249 authors. Seventy-five percent agreed that there was a need to improve the transparency of industry-sponsored research, and of these, 85% felt that including prior peer reviews in subsequent submissions would have at least some impact on doing so. However, 47% of those who have had a manuscript peer reviewed but not accepted ($n=139$) have never been given the option to include previous peer reviews alongside a submission, and 37% of editors said they do not accept them at all.

Conclusions: Of those who feel transparency needs to be improved for industry-sponsored research, most feel that including prior peer reviews alongside subsequent submissions will do this, although that is currently impossible with many journals.

Reference

- Mansi BA, Clark J, David FS, et al. Ten recommendations for closing the credibility gap in reporting industry-sponsored clinical research: a joint journal and pharmaceutical industry perspective. *Mayo Clin Proc* 2012;87:424-9

Success at journal of choice and effect of resubmissions on publication timing for Pfizer-sponsored publications in 2012*

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Objective: Resubmissions of manuscripts following journal rejection can jeopardize the timeliness of information and divert resources from other work. Data on the submission histories of company-sponsored manuscripts were examined to quantify delay when manuscripts were not accepted by first- and subsequent-choice journals.

Research design and methods: Manuscripts published in 2012 were identified in Datavision. Time to acceptance and publication were analyzed and other attributes, including journal impact factor, were recorded.

Results: A total of 410 published manuscripts were included in the analysis. For manuscripts published in the second-choice journal, average time from first submission to publication was 5.16 months longer than for manuscripts published in the first-choice journal. Additional results are presented in Table 1.

Conclusions: Repeated submissions can add considerable time to publication. These data may be useful to support efforts to encourage appropriate journal selection by authors.

The evolution of journals from print to enriched media: an assessment of journal digital characteristics

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Objective: Healthcare professionals (HCPs) are shifting how they access clinical information in response to the dramatic evolution of online and mobile resources. To effectively compete, peer-reviewed medical journals are adapting to provide useful, engaging, and informative healthcare information through digital channels. We sought to understand how medical journals are expanding their use of digital media to provide enriched sources of content.

Research design and methods: We surveyed 100 medical journals to explore what changes they have made to increase their use of digital media to deliver content. In addition, we analyzed 39 medical journal websites to identify how they are using social channels and other new media to expand the reach of their content and facilitate broader, enriched, easier access.

Results: Of the 39 journal websites surveyed, one quarter ($n=10$; 26%) did not have broader digital characteristics. Of the remainder, 26 (66%) solicited inclusion of digital media into publications (e.g., video-enriched manuscripts) or proactively provided unsponsored content via new media (e.g., podcasts). Seventeen journals (44%) had active social media channels such as Twitter or Facebook. We are currently awaiting responses from the remainder of the 100 journals surveyed.

Conclusions: Peer-reviewed medical journals are rapidly evolving to meet the needs of HCPs in accessing healthcare information through mobile and online resources. Journals report this trend will continue, as they seek ways to adapt to an increasing need for rapid and user-friendly access to data and education.

*Oral Presentation.

Transparency in publications: reporting of funding, conflicts of interest and writing assistance – call for standardized declaration for reporting

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Objective: Reporting of funding, conflicts of interest and writing assistance in one therapeutic area were assessed.

Research design and methods: In the setting of a gap analysis, PubMed was searched for publications about a vaccine and the disease it prevents from 01/01/2010 to 08/31/2012. The publications included in the gap analysis were searched for information on funding, conflicts of interest and writing assistance.

Results: Results are presented in Table 1.

Conclusions: In this therapeutic area, lack of transparency in reporting in publications was present; often no details are given. One limitation of this study is that it is based on a convenience sample; a broader sample would have been more meaningful. A standardized declaration should be encouraged so that there is a clear statement of no funding, no conflict of interest and no writing assistance, not an assumption by omission.

Trends in clinical trial publication in open-access journals

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Objective: Open-access publication of scientific articles is receiving increased attention and is mandated for federally funded research. Many journals are now offering a 'hybrid' access model, which requires a fee paid to the publisher. As the effect of open-access policies on publication decisions is not well understood, we examined potential trends in the publication of clinical trials among open-, closed-, and hybrid-access journals.

Research design and methods: Phase 1–4 clinical trials in four key therapeutic categories (neurology, oncology, gastroenterology, and cardiology) were identified between 2008–2012 using PubMed (<http://www.ncbi.nlm.nih.gov/pubmed>). Journal Selector was used to ascertain the publication type of each journal. Journals were categorized into open access (articles publically available in ≤6 months), closed access (articles embargoed for >6 months), or hybrid access. Associations between clinical trial publication, access status, and impact factor were evaluated.

Results: Of the 438 trials analyzed, 50% were published in open-access journals, 36% in closed-access journals, and 14% in hybrid-access journals. Significant differences were observed by disease area ($p < 0.001$), with 67% of oncology

trials being published in open-access journals, and 80% of gastroenterology trials being available in hybrid-access journals. There were also differences by trial phase ($p = 0.004$); notably, 58% of phase 2 trials were published in open-access journals. Average impact factor was similar among all journal types (range: 9.7–13.0).

Conclusions: As open- and hybrid-access publication becomes more common, some therapeutic areas are taking advantage of nontraditional accessibility options for publication of key clinical trial data.

Trends in the perception of industry-related medical publications

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Objective: Since the Senate inquiry in 2009, medical journals and industry have implemented policies to address concerns of 'publication bias'. We conducted a literature survey to understand current perceptions in medical publishing.

Research design and methods: The MEDLINE database was searched for the terms 'industry' and 'publishing' from 2009–2012. Relevant citations were categorized as 'positive' (lack of publication bias), 'negative' (publication bias) or 'neutral' (reporting policies).

Results: A total of 96 citations were analyzed. More than half of the citations in 2009 (59%) were of negative perception and 3 (18%) of positive perception. From 2010 onwards, the percentage of citations with positive perceptions almost doubled, while there was a decline in negative perceptions. The percentage of neutral perceptions increased from 23.5% in 2009 to 35% in 2011.

Conclusions: Since 2010, there is an increased trend in positive perceptions, suggesting that implemented policies to reduce publication bias are in the right direction.

Table 1. Distribution of perceptions: N (%).

Year	Positive	Negative	Neutral	Total
2009	3 (17.6)	10 (58.8)	4 (23.5)	17
2010	8 (34.7)	9 (39.1)	6 (26.0)	23
2011	13 (35.1)	11 (29.7)	13 (35.1)	37
2012	9 (47.3)	7 (36.8)	3 (15.7)	19

Table 1. Analysis of reporting of funding, conflicts of interest, and writing assistance.

	2010 (n = 95)	2011 (n = 64)	2012* (n = 30)	Total (n = 189)
Funding				
Yes, funding	68 (72%)	43 (67%)	15 (50%)	126 (67%)
No funding	4 (4%)	5 (8%)	1 (3%)	10 (5%)**
No details given	23 (24%)	16 (25%)	14 (47%)	53 (28%)
Declaration of conflicts of interest				
Yes, conflicts of interest	37 (39%)	27 (42%)	22 (73%)	86 (45%)
No conflicts of interest	29 (30.5%)	18 (28%)	0	47 (25%)
No details	29 (30.5%)	19 (30%)	8 (27%)	56 (30%)
No details in Vaccine***	6/17 (35%)	9/20 (43%)	3/6 (50%)	18/43 (42%)
Writing assistance				
25/189 (13%) of the papers stated that no writing assistance was given				
148/189 (78%) give no details				

*Search up to August 31, 2012.

**Including four review articles.

***43/189 (23%) of the papers were published in Vaccine; declaration of conflicts of interest is a requirement in their instructions to authors.

Twitter hashtag usage at medical conferences: follow-up analysis

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Objective: In 2012, the first benchmark analysis of Twitter hashtag usage at medical conferences was conducted. This follow-up analysis was conducted to examine notable changes in uptake, engagement, and utilization versus the original benchmark.

Research design and methods: In the 2012 analysis, top medical conferences by attendance in 2011 for four major therapeutic categories (general medicine, oncology, gastroenterology, and cardiology) were identified using Conference Authority. These same conferences were used herein to allow comparison with baseline. Twitter activity for the duration of each conference was assessed using Radian6; tweet/retweet volume and total reach were recorded and compared to the prior year.

Results: Overall conference hashtag utilization increased by 56%, with an increase in all therapeutic areas except for general medicine. There was an 83% increase in retweet volume (47% of all hashtag volume) across all therapeutic areas, extending the reach of the initial communication. There was an approximately three-fold increase in average potential total reach over the prior year. In the previous analysis, a discrepancy in hashtag volume between US and non-US conferences of almost 3:1 was identified. That gap has narrowed to roughly 2:1.

Conclusions: Hashtag usage at medical conferences continues to increase in almost all therapeutic categories. Utilization of hashtags is more consistent across conferences globally. The significant increase in average potential total reach indicates an increase in Twitter users following handles and conversations related to medical communications.

Worldwide implementation of a publication planning and development policy

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Objective: This study's objective was to successfully implement and ensure compliance to the Global Publication Planning and Development Policy at local and regional levels across the organization.

Research design and methods: In 2011, a revision to the corporate Global Publication Planning and Development Policy was instituted. A need to improve communications regarding publication development across affiliates was identified. The global publication management system (Datavision) was expanded for use by the affiliates to document compliance. Training on policy, process, Datavision, and publication planning was piloted in five key affiliates. Feedback was solicited from all participants.

Results: Feedback from the pilot training resulted in enhancements to how the global publications function partnered with affiliates. A practical process was adapted to allow flexibility at each affiliate, taking into consideration local resources, and differences in corporate and cultural interactions with internal and external stakeholders. A phased-training program was launched in early 2012. By the end of 2012, over 75 affiliate representatives were trained. In 2012, 52% of Avonex and 48% of Tysabri publications were developed by affiliates, including local language publications. A total of 24 globally aligned affiliate publication plans across five products were developed for 2013.

Conclusions: Biogen Idec successfully developed and implemented a process for collaborating and training affiliates on the Global Publication Planning and Development Policy, including development of local publication strategies. Through this effort, we improved the alignment of local and global publications across geographies.

The following abstracts were accepted for poster presentation at: Doing the right thing and doing things right. 2013 European Meeting of ISMPP; 2013 Jan 22–23; London, UK.

Author attitudes to professional medical writing support[§]

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Objective: The objective of this survey was to understand academic/clinician authors' perceptions regarding the value of professional medical writers (PMWs).

Research design and methods: An online survey of academic/clinician authors was conducted to understand the value of PMW support in the development of publications (abstracts, posters and manuscripts). Responses were collected anonymously. The survey used a negative-to-positive, 6-point scale to evaluate respondents' opinions and experience of working with PMWs, and multiple choice to indicate in which areas PMWs added value.

Results: Responses from 76/260 authors were received (Europe, $n=57$; 75.0%; North America, $n=16$; 21.1%; Asia-Pacific region, $n=3$; 3.9%). The majority of respondents were either clinicians ($n=45$; 59.2%) or academic researchers ($n=25$; 32.9%). A total of 82.9% (63/76) of respondents felt that it was acceptable to receive PMW assistance with their publications, and 84.0% (63/75) valued the assistance provided. The services most valued (>50 responses) were editing and journal styling, conformity with manuscript guidelines (e.g., CONSORT) and manuscript submissions. Less valued services (25–49 responses) were management of timelines and co-author reviews, scientific/technical writing assistance, and expert guidance on authorship requirements/good publication practice. The least-valued service was the scientific expertise of the PMW (three responses).

Conclusions: Respondents to this survey were generally accepting of medical writing assistance and valued many aspects of the role, in particular editorial support. Although many medical writers come from a scientific background and have relevant expertise, this was not perceived as a value. Education regarding the experience of PMWs may be warranted.

Authoring industry-sponsored research: results from an investigators' survey

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Objective: In 2012, GSK-Vaccines conducted a web-based survey to assess how investigators evaluate its publication authoring practice.

Research design and methods: A 50-question survey (of which 47 were closed) addressed authoring practice and transparency of decision-making. In total, 1273 investigators/researchers, who had authored since 2007 at least one publication reporting GSK-Vaccines-sponsored human subject research, were invited to participate.

Results: Overall, 415 investigators/researchers (32; 6%) responded. Of these, 8% find the criteria from the International Committee of Medical Journal Editors (ICMJE) unclear and 14% are unfamiliar with them. For 76%, the concept of group authorship is unclear and of limited academic value. Eighty-six percent of participants find GSK-Vaccines' authorship questionnaire (Rouxhet *et al.*, CMRO 2012;28(S1):S17) a suitable tool to assess eligibility as per ICMJE criteria. However, 32% evaluate that the outcome of the questionnaire is not shared appropriately with potential authors, and the communication on changes in authorship could be

[§]Encored at the 9th Annual Meeting of ISMPP

improved according to 42% of the investigators/researchers. Briefing meetings prior to publication start, publication steering committees and core writing teams are recognized by investigators/researchers as key to their role in authorship discussions, journal selection and manuscript development. Finally, 63% perceive that having a pharmaceutical company employee as lead author makes manuscript acceptance less likely.

Conclusions: Effective and timely communication is critical to ensure transparency of authorship, decision-making and engagement of all authors. The application of group authorship and also authorship criteria could further benefit from major guidance by the ICMJE.

Conference abstracts: do processes follow best practice?[§]

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Objective: Named authors are required to take a lead role in developing publications; our research evaluates the utility of best practice principles for conference abstracts.

Research design and methods: A questionnaire exploring current practice for industry-sponsored conference submissions involving medical writing support was circulated to the International Society for Medical Publication Professionals and LinkedIn lists. Questions ($n=12$) focused on the role of non-industry authors in developing conference abstracts.

Results: Relevant experience enabled 96/106 people from the United States, United Kingdom, European Union, or Asia/Pacific regions (55.2%; 27.2%; 14.9%; 2.3%) to participate. Most worked in medical communications (60.9%) or the pharmaceutical industry (31%). Non-industry authors initiated abstracts always, most, or some of the time (22.3%; 24.5%; 43.6%) with varying levels of subsequent involvement. The information made available to them depended on data availability and type of study. Where not all authors were involved in the decision to develop an abstract, industry publication managers took the lead role more frequently than lead authors or investigators (84.4% vs. 58.9%). Respondents had experience of abstracts where some authors had not contributed substantially (36.8%) and/or had not given final approval for submission (36.8%). One-half stated they would never submit an abstract using negative approvals, but if given an hour's deadline to submit an abstract without sign-off, 47/96 respondents believed the decision to submit should be conditional; factors included approval of earlier drafts, relationship with the author, and option to withdraw.

Conclusions: The development process for conference submissions differs from that of manuscript development, with possible implications for best practice.

Digital media integration trends in publication planning: use of non-traditional communication channels and contemporary effectiveness measurement

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Objective: Healthcare professionals (HCPs) increasingly use online resources, including search engines, websites and social media, for clinical decisions. In parallel, peer-reviewed journals are frequently accessed online and open-access journal use is increasing. We sought to understand the use of online and open-access journals and non-traditional communication channels by publication planning teams and how they subsequently measure dissemination success.

Research design and methods: We carried out a mini-benchmark of publication planning professionals via invitation to respond to two online surveys. The benchmark was web-enabled using Qualtrics technology.

Results: We received a total of 61 responses to these surveys. Overall, the responsibility for publication planning teams has expanded outside traditional

peer-reviewed publications to include online data dissemination channels. Of respondents, 64% develop content for open-access journals, and 29% also provide content for web-based communication tactics. Primary reasons provided for using open-access journals were accelerating public disclosure of information or publishing manuscripts rejected by higher-tier journals. While 69% of respondents measure effectiveness based on publication quantity and 59% analyze impact based on approved versus rejected manuscript statistics, only a minority use non-traditional metrics to assess impact.

Conclusions: The shift in how and where HCPs access their information is changing how pharmaceutical companies approach publication planning. While there has been some evolution in the type of channel used for data dissemination, there has not been a similarly substantial shift in how to measure dissemination effectiveness.

How do we know if we are doing the right thing? Results of a survey to understand current 'grey areas' in publication management[§]

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Objective: As the management of medical, scientific and technical publications continues to evolve, publication professionals have to handle situations that are not clearly defined by current industry guidelines. Company policies/standard operating procedures can vary quite significantly based on interpretations of published publication guidelines and personal experience of best practice. We wanted to explore the perceived 'grey areas' in publication management and highlight any potential inconsistencies.

Research design and methods: Publication professionals were sent an electronic 14-question survey entitled 'Grey areas in publication management'. The survey comprised multiple choice and open-ended questions developed following review of published literature and responses from previous surveys that addressed similar themes.

Results: Authorship criteria and review articles were the highest ranking 'grey areas'. Over 50% of the respondents reported authorship criteria as a 'grey area', particularly around assessing substantial intellectual contribution. In all, 79% reported that review articles are included in their publication plans, but how to identify the need for, and determine authorship of, review articles lacked consensus. Overwhelming support was reported for the development of standard terminology (93% in favor) and 71% felt that this should be driven by Good Publication Practice 3 or similar guidelines.

Conclusions: Our research shows a real need for better defined publication management guidelines. Providing clear guidance on some of the 'grey areas' would be a positive move towards helping publication professionals do the right thing.

How much do healthcare professionals know about GPP authorship criteria?^{§¶}

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Objective: This study sought to assess knowledge of authorship criteria, as defined by Good Publication Practice 2 (GPP2), among healthcare professionals.

Research design and methods: An opt-in, non-incentivized, Internet-based survey of medically qualified, registered users of EPG Online (www.epgonline.org), a disease and medicines knowledge site for healthcare professionals, was conducted.

Results: In total, 295 individuals (30% women; 62% aged 31–50 years) from 54 countries responded. Half (52%) were specialist physicians, while the majority of the remainder were primary care physicians or allied healthcare professionals. Over 75% agreed that designing the study or writing the paper were qualifications for authorship; 65% agreed that data analysis and 39% agreed that final approval of the draft also merited authorship. However, ~52% thought that data collection was sufficient, and 34% thought that general supervision of the research lab qualified for authorship. Although 58% reported being aware of GPP, knowledge of authorship

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[¶]Poster winner, Best Original Research, 2013 European Meeting of ISMPP

criteria was similar regardless of GPP awareness. When asked to rank by importance, designing the study, analyzing data, and collecting data were ranked most highly. Relatively few respondents rated review or approval of the paper, or supervision of the research lab, as important criteria. Among the 202 respondents who had ever authored a paper, 54% reported having co-authored a paper with a 'guest' author who did not merit authorship, while 70% reported working with 'ghost' authors (who merited authorship but were not named).

Conclusions: Understanding of authorship qualifications among healthcare professionals is generally good, but this does not seem to be related to awareness of GPP.

Incomplete conflict of interest (COI) disclosures – analysis of recent publications[§]

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Objective: The purpose of this study was to evaluate recent conflict of interest (COI) disclosures from key thought leaders in a specific therapy area, to determine whether COIs are reported accurately.

Research design and methods: From a manuscript recently published in the *New England Journal of Medicine*, we identified all academic authors, searched PubMed for publications by these authors in the same therapy area over the 12 months prior to publication, and selected all relevant publications with freely available COI statements or full versions. For authors listed on ≥ 3 of these publications, we developed hypothetical complete COI disclosure statements, compiled from all COI disclosures explicitly stated in the selected manuscripts, and organized according to the standard categories in the International Committee of Medical Journal Editors Uniform Disclosure Form for Potential Conflicts of Interest. Published COI statements were compared against hypothetical complete COI statements, and inconsistencies in authors' disclosures were summarized descriptively. For manuscripts without COI statements, authors were considered to have provided no disclosures.

Results: Eleven authors met the eligibility criteria, with 55 individual disclosures obtained from 43 unique manuscripts included in the analysis. Almost all (54/55; 98.2%) disclosures appeared to be inaccurate. Breaking these disclosures down by COI category, 154/171 (90.1%) separate statements were incomplete/inconsistent. 'Consultancies/Honoraria' was the most frequently inaccurate category (49/55; 89.1%).

Conclusions: The apparent high level of incompleteness in disclosing potential COIs is concerning. We recommend that authors develop and maintain a standard COI statement to ensure consistency and transparency in their disclosures.

Systematic reviews have twice the impact of narrative reviews: a bibliometric analysis

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Objective: Systematic reviews are increasing in popularity owing to the transparent, unbiased and reproducible means by which they review published data. By virtue of the rigorous search techniques they employ, systematic reviews can be more time-consuming to produce than other publications. Here we used bibliometrics to evaluate whether the added investment is reflected by a high impact on the literature.

Research design and methods: All systematic reviews, narrative reviews and primary manuscripts across three client accounts published in peer-reviewed journals between 2003 and 2011 were included. Each paper was authored by, received professional medical writing support from, or was coordinated by writers at Oxford PharmaGenesis. An analysis of all citations of each paper was carried out using Google Scholar (April 2012). The time since publication and number of citable years were calculated for each paper. Current impact factors of the publishing journals were captured using Journal Selector.

Results: We analyzed 125 papers (31 systematic reviews, 14 narrative reviews and 80 primary manuscripts). Mean citations per citable year were 11.0 for systematic reviews, 4.1 for narrative reviews and 4.9 for primary manuscripts. Systematic reviews were, in general, published in high-ranking journals; mean impact factor of publishing journal: 5.02 for systematic reviews, 2.10 for narrative reviews, 3.98 for primary manuscripts.

Conclusions: Well conducted systematic reviews are accepted by high-ranking journals, form a legitimate component of a clinically focused publication plan and are valued by the scientific community.

What do healthcare professionals think about professional medical writing support for peer-reviewed publications?[§]

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Objective: The aim of this study was to understand the attitudes of healthcare professionals towards the involvement of professional medical writers in peer-reviewed publications.

Research design and methods: An opt-in, non-incentivized, Internet-based survey of medically qualified, registered users of EPG Online (www.epgonline.org), a disease and medicines knowledge site for healthcare professionals, was conducted.

Results: In total, 295 individuals (30% women; 62% aged 31–50 years) from 54 countries responded. Half (52%) were specialist physicians, while the majority of the remainder were primary care physicians or allied healthcare professionals. Some 66% of respondents reported concern about pharmaceutical employee involvement in manuscript preparation as authors or reviewers, even if disclosed. Furthermore, while 78% of respondents reported being aware that some publications are produced with the help of professional writers, 30% reported that they would trust a peer-reviewed publication less if medical writers were involved and only 14% would trust it more. In fact, 11% reported that their institution had rules in place to restrict collaboration with professional medical writers when developing manuscripts. However, among those with previous publications ($n=204$), 68% said that they would agree to be an author or co-author of a publication developed with the assistance of a professional medical writer.

Conclusions: There are high levels of concern among healthcare professionals about the involvement of the pharmaceutical industry and professional medical writers in the production of peer-reviewed manuscripts. However, most express openness towards such collaborations, suggesting that positive engagement could lead to more positive opinions.

[§]Encored at the 9th Annual Meeting of ISMPP

