11th Annual Meeting of ISMPP
Meeting Summary

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Dear Colleague,

The International Society for Medical Publication Professionals (ISMPP) organizes an annual meeting to engage medical publication professionals and to foster support for ethical publication practices. The meeting provides valuable information for individuals and companies who aim to keep abreast of the latest developments impacting medical publication practices. It is also the ideal setting for networking among individuals at all levels of experience in the industry.

Our team of publication professionals gained valuable insights, earned Certified Medical Publication Professional™ (CMPP™) credits, and networked with colleagues in various settings at the 11th Annual Meeting of ISMPP. This year’s meeting highlighted the need for a patient-centered focus in publication practices. Some interesting topics discussed included:

- Publication planning practices
- Patient-centered outcomes research and patient involvement in clinical trial design and publications
- Social media, technology, and metrics in healthcare and publications
- Emerging healthcare markets
- Sunshine Act and the Open Payments Database
- Health Economics and Outcomes Research
- The Certified Medical Publication Professional™ (CMPP™) credential
- Updated guidelines for Good Publication Practices (GPP3)
- Publication of “negative” clinical trial data
- Rare diseases and orphan drugs

This meeting summary is a compilation of our team’s notes and highlights from the sessions we attended. For the full schedule of events, see the official program brochure. We hope you gain as much from this as we have from the meeting. Please feel free to share this with your colleagues and contact us with any questions you might have.

Sincerely,

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**Monday, April 27, 2015 – Pre-Conference Workshops**

**Introductory Publication Planning: The Best of the Basics for New Publication Planning Professionals (Formerly Publication Planning 101)**

**Faculty**

- **Gregory Bezkorovainy, MA, ISMPP CMPP™**, Vice President, Scientific Services, Adelphi Communications
- **Judy Fallon, PharmD, ISMPP CMPP™**, Vice President, Clinical Content, C4 MedSolutions, LLC, A CHC Group company
- **Brian Jenkins**, Executive Multimedia Editor, Multimedia Publishing, Elsevier
- **Carol Sanes-Miller, MS, ISMPP CMPP™**, Sr. Manager, Medical Communications, Baxter Healthcare

**Learning Objectives**

At the end of this workshop, attendees will:

- Understand the value and goals of effective publication planning
- Identify the major components of a tactical publication plan
- Be familiar with publication planning terminology and good publication practices
- Appreciate the importance and benefits of a collaborative team environment

**Notes**

Gregory Bezkorovainy presented on good publication practices, Judy Fallon provided an overview of publication plan components, Carol Sanes-Miller discussed the publication planning team, and Brian Jenkins reviewed journal selection from the publisher’s perspective.

- Publication planning is not only the dissemination of scientific and clinical data, but it has also become a well-established and important tool by which to educate healthcare professionals
• Current challenges include tension between for-profit journals and the pharma industry, evaluation of data generation vs data expression, and proper assessment of integrity, just to name a few. Other concerns among journal editors regarding industry publications include bias, improper reporting of data, redundant publications, lack of transparency, and inappropriate authorship.

• Solution: Recognize importance of following the Good Publication Practices (GPP) guidelines and our roles and responsibilities as sponsors and authors. Also recognize the importance of following all the steps in publication planning.

• Perspective: The core of a good publication team, publication plan, and publication itself is communication. There are many moving parts in developing a publication, and our role as a communication agency should be to assist in the plan and tactics while adhering to the guidelines and client SOPs.

Advanced Publication Planning: Ethical and Regulatory Challenges and Scientific Communication Plan Development in the Age of Transparency (Formerly Publication Planning 201 and Publication Planning 301)

Faculty
Jorge Moreno-Cantu, MSc, PhD, ISMPP CMPP™, Associate Director, Global Scientific and Medical Publications, Merck Research Laboratories, Merck
Louise Norbury, MSc, ISMPP CMPP™, Senior Director, Scientific Strategy and Innovation, PAREXEL Medical Communications
Wil Glass, PhD, Senior Director, Global Publication Planning, Allergan

Learning Objectives
At the conclusion of this activity, the participant should be able to:
• Identify best ethical practices in achieving publication goals in a highly regulated environment
• Understand the need for continuing education to remain informed about evolving laws and guidelines
• Understand the contemporary challenges that may affect strategic publication planning
• Know the key steps to work with authors and journals according to current GPP
• Share best practices and effective tools for publication planning

Notes
The attendees participated in a group discussion around the following question: What are some key information needs for a publication professional to address with a publication plan? What should be left out?
• Key information needs: budget, timelines for release of clinical data, medical objectives for the year, primary and secondary target audiences (journals and congresses) and how they fit with timelines, gap analyses, competitive...
landscape, needs assessments, and stage of product development, and marketing strategy (data-driven)

- Leave out: key messages/statements, lead authors, share of voice analysis

**Ethics, Guidelines, and Regulations**
The faculty provided a review of ethics, guidelines, and regulations, including a look at the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements, ghost authorship and ghost writing, publication bias, study registration, and response from industry. Industry positions from the Biotechnology Industry Organization (BIO) and the Pharmaceutical Research and Manufacturers of America (PhRMA) on clinical trial data sharing were compared, including their views on publication, patient-level and study-level data, clinical study reports (CSRs)/result summaries, and patient summaries. There was also a discussion around individual company commitments, such as publication within 1 year of “study completion,” publication of all clinical study results, posting of an entire study protocol or CSR, and making available de-identified patient-level data upon request. Participants discussed what their respective companies were committing to and what their policies were. There was some discussion around what “study completion” should be defined as, and most participants agreed to using either the database lock or CSR publication for primary data and author kick-off calls for secondary analyses.

After a brief review of the Sunshine Act, the faculty led a discussion on how different pharmaceutical companies viewed payments for medical writing and what their reporting practices were. Every company had a different interpretation of the rule, which varied from not considering any publication support as a transfer of value (ToV) to considering all publication support as ToVs. Session participants discussed their company interpretations and rationales, which included:

- All considered ToV
- None considered ToV because publication is perceived to be of value to pharmaceutical company
- Depends
  - Based on use of internal writers vs external agency support
  - Based on internal vs external authors

There was a brief discussion of Corporate Integrity Agreements (CIAs), how they can improve publication plans, and whether CIA-type protocols should be used even without a CIA in place. The group agreed that in most cases, after their CIA expired, they tended to keep certain helpful aspects of CIA protocols in place, while removing some of the more laborious tasks.

**Implementing Best Practice: GPP2, Authorship, and Publication Processes**
The next part of this workshop focused on implementing best practices. The faculty reviewed GPP2 guidelines and recommendations, ICMJE authorship and contributorship criteria, acknowledgement for medical writing support, and publication steering committees. There were discussions on authorship issues and publication steering committees in which participants shared common problems and how each company handled them, including:
• The need to apply authorship criteria to all authors consistently
• The need to request detailed feedback from authors who do not provide it or who give approvals without comments
• How to help authors fill out contribution forms
• How to determine the order of authorship to list in the publication
• How to manage control of the paper between internal and external authors
• How to manage the inclusion or exclusion of study investigators
• How to handle requests for honoraria
• How to manage author expectations for target journals

Developing the Strategic Publication Plan

Some final discussion included topics, such as how to measure the reach of your publications and how to forecast competitor publications. Methods of measuring reach included looking at the number of congresses data were presented at, in how many countries data were released, QR code access, citations through Scopus, downloads, and social media activity. The faculty mentioned an interesting method of comparing your authors with the publication leaders in the therapeutic area to determine where your publications stand. They also discussed the use of internal records of journal acceptance rates to compare with the journals’ published acceptance rates, which can be used to inform journal selection. Useful ways to forecast competitor publications include monitoring ClinicalTrials.gov and EudraCT to predict publications and congress activity. This could then be used to inform your publication plan.

Takeaways
• It is important to be aware of the relevant ethical publication practice guidelines (GPP2 and ICMJE)
• Different pharmaceutical companies have different interpretations and practices with regard to clinical trial data sharing, patient-level data sharing, CSR posting, and ToV designation. It is important to be aware of the requirements and determine what level of involvement, beyond those requirements, best fits the company’s goals
• It is important to be aware of guidelines for authorship and contributorship criteria and to develop standard practices for ensuring optimal author engagement
• There are many metrics available for measuring publication impact and guiding your publication plan. It is important to determine which ones best fit your needs and how to use them effectively
Ethics in Publications Practice: Real-World Case Studies in Determining Authorship

Faculty
Mukund Nori, PhD, MBA, ISMPP CMPP™, Senior Medical Writer, Scientific Solutions, Envision Pharma Group
Charlotte Singh, MD, ISMPP CMPP™, Vice President, Group Medical Director, The Lockwood Group

Learning Objectives
At the end of this workshop, attendees will:

- Expand and explore the ICMJE guidelines, which do not address all authorship situations
- Review issues relating to data transparency and the use of metrics in publications
- Probe related ethical considerations and practical options available in these situations
- Discuss potential solutions and what resources are needed to achieve them
- Discuss stakeholder roles in achieving consensus and implementing solutions to ethical challenges

Notes
The workshop began with an overview of the ICMJE criteria for authorship and comments by the moderators regarding data transparency. Attendees were broken up into smaller groups and discussed case studies:

- **Missing Authorship**
  - Nearly completed manuscript was circulated to non-author investigators from a study
  - Non-author investigator objected—wanted to know why he/she was not an author
  - Discussion centered around steps taken at the beginning of the process (who made decisions re: authorship? what criteria were used? sponsor involved?)
  - The consequences of modifying author byline at a late stage were also discussed (eg, perception of “guest authorship”)

- **Author Accountability**
  - Investigator balks at participation as an author on a manuscript due to issues with vendor in past work
  - Does not want to take responsibility for vendor’s work
  - Discussion centered around whether all authors can reasonably take responsibility for work outside of their expertise
  - Most agreed that accountability could be met by agreeing to pursue any inquiries re: discrepancies
• Social Media
  – Investigator is asked to do a podcast on a recent publication on which he or she is an author; other authors are upset upon release of podcast and question sponsor
    ▪ Discussion on responsibility – most agree sponsor may not have any control
    ▪ Consult other authors?
    ▪ Lead author vs other authors
    ▪ Internal vs external authors

• Honoraria
  – Manuscript based on a trial in a developing country. Authors were paid for services but demand honoraria for being authors. Honoraria have been standard in the past
    ▪ Difficult issue. In some countries, author honoraria are part of investigator’s salary or are part of criteria for advancement
    ▪ Better to negotiate in advance; may need to adjust research fees

Monday, April 27, 2015 – General Sessions
Keynote: Ide Mills

Speakers
Ide Mills, CSW, Principal, Strategic Healthcare Communications
Introduction: Ira Mills, PhD, Senior Scientific Specialist, PAREXEL
Moderator: Juli Clark, PharmD, Co-Chair, ISMPP Annual Program Committee; Executive Director, Global Medical Writing, Scientific Affairs, Amgen, Inc.

Notes
Ide Mills discussed:
• The patient experience in clinical trials
• The importance of patient feedback in design and conduct of clinical trials
• The challenge of patient health literacy, how it must be accounted for in disease education and clinical trial information, and how healthcare providers (HCPs) need to learn to speak to patients at their level
• The challenge of getting patients engaged and active in the publication process
• The challenges patients face in the clinical trial arena
• How publication professionals can impact patient education and address unmet needs
Optimizing Patient-Centered Outcomes Research

Speaker
Jean R. Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer, Patient-Centered Outcomes Research Institute (PCORI)

Learning Objectives
By the end of the session, attendees will:

• Understand the methods by which comparative effectiveness research can take on a more patient-centered approach
• Recognize the ways in which patients and all stakeholders can have a more active role in the design, conduct, and reporting of studies
• Discuss methods of rapidly communicating study results to stakeholders while protecting the privacy of patients and the autonomy of researchers

Notes
Jean Slutsky discussed the Patient-Centered Outcomes Research Institute (PCORI) and their work in involving patients in all stages of meaningful health outcomes research. PCORI is an organization which supports the idea of patients having a more active role in the development and reporting of clinical studies. Their goal is to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make informed health decisions. They also aim to execute comparative clinical effectiveness research (CER) as well as support work that will improve the methods used to conduct such studies.

The current issue is that it is not being done everywhere, which could be because organizations do not know how. We need methods by which patients can be involved early on from idea generation all the way down to the peer review process, which would involve both scientists and patients. Increasing awareness about the need and importance of doing this will open organizations’ eyes to this approach. There are already methods in place for supporting a more patient-centered role; this is the time to start implementing them in places that do not currently use them.

PCORI is fielding studies on patient-centered outcomes, but initial data are not expected until 2016. Currently there are over 400 approved studies and over $850 million of funding committed. Publication of those data will be of great interest and should be utilized to better inform healthcare decisions and improve healthcare delivery and outcomes. The ultimate question is does the research outcome reflect what the patient wants?
The Patient Voice: How is Industry Leveraging the Patient Perspective to Inform Development Plans and Optimize Treatment Decisions?

Panel
Patricia Cornet, MA, Associate Director Advocacy, Diversity & Patient Engagement, Global Development Operations, R&D, Bristol-Myers Squibb
Ide Mills, CSW, Principal, Strategic Healthcare Communications
Mary Uhlenhopp, RN, MS, MPH, Advocacy & Ally Development Lead, Amgen (Europe) GmbH
Moderator: Diane Moniz Reed, PharmD, ISMPP CMPP™, Head, Oncology Medical Publications, Bristol-Myers Squibb

Learning Objectives
By the end of the session, attendees will:

• Understand the increasing role of the patient in treatment decision-making
• Describe how pharma/biopharma companies are working to integrate patient insights into clinical development and data dissemination plans
• Provide examples of how publication professionals can integrate patient perspectives into scientific communications

Notes
The panel discussed their experiences in working with patient advocacy groups and the key step involved. Currently, patients are not involved in dissemination of information. We need to make the patient less of a consumer and more of an advisor. Patients are not just subjects, but also our partners. It has been shown that if patients are engaged from the beginning, it will ultimately lead to better outcomes. We tend to lose sight of the patient voice. It will take industry some time to recognize this and make the shift because it is not usual practice. The biggest challenge is how we start.

We need clinical trial summaries to be understandable for patients. We should make use of Patient Advisory Forums, which identify barriers to patient participation and let them have input on endpoints for trials. The patient’s voice has been missing from the development and life cycle management of therapeutic agents, but that is changing.

Patients are more active in the European Medicines Agency (EMA). In the EU, a patient sits on every panel evaluating approval of a new therapeutic agent. The European Patients’ Academy on Therapeutic Innovation (EUPATI) is a collaborative team from all areas of life with a stake in healthcare and medicine. EUPATI convenes to develop training and information to empower patients to have an active role in medicines research and development. This is a 5-year, patient-led project that serves as an educational toolbox for patients.

In the US, some pharmaceutical companies are looking for areas to integrate the patient voice in the clinical development and life cycle of therapeutic agents.
Relevant activities may include:

- Reviewing or having a voice in protocol development
- Providing feedback on CSRs
- Reviewing or co-authoring manuscripts

We have to recognize the need to establish work practice guidelines early on, learn how to work with patient advocacy organizations, and focus on internal and external awareness of the patient voice.

We need to engage and leverage patients in our clinical trials as more than just participants. They have different perspectives and insights to offer, as they are the ones taking the medications and dealing with their diseases. We should acknowledge that and take the next step to figure out what sort of training is required for a patient to participate in decisions regarding the planning and conduct of clinical trials.

The time for patients has come.

**Monday, April 27, 2015 – Parallel Sessions**

**Patient Lay Summaries: Internal Coordination of Scientific Communications**

**Faculty**

Barbara E. Bierer, MD, Faculty Co-Director, Multi-Regional Clinical Trials (MRCT) Center at Harvard, Harvard University

Joseph P. Kim, MBA, Senior Advisor, Clinical Innovation, Eli Lilly and Company

**Moderator:** Zachary Hallinan, Director, Patient Communication and Engagement Programs, Center for Information and Study on Clinical Research Participation (CISCRP)

**Learning Objectives**

By the end of the session, attendees will:

- Be familiar with the lay patient summary commitment within the overall framework of the Joint Principles for Responsible Clinical Trial Data Sharing
- Gain an appreciation for the role and generation of lay patient summaries in scientific communications
- Understand from an operational standpoint how to best coordinate and maintain consistency in external scientific communications between various stakeholders

**Notes**

Many patients see themselves as guinea pigs, and as many as 77% say they never hear back or receive any feedback/follow up results from trials. Many say that they would not participate in future trials. This makes it clear that we do not thank the patients enough. We must move forward and put patients first. We know patients and researchers WANT to know the outcomes of the trials, as none have opted out of being notified (per Lilly experience). Unfortunately, investigators do not have results in lay language to have a good discussion with patients at follow-up.
What can be done?

- Plan for patient contact early and get funding for this as part of the trial costs
- Stay in contact throughout the process and set expectations as to when final results will be available
- Develop lay summaries and have someone available for questions

Creation of lay summaries:

- These summaries need to be unbiased and non-promotional
- Use lay language and apply health literacy principles (6th grade level, active voice, short sentences, formatting aids)
- The EU has lay person summary guidelines
- Numeracy: less is more (ask yourself which numbers are critical to include); pictorial representations are very helpful
- Be aware of cultural literacy
- Use neutral language

Distribution of summaries:

- Give to site to give to patients via mail, email, etc
- Digital distribution via website option (this removes burden from the site)
- Text option with multimedia capabilities

ICMJE does not consider these summaries or results on clinicaltrials.gov to be prior publication. These summaries are mandatory per new EU Clinical Trials Regulation. Review by IRB/ethics board is country dependent.

PhRMA and the European Federation of Pharmaceutical Industries and Associations (EFPIA) have adopted the Joint Principles for Responsible Clinical Trial Data Sharing, with the following items:

- Patient-level clinical trial data, study-level clinical trial data, full CSRs, and protocols from clinical trials in patients for medicines approved in the US and EU will be shared with qualified scientific and medical researchers upon request and subject to terms necessary to protect patient privacy and confidential commercial information. Researchers who obtain such clinical trial data will be encouraged to publish their findings
- Companies will work with regulators to provide a factual summary of clinical trial results to patients who participate in clinical trials
- The synopses of CSRs submitted to the Food and Drug Administration (FDA), EMA, or national authorities of EU member states will be made publicly available upon the approval of a new medicine or new indication
- The Principles are available on the EFPIA and PhRMA websites.

Implementation of the commitments began on January 1, 2014

Implementation of The Principles and prevention of “prior publication” issues are essential to meeting the new standard, and companies must be diligent in mitigating the risk that lay summaries will be considered prior publication, while providing effective information to patients.
The Multi-Regional Clinical Trials Center (MRCT) was established at Harvard to:

- Improve the design, conduct, and oversight of multi-regional clinical trials, focusing on trials sited in or involving the developing world
- Simplify research through the use of best practices
- Foster respect for research participants as well as efficacy, safety, and fairness in transnational, trans-cultural human subject research

The MRCT is autonomous and their processes are as follows (resource slides available on their website):

- Identify initiatives
  - Projects selected for launch will be those with demonstrated:
    - Impact
    - Significance
    - Expertise within stakeholder base
    - Actionable within a defined time line
  - Form Working Groups
    - Multi-stakeholder teams will be formed through careful selection and include:
      - Global diversity
      - World-class experts
      - Enthusiastic leaders
      - Deliverables and clear timeline
  - Pilot solutions
    - Identified project solutions will be:
      - Piloted within our sponsor organizations
      - Evaluated and the results published
      - If positive, work towards widespread adoption
  - Implement and adopt
    - Project solutions will be implemented through:
      - Training programs conducted by us and through our partner organizations
      - Deploying MRCT members and stakeholders to disseminate guidelines and practices
      - Working with MRCT partner associations to deploy sustainable training
  - Disseminate and communicate
    - The MRCT Center at Harvard team will:
      - Identify end users of the project solution
      - Deploy the dissemination strategy among our stakeholder base
      - Develop a feedback mechanism for providing input into future revisions of the work product
– Revise and improve
  • Project deliverables will be:
    ♦ Modified with real world experience and feedback
    ♦ Updated as global regulations change
    ♦ Amended as feedback is provided by users
    ♦ Refreshed based on changes in current practices

The MRCT@Harvard Toolkit may be a good resource.

The Democratization of Healthcare Information via Social Media

Faculty
Andrea Conners, Director, Media Services US, pharmaphorum media
David Lee Scher, MD, FACC, FHRS, The Heart Group of Lancaster Health; Clinical Associate Professor of Medicine, Penn State University College of Medicine; syndicated blogger, Frontline Medical Communications
Moderator/Faculty: Paul Tunnah, CEO and Founder, pharmaphorum media

Learning Objectives
By the end of this session attendees will:
• Better understand how social media is being used to share medical information among different healthcare stakeholders
• Appreciate the challenges created by medical misinformation and current attempts to rectify this situation
• Understand the current regulatory environment with respect to pharmaceutical companies using social media and correcting misinformation
• Gain insights into the future direction of medical publishing alongside open social media

Notes
Paul Tunnah discussed the widespread use of the internet for medical information and how patients and doctors alike are using it as a resource. More and more HCPs and patients are being born in the social media age and are becoming increasingly comfortable and reliant on it.

He also discussed the available FDA guidances related to the use of social media, including how to use platforms with character space limitations, such as Twitter, and how to correct misinformation about prescription products and medical devices. The panel reiterated sentiments from the earlier sessions about using a patient participatory model and discussed how social media can be used as a critical part of health technology. Patient support groups are recognized by pharma and should not be forgotten. The geriatric population should also not be overlooked since
their caregivers are techno-savvy. The panel described how a single “tweet” from an author can have a wider reach than a publication and how this free, widely available information can provide the public and HCPs with more immediate and more comprehensive updates than are normally possible with monthly journal releases.

The audience asked about the possibility of presenting pre-FDA approval data and whether there would be any regulatory restrictions involved. The panel agreed that the most responsible method of handling that situation is to present the information in the context of the disease state for the purpose of patient education. The study or press release can then be provided as a link for further information.

The panel discussed that every company will have their own levels of comfort and acceptable risks. They will have to evaluate this when considering the use of social media and utilize the right people in order to mitigate risk. They also discussed the possibility of using “digital key opinion leaders (KOLs)” who can send out messages or linking to an area that requires HCP verification to access.

Social media can be used to condense relevant information for KOLs who do not have time to read the literature otherwise. This can help to establish relationships with a focus on benefiting patients. The panel discussed the idea of using smart, “sticky” content that is relevant and precipitates action. You should consider what kind of messages would motivate action and engage your audience to determine what their needs are. An example that was provided was to send a tweet in the morning to remind patients with diabetes to think about what they are having for breakfast to keep them thinking about their disease management. Social media should become a part of the normal channels of communication with HCPs and patients.

**Patient Participatory Model: A New Paradigm for Medical Journals?**

**Faculty**
Daniel Shanahan, MA, MSc, Associate Publisher, BioMed Central
Moderator: Neil Adams, ISMPP CMPP™, Publishing Manager, Nature Publishing Group

**Learning Objectives**
By the end of the session, attendees will:

- Be introduced to innovative methods for co-production within academic publishing, with a focus on the patient peer review process
- Understand the learnings gained thus far from integrating a patient perspective into the peer review process
• Gain insight into ways in which increased patient involvement might impact medical journal processes and decision-making

Notes
Patients are not a blank slate – they have a role in research appraisal and dissemination. The current issue is that there needs to be patient inclusion, with distinction between patient vs academic review AND between clinical vs statistical value in specific settings.

Daniel Shanahan talked about the BMJ and its “Partnership with Patients” initiative, which has been ongoing since June 2014. The internal changes that BMJ has introduced are aimed at making patient partnership integral to the way the journal works and thinks, as well as something we advocate for in healthcare. Steps taken include:

• Asking authors of educational articles to co-produce their papers with patients and state the nature of their involvement
• Requesting authors of research papers to state whether and how they involved patients in setting the research question, the outcome measures, the design and implementation of the study, and the dissemination of its results
• Embedding patient review of papers in their standard peer review processes
• Appointing patients and patient advocates to their editorial board

Patient reviews are posted on the website. Patients are looking for what is relevant to them, and authors are being asked to consider the value to the patient.

Mr. Shanahan also spoke about a new journal created by BioMed Central, Research Involvement and Education. It is an interdisciplinary health and social care journal focusing on patients and wider involvement and engagement in research at all stages. The journal is co-produced by all key stakeholders, including patients, academics, policy makers, and service users. There are patient reviewers and patient editorial board members. Every article is reviewed by at least one academic referee and one patient/public referee. The co-editors (academic and patient) are given equal weight. The patient reviewers comment on the quality of the research and how it was conducted and reported. They determine whether the rationale for what the authors did has been clearly demonstrated and whether the interpretation makes sense.

Takeaways
In the era of the internet, results are not just for researchers. Patients have a huge amount to offer, and this is just starting. The thought of clinically meaningful versus statistically significant is an important one, and there will be a growing trend towards greater patient involvement with research and publications in some way. While we are quite a distance away, just as we recommend publication steering committees early in the process, we should recommend patient/public involvement as well.
Monday, April 27, 2015 – Roundtable Sessions
Emerging Markets: Challenges and Opportunities

Moderators
Juliana Newman, ELS, ISMPP CMPP™, Director, Global Publication Operations and Strategy, AstraZeneca
Kanaka Sridharan, MS, RPh, ISMPP CMPP™, Global Head Scientific Communications, Cell & Gene Therapies Unit, Novartis Pharmaceuticals Corporation

Notes
When a drug patent is ending in the US, there are many opportunities and challenges in emerging global markets. Some of the challenges include having enough resources, time, and money to expand into an emerging market. Depending on the location, there could be a language barrier and relevant publications would have to be appropriately translated for local journals. Identifying which journals these are and their specific requirements represent another issue.

Another challenge is going from a local to global market. To overcome some of these challenges, we need to first ask what are the key questions that need to be addressed for that drug in that particular region. Based on the feedback we receive, our next step would be to see whether our literature answers those questions. From there we can think about putting together small scale trials or data mining, if needed. In terms of going to a global market, we need to first look at needs and operations at a local level. It is much easier to transition from local to global, rather than pushing the values of global down to local, because that will never work.

Industry-Agency Relationship – Working as a True Team

Notes
There were approximately 8 attendees at this roundtable, all agency/client service-based, with approximately 2-5 years of experience in their respective capacities (Cello Communications, Cactus Communications)

Review of the case selected for discussion revealed that nearly all had a sound familiarity with ICMJE authorship eligibility criteria and most could relate to the challenges posed within this fictitious scenario.

Challenges exist with agency/client relationships as to the divide between responsibilities. Some clients, mostly “smaller pharma in particular,” have a complete “hands off” approach to publication development, imparting the majority of (if not all) primary responsibility to agency partners for fulfillment. Agency partners/medical writers that have clear ICMJE eligible author contributions should not be censored or deemed ineligible for authorship. Clear disclosure of the specific financial relationship with their respective employer needs to be acknowledged in a clear/transparent manner. Accountability for all aspects of publication planning and development ultimately lies with both the client and agencies (not unilaterally).
Social Media and Medical Publications

Moderator
Sarah L. Feeny, BMedSc, Head of Scientific Direction, Complete Medical Communications

Notes
Sarah Feeny led the discussion by providing an overview of how social media is currently used by the pharmaceutical industry and medical journals. The channels that are most relevant to publication planning are Twitter and non-industry forums and blogs, both of which are multi-media platforms. Social media can be used to inform your publication planning and internal strategy by providing alternative metrics. Some of the challenges in using social media in this manner involve:

- Finding partners with the knowledge to undertake monitoring that has value
- Identifying the best sources of information, especially from forums and blogs
- Being able to demonstrate a return on investment
- Understanding the value of “altmetrics”

Using social media to inform externally involves more risk in terms of regulatory and legal restrictions. Some methods of dealing with these issues were discussed, including:

- Having an independent publication steering committee oversee outreach to avoid risk. It is important to not have the sponsor driving the message
- Becoming familiar with FDA guidances on the use of social media and correcting misinformation
- Ensure than communication is data-focused and used for educational purposes
- Looking into using digitally active authors who can help disseminate information

Monday, April 27, 2015 – Poster Presentation Assembly
For a complete listing of posters presented at the ISMPP 11th Annual Meeting, please refer to the program brochure.
Tuesday, April 28, 2015 – Parallel Sessions: Part 1

Collaborative Technology Real-World Case Studies

Faculty
Robert Creutz, Executive Account Manager, iThenticate Division
Michael Platt, MS, ISMPP CMPP™, President, MedVal Scientific Information Services, LLC
Nicole Rapior, PhD, Head of Global Scientific Communications, Boehringer Ingelheim Pharma GmbH & CoKG
Russell Traynor, PhD, MSc, ISMPP CMPP™, Business Lead, Envision Technology Solutions
Moderator: Donna Simcoe, MS, MS, MBA, ISMPP CMPP™, Principal, Medical Publications Consultant, Simcoe Consultants

Learning Objectives
By the end of this session attendees will:

- Understand the functionality of collaborative platforms
- Identify the potential advantages/disadvantages of using collaborative platforms
- Be knowledgeable about available collaborative platforms that conform to their budgetary allowance
Notes:
Plagiarism is a larger issue than is perceived, and plagiarism detection is important to all stakeholders involved in the development of publications. There are various options for detection platforms:

- iThenticate (CrossCheck), Google, Copyscape, eTBlad, MOSS
  - Keyword search vs pattern recognition
  - Integration with other technologies (API)
  - Content, content, content
  - iThenticate

- Key learning detection software that can check any writer. The purpose is to protect medical communication agencies, writers, and clients

- We use the system for internal or contract writers. New or questionable writers will also be checked

- If the internal score is 20% or greater, then we need to take a look into it. The process of detecting plagiarism in translation is still in the beta test stage.

- DataVision (DV)
  - Planning, plan execution
  - Many steps in working with authors
  - Challenges: Overall processes are too time consuming and complex
  - Takeaways: More complex = more conflicting requirements, tailored solutions are allowed for by DV, and authors can be managed.

- Reviewed 3 cases:
  - Self-plagiarism
  - Asia-PAC issue with direct plagiarism. Author noted it was a compliment to the original authors
  - Contract writer committing plagiarism and then admitting (he/she) ran out of time

Plagiarism detection software is widely used to support editorial review throughout the medical research community. Options are available to accommodate the various needs and budget considerations of the pharmaceutical industry, agencies, and the individual authors/editors.

- Who should include plagiarism detection software in their SOPs?
  - All stakeholders involved in publications. The offerings are scalable to the organization

- When should organizations use the detection software?
  - New writers/contract writers
  - Authors developing initial or revised drafts
  - Any time a team member is concerned
Advancing Good Publication Practices in the Asia-Pacific Region: Focus on India

Faculty
Elvira D’souza, ISMPP CMPP™, Sr. Vice President, Medical Writing Operations, Cactus Communications Pvt Ltd., Mumbai, India
Madhavi Patil, PhD, Senior Manager, Publications & Medical Communications, SIRO Clinpharm Pvt. Ltd., India
Moderator/Faculty: Renu Juneja, PhD, Head of Medical Communications, Medimmune

Learning Objectives
At the end of the session attendees will:
- Understand the importance of increasing awareness of ISMPP in India
- Participate in exploring challenges around publication guidelines in India

Notes
There was discussion about using Indian doctors and journals as well as using offshore medical writing. There are some companies, such as Novartis, that are using medical writers from India. There is clear evidence of growth in pubs output in India, but they need to sharpen the overall acumen of publication professionals. While education is in English, proper use of grammar is an issue. Indian physicians do not have time to publish, either as they are far too busy seeing patients (0.6 MDs to 1000 patients in India vs 2.4/1000 in US and 1.8/1000 in China). If we want to try to cut our costs by having our writing done offshore, then Ireland and Singapore are the places to go.

Sunshine Act: Examination of the Open Payments Database

Faculty
Laura C. Conway, JD, Director, Regulatory and Compliance Services, Porzio Life Sciences

Learning Objectives
By the end of this session attendees will:
- Gain insights into what covered recipients have been questioning and how disputes are being handled
- Have an appreciation for the real-life experience of the CMS Open Payments database system, including issues and challenges
Notes
Guidelines for reporting publications’ ToVs are very unclear since we do not actually write checks to authors. Most of the time, publication support provided to authors are of indirect value to them. The problem arises when trying to figure out how to assign value and how to communicate that to others. Many companies report seeing fewer physicians willing to publish or willing to accept publication support, mostly because they are confused about the requirements and/or process.

Only 7% of physicians registered to see their Open Payments data, and registration is not easy. In addition, with only a small number of physicians, there were still 12,000 disputed records. Some companies have internal assumption documents on how to interpret ToVs for publication support, but did not submit assumptions to CMS, especially since there is a 4,000-character limit. This and other factors have led to a lack of consistency in reporting from company to company.

Possible solutions to avoid confusion involve:

- Including the TOV process in author agreements
- The option to report as either research or non-research ToVs
- Companies reporting as different entities
- Differentiating internal support from client vs external support

The reporting system needs work. The timeline for this is:

- June 30 will be the date for displaying the 2014 data
- 2013 focus was to address non-reporters
- 2014 will focus on accuracy

There have not been any penalties established; however, they may be put in place later on, for accidental or purposeful non-reporting. The ultimate questions are: is it really useful? is it worth the time and effort to collect the data? who is using the data?

Faculty
Michael J. Sax, PharmD, President, The Pharmacy Group LLC
Moderator: Sharon Suntag, MS, ISMPP CMPP™, Medical Director, Quintiles

Learning Objectives
By the end of this session attendees will:

• Be able to describe the types of information considered when making formulary and/or health system-based decisions
• Understand how decisions are made when there is a lack of optimal data
• Know ways to make publications and other forms of evidence most useful for decision-makers

Notes
Both providers and consumers need information that is easy to obtain and understand but is also reliable. There are several drivers of change in the role of P&T Committees: cost (reimbursement), quality, access, and accreditation. Certain questions that should be addressed include:

• Can it work? (consider for randomized controlled trials)
• Does it work? (consider for comparative effectiveness research, clinical guidelines, and evidence based medicine)
• Is it worth it? (consider for HEOR)

The decision-making process must take the total healthcare cost, not just drug cost, into account. Evidence based medicine (EBM) helps to quantify and manage uncertainty and links clinical practice with policy decisions. EBM is often incorporated into medication management and is involved in looking at coverage, disease management, provider profiling, pay for performance, and consumer-directed care programs.

Takeaways
Peer-reviewed publications are critical, and all evidence must be reviewed. P&T Committees want pharmacoeconomic (PE) outcomes and real world evidence. Comparison of value is important, and expert opinions matter.
Health Economics and Outcomes Research (HEOR): Roadmap of Top 10 Principles to Follow When Developing HEOR Publications

Faculty
Moderator/Faculty: Hester van Lier, PhD, ISMPP CMPP™, Program Director, Excerpta Medica
Stella Wang, BSPharm, MS, MPH, Manager, Evidence Based Medicine Communications, U.S. Medical Affairs, Sanofi
Rina Mehta, MBA, PharmD, Senior Manager, I&I Publication Solutions, Celgene

Learning Objectives
By the end of this session attendees will:

• Understand the different phases of HEOR
• Understand the implications of HEOR with respect to publication planning
• Gain ideas for how to continue to build credibility for these types of publications

Notes
The panel provided a roadmap of the top 10 principles to follow when developing a HEOR publication:

1. HE ≠ OR
2. The goal
3. Publication turns data into evidence
4. \( G_{\text{clinical PP}} = G_{\text{HEOR PP}} \)
5. Follow the guidelines
6. Understand the authors
7. Know the audience
8. Talk the talk
9. Getting published
10. HEOR/clinical integration

• Principle 1: Health Economics is a lot of extrapolation and cost models, whereas Outcomes Research is real world data
• Principle 2: What is the goal? Build HEOR data early; know the audience, and how and when to get the data to them; the bulk of the work is post-launch and about real life stories
  – Communicate the evidence and value that pharma wants to convey
  – Most HEOR work is done post launch
  – If you do not communicate it, others will do it for you and you may not like the message
• Principle 5: If you follow the guidelines, you will have quality, and quality builds credibility. Some guidelines include:
  – ISPOR: guidelines on conducting studies
  – Ethical reporting: GPP, ICMJE
  – HEOR: CHEERS, GRACE, STROBE
• Principles 6,7,8: you want authors who are peers of your audience, who can account for regional differences
• Principle 9
  – What will the impact be?
  – Payor vs clinical journals: required language may be different
  – Is the topic right for the audience?
• Principle 10: HEOR/clinical activities should be complementary and seamlessly integrated
  – They both should support and elevate brand objectives
  – Publications should be in alignment with the value story and the clinical story
  – Having a full body of evidence will maximize your impact

Takeaways
The ultimate goal is behavior change. Build your story with the end goal in mind and back into it: define your goal early. Always align HEOR and clinical stories.

Making the Most of Your ISMPP Certified Medical Publication Professional™ (CMPP™) Credential

Faculty
John Gonzalez, PhD, ISMPP CMPP™, Publications Director, AstraZeneca
Steven Palmisano, ISMPP CMPP™, Vice President, Managing Director, MedThink SciCom; Chair, ISMPP Certification Board (2014 – 2015)
Michael Platt, MS, ISMPP CMPP™, President, MedVal Scientific Information Services, LLC
Suzann Schiller, ISMPP CMPP™, Executive Vice President, Strategic Collaborations, Cello Health Communications | MedErgy and SciFluent
Moderator: Laine Capaccio, ISMPP CMPP™, Director of Credentialing, International Society for Medical Publication Professionals (ISMPP)
Learning Objectives
At the end of the session the attendees will:

- Understand the rationale for the ISMPP CMPP™ credential
- Gain insights into how some companies are utilizing the CMPP™ credential to educate their internal staff
- Be knowledgeable about recent developments and resources within the CMPP™ credential program

Notes
CMPP is a formal, voluntary, professional certification program that aims to promote adherence to the high standards of integrity and transparency required in the field of medical publication. This is especially crucial today, amidst increasing scrutiny into publication practices.

The ISMPP CMPP™ credential certifies:

- Expertise as a medical publication professional
- Proficiency in good publication practices
- Commitment to ethical and transparent data dissemination standards
- Leadership in upholding and fostering integrity and excellence in medical publication

The CMPP™ exam is made up of 4 domains, and the credential requires renewal every 5 years through continuing education credits. ISMPP provides updated CMPP™ exam resources; however, they are no substitute for practical experience.

The CMPP™ board uses various psychometrics to ensure the validity and reliability of the exam. The exam undergoes continuous cycles of reviews and updates to evaluate fairness and scoring of exam questions. ISMPP is currently seeking accreditation for the CMPP™ credential.

The impact of pursuing, obtaining, and maintaining the CMPP™ certification is:

- Increasing
- Adding personal value
- Adding organizational value
- Playing a role in securing new positions
- Leading to increased requests or requirements for certification in RFPs

The pursuit of a nationally/internationally recognized oversight accreditation body will further enhance the value. If you are a leader in your organization, your voice and support for the credential matters.
Quotes on the value of CMPP™:

- “Being one of the few CMPPs™ in Japan, I was given a leadership role, not only within my organization, but in professional societies, too. It is serving me to further my career.”
- “All things being equal (rare) among two candidates, I would opt for the one with the CMPP™.”
- “Having received the CMPP™ credential, I feel a little more confident in terms of doing my job as a medical writer and providing authors with advice in dealing with certain situations.”
- “I’m more inclined to believe a person with CMPP™ certification clearly understands the general expectations of one working in the field.”
- “The CMPP™ distinguishes candidates who have experience in this field and are committed to growing in the field.”

How can you make the most of your CMPP™ credential?

- Include the CMPP™ credential in your e-mail signature and on your business card
- Highlight in RFI/RFP responses that you and/or your colleagues are credentialed
- Become an official CMPP™ mentor to help others earn theirs
- Recognize that you are now eligible for other ISMPP Committees and ISMPP jobs
- Market yourself as a CMPP™ certificant
- Wear your CMPP™ pin proudly
- Tell your friends and colleagues!

Research Technology Real World Case Studies

Faculty

George Kowal, Senior Director, Global Publishing & Association Sales, Scientific & Scholarly Research, IP & Science, Thomson Reuters

Ira Mills, PhD, Senior Scientific Specialist, PAREXEL

Moderator: Donna Simcoe, MS, MS, MBA, ISMPP CMPP™, Principal, Medical Publications Consultant, Simcoe Consultants

Learning Objectives

By the end of this session attendees will:

- Understand real-time collaborative referencing programs and the potential advantages/disadvantages of using such platforms
• Be knowledgeable about different sites, applications, and associated services that provide referencing publication information
• Identify referencing tools to more efficiently stay abreast of the ever expanding literature in one’s field of interest

Notes
Reference Manager and EndNote are two widely used platforms:
• Reference Manager (communication management agency)
  – Finite lifespan. Thomson Reuters will not be supporting it anymore, so conversion to EndNote or another program will be required
• EndNote (academic experience)
  – Organized and collected references
  – Easily move references
  – Building a personalized library (create groups, smart groups that will auto-populate based on rules)
  – Automate the process (can add full text and missing data)
  – There are many files to attach (organize document with references – PDFs, Word documents, podcasts)
  – “Cite while you write”: Simplify bibliographies and report citations.
  – Reason to do this if you already have a forum: connectivity to other platforms, such as LinkedIn
  – It is not just about the tool, but what the tool can do to engage with other researchers
  – EndNote online:
    ▪ Can attach the EndNote library to an online account and perform direct export
    ▪ One click to find full text that can link and be annotated
    ▪ Manuscript matcher: suggests journals where you should be submitting, based on keywords and abstracts. Pulls from web of science collection of 12,000 journals in database and shows you up to 10 matches that you may want to consider
  – Drawback: maximum of 15 users for collaborative sharing

Takeaways
Technology is key and changing. Referencing platforms provide ways of organizing references with features beyond basic reference documents. These also allows us to build a personalized library. With this we can have an enhanced community experience.
Copyright Infringement: A Case Study

Presenter
Manon Boisclair, MSc (RN), ISMPP CMPP™, Director, Global Publication Operations, Celgene

Notes
Manon Boisclair presented a case in which data (word for word) and 2 figures from a recent American Society of Hematology (ASH) plenary presentation were published in a “meeting highlights” article and cited on PubMed. This was discovered by the original presenting author while perusing through PubMed. None of the original authors were involved in the “highlights” manuscript. At the time, the authors had submitted the full manuscript of their research to NEJM and were in discussions regarding revisions for their manuscript.

Publication of these data in a “meeting highlights” article would constitute prior publication and violate the requirements of the NEJM submission. Celgene contacted the journal that published the “highlights” article and PubMed to remove/retract the article. The journal retracted the article in about 2 days, whereas PubMed took a couple of weeks to remove the citation.

All congress abstracts and presentations are copyright protected.
Optimizing Scientific Poster Production

Presenter
Joelle McCaslin, MA, ISMPP CMPP™, Associate Director, Medical Publications, Biogen

Notes
Ms. McCaslin discussed how, during the course of their work, she and her colleagues found that posters were often overcrowded, hard to read, and inconsistent due to the use of different publication managers and medical communication companies. They looked at parameters of posters in the past and determined the amount of space taken up by words compared to space taken up by graphics. They then determined what the ideal parameters would be and developed style guides and templates to be given to all vendors. Each section was limited to a certain word count and each poster had 4 figures/tables. Increasing word count in one section meant decreasing word count in another. All parties involved in poster development had to follow these requirements. Posters developed using these new guidelines were easier to read and follow, and much better conveyed a study’s key characteristics and findings.

Monitoring Adherence to Good Publication Practices (GPP): Insights from a Global Biopharmaceutical Company

Presenter
Sonia A. Schweers, PharmD, ISMPP CMPP™, Global Publication Practices Monitor, Medical Publications, Bristol-Myers Squibb

Notes
When you develop a plan, it is important to ask “what are we monitoring?” You should look at the relevant SOPs and identify the gaps. In ex-US markets, there needs to be disclosure on publication support, research support, name of the writer, and affiliation.

After a review of their publications, it was found that none of the four areas of disclosure were complied with. In fact, 100% of publications failed author acknowledgement. Three root causes from this experience were:

- Inadequate understanding of requirements
- Difference in external author expectations/documentation tools were not used.
- Ineffective oversight

Steps to resolve this issue include:

- Training specifically to the gap
- Making sure there is increased documentation and monitoring
- Looking at SOPs and simplifying them when possible
- Asking what is required when documenting
- Making sure the documentation tool mirrors the SOP requirements
- Simplify the reporting process so it is easy to monitor
• Partner to improve the process

It was found that implementing a global publication monitor program led to improved adherence to GPP. The program raised awareness of requirements for compliant publication development and the importance of staying compliant to mitigate risk.

Tuesday, April 28, 2015 – Roundtable Sessions
Publication Steering Committees – The Basics

Notes
A publication steering committee is made up of the sponsor and external parties, such as the investigator, PI, and/or those who contributed to the study design. The objective of this committee is to enhance the transparency and collaboration of the components of publication planning.

Some of the issues to deal with are:
• Agreeing on a timeline for the publications
• Deciding authorship criteria
• Determining what unmet needs still need to be addressed

Another question is how do we move from the publication to the publication steering committee? Some individuals have successfully used charters/agreements/collaborations with clients to start the steering committee. Some are going back to revamp charters because there are problems with expectations, especially in alliance with ICMJE criteria. Members can even decide to have the charter agreement for only a year. This can serve as a limitation on safety – is the situation really out of hand? At the end of the day, all the authors have a final say in the charter; therefore, establishing the author during enrollment or as early as possible is essential. Using an engagement tool is best to avoid getting narrow-sighted.

Publication steering committees are a collaborative approach.

Unique Considerations for Medical and Laboratory Devices Publications

Notes
There are a lot of differences separating medical devices from pharmaceuticals:
• Product life cycle: 15 years for pharma vs 15 months for devices
• Very technical information: it can be difficult for physicians to convey data to a writer. You usually need technical, hands-on expertise
• Very limited clinical data: usually have studies of 20-30 patients
• Need for human factor data
• Preclinical data is very important for follow-on products
• Regulation
  – Class 1: no real testing required
  – Class 2: some clinical testing needed
– Class 3: lots of clinical testing needed, but may be able to remove some redundant studies by using comparisons to previous devices

- Often start marketing before publications
- Updates to device design can be made while old data are still coming out of studies
  – Often have clinical trials with both old and new versions
- Publications: need to target the device audience, multiple audiences can be targeted at conferences

**Tuesday, April 28, 2015 – General Sessions**

**Keynote: Iain Hrynaszkiewicz**

**Speaker**

*Iain Hrynaszkiewicz, MA*, Head of Data and Humanities & Social Sciences Publishing, Nature Publishing Group & Palgrave Macmillan

**Notes**

There is a need for open data. Clinical data disclosure can facilitate study reproducibility and transparency. However, this can be difficult with publication and reporting biases. The following are currently driving data transparency:

- Funding policy
- Regulatory agencies (EMA)
- Legislation (FDAAA)
- Non-government/academic organizations (IOM/Yale University Open Data Access [YODA])
- Industry (CSDR)
- Journals and ICMJE

Specialized repositories are a challenge for editors and publishers. There should be a better way to publish data on request. An example would be if primary journals were required to have a more robust system to make data available.

Possible methods of sharing clinical data can involve publishing de-identified study reports online or in a journal supplement. It is important for these resources to be accessible and for them to allow data mining for research purposes.

There are mechanisms in place to allow for data sharing. The YODA project allows for researchers to request from participating organizations clinical study data that are not publicly shared.
Data Sharing Partnerships: Impact on Future Research and Publishing

Faculty
Karla Childers, MS, Director, Strategic Projects, Johnson & Johnson, Office of the Chief Medical Officer

Learning Objectives
By the end of the session, attendees will:

- Be knowledgeable about YODA and other industry and academic data-sharing partnerships
- Understand how these data-sharing partnerships will impact future research and publications

Notes
Data sharing can maximize the benefit of conducting clinical trials. The current landscape shows that there is an increase in the number of publications.

J&J partners with the YODA project, which makes clinical research available to the public and allows for data sharing for different types of medical products (prescription products, devices, and consumer products), old and new alike. The project has been successful so far, and none of the data requests have been rejected yet. In general, requests have been for secondary novel analyses.

In addition, BMS engages with Duke to serve as an independent review panel (similar to YODA).

Possible issues for the future include:

- How do we move to a system that is easier to use?
- How can we search YODA for data that may support gap analysis, competitive surveillance, and supplemental data for clients and papers?
“Negative” or Non Confirmatory Data Publications: Practical Approaches to Getting Published

Faculty
Maria Alu, Cardiology Publications Manager, Columbia University Medical Center
Daniel Shanahan, MA, MSc, Associate Publisher, BioMed Central
Moderator: Kanaka Sridharan, MS, RPh, ISMPP CMPP™, Global Head Scientific Communications, Cell & Gene Therapies Unit, Novartis Pharmaceuticals Corporation

Learning Objectives
By the end of the session, attendees will:

• Understand the importance of publishing negative data in the face of increased transparency
• Learn how to best approach writing a publication with negative data
• Gain insights into journal selection and managing author challenges while developing the publication

Notes
Neurology calls for negative data through an OPEN initiative.

Research has shown that “negative” data take up 10% to 40% of the literature, when statistics and probability tell us it should be closer to 90%. In addition, about 1/3 of the available “positive” data could be false positives. Unfortunately, we are obsessed with “positive” results and the literature is skewed towards positive data.

This is due to publication bias and selective reporting. The solution is to move away from thinking of data as “positive” and “negative.” We need to have better acceptance and understanding of the value of “negative” data in journals and in general.

A survey of journal editors revealed that they view “negative” data as being important, but they do not receive many submissions with “negative” results. To them, design and conduct of the study are the most important factors, rather than the results. Scientific values should not just be the outcome. The hypothesis, not the results, should drive the study.
Building a Publishing Partnership

Faculty

John G. Ryan, DrPH, Associate Professor of Family Medicine, Director, Division of Primary Care/Health Services Research and Development, Director, United Health Foundation Center of Excellence at Jefferson Reaves, Sr., Health Center, University of Miami Miller School of Medicine, Miami, FL; and Editor, Endocrinology, Diabetes, and Other Endocrine Disorders, Clinical Therapeutics

Richard I. Shader, MD, Editor-in-Chief, Clinical Therapeutics; Editor-in-Chief, Journal of Clinical Psychopharmacology; Professor Emeritus, Department of Integrative Physiology and Pathobiology (DIPP) and Department of Psychiatry, Tufts University School of Medicine, Boston, MA

Moderator/Faculty: Terry Materese, Executive Publisher, Health and Medical Sciences, Elsevier

Learning Objectives

By the end of the session, attendees will:

- Learn how manuscripts should be constructed and assembled for submission, to maximize the chances for acceptance
- Recognize the associated or supplemental materials that should be considered as part of a submission process to enhance both the manuscript and the authors’ reputations
- Be knowledgeable about the kind of communication and schedule authors should expect and demand
- Understand the post-publication relationship one should develop to maximize the scientific value and reach for each publication

Notes

Richard Shader spoke about important questions to keep in mind when building a partnership:

- Who are our readers?
- Do I have adequate peer reviewers?
- How timely is the topic?
- Does the paper answer the question?
- Are the statistics appropriate to the question?
- How readable is the manuscript?
• Does it test the hypothesis, is it something new, or is it a replicate of others?
• Is it original, novel, important, relevant?
• Does it describe the state of affairs?
• Does it deal with special populations?

Terry Materese spoke about global publications and how the US is the current leader (21%), but China (10%) is predicted to overtake the US in 2020. Open access publications (13%) are also increasing, along with digital and social media and mobile device use. We need to add more material online, outside of print media, to keep up (audio slides, Twitter campaigns, etc).

John Ryan took an interesting stance on the journal-author relationship: “What can the journal do for your author?”

Dr. Ryan also discussed social media and how much we underestimate it. Tweeting at meetings can influence page views of an article.
Medical Publishing Insights and Practices Initiative (MPIP)

Faculty
Susan Glasser, PhD, Senior Director, Scientific & Medical Publications, Reg MW Company, Janssen Research & Development, LLC

Learning Objectives
By the end of the session, attendees will:

- Be knowledgeable about MPIP’s current initiative on improved adverse event communication
- Understand key areas for improvement based on journal editor feedback
- Become familiar with the research methodology and data dissemination plans for broader outreach

Notes
Susan Glasser discussed how useful medical insights can be gathered from surveys and findings from advisory boards and roundtables.

She noted how, in general, adverse events (AEs) are underreported and need to be properly displayed.

She also discussed how if there is no room in the publication for adequate AE reporting, journal supplements can be useful for providing additional details. Manuscripts should contain information on common, relevant, and severe AEs. Summaries should avoid general language and should align with the main text of the publication.

The Sunshine Act, Medical Publications, and Authors: Results of the ISMPP Survey

Faculty
Robert J. Matheis, PhD, ISMPP CMPP™ (Chair, ISMPP Sunshine Act Task Force); Executive Director, Global Scientific Communications, Celgene Corporation; President, ISMPP (2011-2012)
Moderator/Faculty: Kim Pepitone, BA, ISMPP CMPP™ (Vice Chair, ISMPP Sunshine Act Task Force); Scientific Director, Cactus Communications
Renu Juneja, PhD, Head, Medical Communications, Medimmune
Angela Cairns, BSc, ISMPP CMPP™, Senior Vice President, Global Compliance Team Leader, Ashfield Healthcare Communications
Learning Objectives
By the end of the session, attendees will:

- Differentiate the varied approaches taken by industry for reporting publication support ToV
- Be informed about the reaction of authors regarding the reporting of a ToV for medical publication support
- Identify strategies for engaging in Sunshine Act-related discussions with authors

Notes
An audience poll showed that while most are reporting publications as ToV, most do not want to. Companies are currently evenly divided on the issue. There are additional time, budget, and resource expenditures related to reporting and tracking TOVs that are due to the ACA. One issue that has been noticed is how the legal department will set the rules on reporting, while the medical team is left to discuss it with authors. There is confusion among authors who work with various companies, as some report publications as ToV and other do not. Some authors have refused to be authors over ToV policies, and 33% of the audience confirmed loss of authors. Physicians may have more concerns over ToV with regard to institution caps.

Tuesday, April 28, 2015 – Annual Evening Networking Reception
Wednesday, April 29, 2015 – Parallel Sessions

Innovation in Metrics: Capturing the Full Impact of Publications

Faculty
Michael Buschman, MLIS, Co-founder, Plum Analytics
Bhakti Kshatriya, PharmD, Global Scientific Communications, Novartis
Tom Rees, PhD, Scientific Strategy Advisor, PAREXEL International
Moderator: Sarah L. Feeny, BMedSc, Head of Scientific Direction, Complete Medical Communications

Learning Objectives
By the end of this session attendees will:
• Understand the process of developing publication plan metrics
• Be conversant in the various types of newer publication metrics
• Be educated on which metrics are most importance to various stakeholders

Notes
Bhakti Kshatriya introduced some key questions to consider for metrics:
• What do you want to measure?
• Why do you want to measure it?
• What is the best way to measure it?
• What are you going to do with that information?

We establish metrics to help establish goals, prioritize publication activities, ensure appropriate resources/budgets, identify areas for improvement, and measure progress.

Metrics can vary, depending on the life cycle and other opportunities, and are affected by both internal and external factors:
• Volume
  – Number of names
  – Number of abstracts
  – Number of acceptances
• Timing
  – Guidelines
  – Life cycle management
  – General and specific timelines
  – Prioritize and measure how well we do here. Define “start” and “end”
• Quality (speaks to the article level)
  – Impact factor
  – Acceptance in first-choice journal
  – Number of times cited in other journals
• Topics
  – Literature gap analyses

One of the challenges is acceptance rate, because what should we use as the benchmark? We need to ask ourselves what we want to achieve – why do we need metrics? Michael Buschman introduced altmetrics as an alternative to use in citations and articles. This can be broken down into:
• Usage
• Captures
• Mentions
• Social media
• Citations
In addition, we cannot underestimate the use of social media to help in metrics. Twitter is not something that has been read and digested, it is something they want you to know about. Few researchers are currently using social media to discover recommended research papers.

Tom Reese discussed how the type of article can affect your metrics (e.g., purpose, therapeutic area, pages, references, title length, and countries).

Journal impact factors are still important for evaluating use; however, there are other methods that can be used as well.
Rare Diseases and Orphan Drugs: Publications and Perspectives

Faculty
Scott D. Newcomer, MS, ISMPP CMPP™, Assistant Director, Publications, Shire Pharmaceuticals
Lisa Schill, Vice President, RASopathies Network USA; Patient Advocacy Outreach Consultant
Louise Wyhopen, BSN, RN, ISMPP CMPP™, Associate Director, Scientific Communications, Novartis Oncology, Global Medical Affairs

Learning Objectives
By the end of this session attendees will:

• Better understand the rare disease drug development landscape and pathways to approval
• Explore the challenges related to publications in rare disease fields from both large and small company perspectives
• Gain insight into the needs and perspectives of patient advocacy groups as related to industry-sponsored rare disease research and publications

Notes
Dr. Goldsmith of the Rare Diseases Program/Office of New Drugs/CDER gave an insightful presentation on how the government views rare diseases. His department facilitates, supports, and accelerates the development of drugs/biologics for rare diseases. They give informal advice but do not conduct the formal review. His group does attend all review meetings and ensures review consistency. A good reference is the FDA guideline from 2014 on Expedited Programs for Serious Conditions.

“Rarity is often inversely proportional to the understanding…”

He walked through the various types of reviews (fast track, priority, accelerated, etc), noting that with rare diseases, there is regulatory flexibility. They don’t require 2 randomized controlled trials performed the same way.

He explained patient registries and natural history studies, which are observational studies with minimal entry requirements that are important in shaping drug development. For example, they help define the design of future studies, inform the risk/benefit analysis, identify biomarkers that guide proof of concept (POC) and safety signals, provide POC, and provide a study of the natural history of the disease. Studies just need to measure some effect of the disease (eg, can get off a ventilator sooner or put a cup to the mouth).

More information on rare diseases can be found at the Orphanet website and in their Journal of Rare Diseases.

Lisa Schill from the RASopathies Network emphasized the importance of publishing and how lay people rely on journal articles for information. She stressed the need to get publications to caregivers and encouraged the writing of abstracts at an 8th Grade level. Data provided to patients and caregivers can be brought to their physicians to facilitate the conversation. Including patient advocates as authors and in advisory board settings can also help the process.

Bottom line: it all ties back to the patient, whether a disease is rare or not.
Wednesday, April 29, 2015 – General Sessions

Medical Journalism and ISMPP: What Level of Engagement is Best for Scientifically Sound Reporting?

Faculty
Kathryn Foxhall, BA, Freelance reporter
Joyce Frieden, BA, News Editor, MedPage Today
Peter Wehrwein, BA, Editor, Managed Care
Moderator: Kevin Ryder, PhD, Senior Vice President, Clinical Content and Editorial Services, Complete Healthcare Communications

Learning Objectives
By the end of the session attendees will:
• Understand current journalism practices for gathering information and reporting to the public on clinical/medical data
• Learn current barriers and challenges in reporting medical information to the public
• Develop insights into potential opportunities for improving communication between journalists and medical publication professionals

Notes
Peter Wehrwein broke down the journalist’s writing process:
• Initial conception
• Collection of supporting information
• Focus – what the story is within the topic: “The story is what drives the bus; everything else is just the passengers”
• Organizing
• Drafting
• Collecting

Joyce Frieden discussed how, if a journalist is unfamiliar with a therapeutic area, he or she will get help on the topic. Journalists are also often involved in CME programs.

Kathryn Foxhall discussed the need for good sources and how to go about talking to journalists. She stressed the importance of establishing the terms up front.
The panel discussed how the response from the pharmaceutical industry can vary. Most companies reply to requests for information with prepared statements and it is very rare to get an interview.

Keynote: John Kamp

Speaker
John Kamp, PhD, JD, Executive Director, Coalition for Healthcare Communication

Notes
Dr. Kamp offered a tribute to the 10 years of ISMPP.
He went on to discuss important initiatives, including the Sunshine Act and data privacy and security, and shared some words for inspiration.

Practical Implications of GPP3: Are You Prepared?

Faculty
Teresa L. (Terry) Peña, PhD, CQE, Executive Director, Global Medical Publications, Bristol-Myers Squibb

Learning Objectives
By the end of the session attendees will:

- Understand the GPP3 development process and its scope
- Understand key new recommendations to be made in GPP3
- Gain insights into how these recommendations might further improve day-to-day publications activities
- Be knowledgeable about steps an organization can take to prepare for these recommendations

Notes
Teresa Peña provided an overview of the process behind GPP3, including the steering committee and review process.

The steering committee submitted GPP3 to Annals of Internal Medicine in January 2015 and has received comments. Teresa provided information about updates on GPP3, areas to focus on, and how to implement its use.
Closing Remarks: What’s Next for ISMPP?

Speaker
Al Weigel, MEd, ISMPP CMPP™, President and COO, International Society for Medical Publication Professionals (ISMPP)

Notes
Al Weigel closed the Annual Meeting by acknowledging ISMPP’s accomplishments over the past 10 years and highlighting some key considerations ISMPP will be working towards in the future.

He also presented a Summary and Highlights Video of the meeting that is available on ISMPP’s YouTube channel.

Wednesday, April 29, 2015 – Post-Conference Workshops
HEOR: What Constitutes a Good Health Outcomes Manuscript?

Faculty
Chris Carswell, MSc, Editor-in-Chief, Pharmacoeconomics, Springer Science and Business Media, LLC
Keith Evans, PhD, Director, Global Health Outcomes, InScience Communications

Learning Objectives
At the end of this workshop, attendees will:
• Know the components of a high-quality HEOR manuscript
• Be familiar with health outcomes trends
• Understand the implications of HEOR with respect to publication planning
This session provided an excellent overview of the evaluation of a good HEOR manuscript. The faculty provided a checklist of 13 points that are the minimal parameters/content of a good HEOR manuscript:

- Study aim
- The type of analysis performed
- The study perspective
- Appropriate effectiveness measures included
- Clear statement of study design
- Source of clinical and cost data made clear
- Appropriate time horizon
- Cost components included
- Year of costing made explicit
- Discounting of costs/benefits if appropriate
- Sensitivity analysis
- Can you find incremental ratios?
- Discussion of generalizability and limitations

@MedValSci & @PharmaWrite teams had a blast @ISMPP AM! Check us out: pwmedval.com #ISMPP #InfoToKnowledge
ISMPP’s YouTube channel features several video interviews from the ISMPP 11th Annual Meeting. Click below for more!