THANK YOU FOR JOINING ISMPP U TODAY!

The program will begin promptly at 11:00 am EDT

June 24, 2015
ISMPP WOULD LIKE TO THANK...

...the following Titanium and Platinum Corporate Sponsors for their ongoing support of the Society:

- Amgen
- AstraZeneca
- Biogen Idec
- Bristol-Myers Squibb
- Caudex Medical
- CHC Group
- Complete HealthVizion
- CMC MedErgy
- MedThink SciCom
- Pfizer
ISMPP ANNOUNCEMENTS

• Did you earn your ISMPP CMPP certification in 2010? Find out what you need to do to recertify (www.ismpp.org/recertification)

• Presentations from the 11th Annual Meeting are now available in the Archives (www.ismpp.org/annual-meeting-archive)

• Watch interviews with key presenters and stakeholders from the 11th Annual Meeting on our YouTube channel

• ISMPP is pleased to announce our first Asia Pacific meeting – registration is now open!
REGISTRATION IS OPEN!

COLLABORATING FOR
ETHICAL & EFFECTIVE MEDICAL PUBLICATIONS

Beijing, China • August 30, 2015
Tokyo, Japan • September 2, 2015

http://www.ismpp.org/asia-pacific-meetings
To optimize your webinar experience today:

• Use a hardwired connection if available

• Use the fastest internet connection available to you

• If you are accessing the presentation over your computer, please be sure to increase the volume of your computer speakers
QUESTIONS...

- To ask a question, please type your query into the Q&A box
  - To ensure anonymity and that all panelists receive your question, please choose the drop down box option, "Hosts, Presenters and Panelists." Otherwise, all audience members will be able to see your submitted question
- We will make every effort to respond to all questions

NOTE: Make sure you send your question to "Host, Presenter and Panelists"
11th ANNUAL MEETING OF ISMPP
HIGHLIGHTS

OPTIMIZING SCIENTIFIC VALUE:
SMART AND SYSTEMATIC APPROACHES
TO MEDICAL PUBLICATIONS
INTRODUCTIONS

- Jennifer Ciafullo, MPH, ISMPP CMPP™, Education Content Manager, ISMPP
- Juliana Clark, PharmD, Executive Director, Global Medical Writing, Amgen, Inc.
- Donna Simcoe, MS, MS, MBA, ISMPP CMPP™, Medical Publication Consultant, Simcoe Consultants, Inc.
- Susan Pacconi, Senior Manager, Global Medical Affairs, Strategic Planning, Corporate Headquarters
- Paul Farrow, DPhil, MSc, ISMPP CMPP™, Communications Director, Oxford PharmaGenesis
- Gary Burd, PhD, CMPP™, SVP, Global Medical Director, Caudex
INTRODUCTIONS

• **FACULTY: Jennifer Ciafullo** has served as Education Content Manager at ISMPP for the past 3 years, directing content for ISMPP’s Annual Meetings as well as monthly webinars and other educational initiatives. She has worked in the medical publications field for the past 10 years, most recently as Manager of Medical Writing Services at Quintiles. Prior to medical publications, she was immersed in the world of academia, working alongside fellows as Manager of Educational Projects at the Brookdale Department of Geriatrics and Adult Development, Mount Sinai School of Medicine. Jennifer obtained her MPH from the Columbia University Mailman School of Public Health and is a Certified Medical Publication Professional (CMPP).
FACULTY: Juli Clark has directed the Global Medical Writing department at Amgen for 8 years, and has 18 years of experience in the biotech industry, having managed staff and services in Medical Writing, Medical Information and Medical Communication roles. Prior to working in industry, she worked for two smaller companies (Pathogenesis, and Otsuka). Juli earned her B.S. Pharmacy and Doctor of Pharmacy degrees at University of Iowa, and completed a General Hospital Pharmacy Residency program and Fellowship in Ambulatory Care Clinical Pharmacy.

Prior to entering the biotech/pharma industry, Juli practiced as a clinical pharmacy specialist in a variety of settings including managed care, Indian Health Service, private and large University Hospitals. Juli is currently serving as Trustee at Large on the ISMPP Board of Trustees, and has been an active participant/presenter in the Medical Publishing Insights and Practices Initiative (MPIP) as well as with ISMPP, AMWA and DIA.
INTRODUCTIONS

• **FACULTY: Donna Simcoe** has managed publications at Cadence, AstraZeneca, Wyeth and Cephalon. Donna holds 3 Master degrees in Biomedical Writing, Biotechnology and an MBA, and is a Certified Medical Publication Professional (CMPP). She is an active member in AMWA, ISMPP and TIPPA. Donna recently served as the Chair of the ISMPP U Committee (2013-2014) and is the current AMWA Pacific Southwest Chapter President (2014-2016). Donna is now a Medical Publications consultant and principal at Simcoe Consultants, Inc., a biomedical consulting company focusing on medical publication strategy and medical writing.
• **FACULTY: Susan Pacconi** has ~ 15 years of experience in various roles in scientific communication, medical education, and most recently, as Senior Manager at Celgene on the Global Medical Affairs Strategic Planning team. Prior to joining Celgene, Susan was employed as a scientific communication manager at Sanofi where she worked in oncology, specializing in comparative effectiveness research and health economics/outcomes research publications. Susan has been a frontrunner in utilizing novel technologies for the dissemination of scientific data and has been sought after to present at various congresses. Susan additionally brings extensive agency experience, having worked with numerous vendors on educational materials for many blockbusters products in cardiology and immunology. Susan is currently employed by Celgene in corporate headquarters in Summit, NJ.

Susan’s educational background is in business, having earned her B.S. from William Paterson University (NJ, USA). Her hobbies include chasing her two young daughters, physical fitness, DIY home improvement and volunteering in her local community.
**FACULTY:** Paul Farrow has led publications programs in nephrology, gastroenterology, cardiovascular medicine, oncology and neuroscience over the past 9 years at Oxford PharmaGenesis. He is currently responsible for providing strategic, scientific and editorial direction and contract Global Publications Lead support on accounts for a top-10 pharmaceutical client. Paul has a DPhil in Clinical Pharmacology (genetic therapies in oncology) from the University of Oxford, UK, and won the AstraZeneca prize for his MSc research at the University of Birmingham, UK. As an ISMPP-Certified Medical Publications Professional and GPP3 reviewer, head of the Oxford PharmaGenesis Publication Ethics Planning and Research (PEPR) Group and lecturer on good publication practice at Oxford University, Paul is well qualified to advise on good publication practice.
• **MODERATOR:** Gary Burd is Senior Vice President and Global Medical Director at Caudex with 12 years of medical communications and scientific publishing experience. Gary has led communication planning and publication planning activities in several therapy areas, including diabetes, solid tumour oncology, haematological malignancies, transplantation, multiple sclerosis, rheumatoid arthritis, and respiratory and lung disease. Prior to his medical communications work he gained valuable editorial experience in journal publishing with Portland Press. Gary obtained his PhD from the Kennedy Institute of Rheumatology, London working on a monoclonal antibody therapy for systemic lupus erythematosus.
DISCLAIMER

- Information presented reflects the personal knowledge and opinion of the presenters and does not represent the position of their current or past employers or the position of ISMPP
At the end of this presentation, attendees should be able to:

• Be knowledgeable about the planning process for ISMPP’s Annual Meetings
• Understand key influencers to the current and future medical publications landscape
• Understand how to identify an optimal model for cost-effective and timely publications
• Appreciate how professional medical writing support influences the quality of research reporting
THE MAKING OF AN ISMPP ANNUAL MEETING

Jennifer Ciafullo
Education Content Manager
ISMPP
11TH ANNUAL MEETING OF ISMPP

OPTIMIZING SCIENTIFIC VALUE: SMART AND SYSTEMATIC APPROACHES TO MEDICAL PUBLICATIONS

April 27–29, 2015
Hyatt Regency Crystal City
Arlington, VA, USA
It Takes a Village...

Across the three days:
- 15 parallel sessions
- 11 new roundtable topics
- 3 keynote speakers
- 2 Roundtable sessions
- 2 new workshops
- 41 posters
Snapshot of Topics Covered at Meeting

- Rare Disease/Orphan Drug Publication Planning
- Medical Journalism
- How to get the most out of Congress activities
- Patient Participatory Peer Review
- Publishing Partnership
- Sunshine Act
- PCORI
- Doing More with Less
- HEOR
- Metrics
- Real World Data
- Social Media
- How do organized healthcare systems use pubs?
- New Technologies in Publication Planning
- Lay patient summaries
- Real World Data
- Advocacy
- Regional Challenges
- Working with Medical Fellows
- GPP3
- CMPP
- India
- 3rd to market publications and beyond
- Patient Experience
- Publishing Partnership
- Latin America
- MPIP
- YODA Project
- Data Sharing
- Publication consultants
- Doing More with Less
- Doing More with Less
- Lay patient summaries
- Latin America
- MPIP
- YODA Project
- Data Sharing
- Publication consultants
- Doing More with Less
- Lay patient summaries
- Latin America
- MPIP
- YODA Project
- Data Sharing
- Publication consultants
- Doing More with Less
Achieved Goals Set for this Year’s Meeting

- More choice
- More interaction
- More faculty variety
- More balance

Meeting evaluations indicated a very successful meeting...
Special Thanks - 11th Annual Meeting Program Committee

- Juli Clark (Chair - BOT)
- Steph Tortell (Chair)
- Tim Day (Vice-Chair)
- Maria Alu
- Jennifer Ciafullo (ISMPP)
- Jill Condello
- Marc Eisenberg
- Samantha Gothelf (BOT)
- James Gurr
- Bhakti Kshatriya
- Caitlin Lentz
- Sue Marek (ISMPP)
- Terry Materese
- Ira Mills
- Paul O’Grady
- Kevin Ryder
- Karen Spach
- Donna Simcoe
- Kanaka Sridharan
- Sharon Suntag
- Erin Sternberg
- Celeste Williams-Hughes (ISMPP)
- Holly Zoog
Special Thanks – 11th Annual Meeting Workshop Committee

- Tuli Ahmed
- Irene Durham
- Elif Fincanci-Smith
- Courtney Leo
- Kimberley Gertsen
- Namit Ghildyal
- Nicole Harrold

- Laura LeGower
- Stephanie O’Connor
- Tom Rees
- Anca Serban (Chair)
- Charlotte Singh
- Celeste Williams-Hughes (ISMPP)
THE PATIENT VOICE

Juli Clark, PharmD,
Co-Chair, ISMPP Annual Program Committee
Executive Director, Global Medical Writing,
Scientific Affairs, Amgen, Inc.
Patient-Focused Presentations

Monday Keynote: Insights from the Patient Experience: A Personal Account
- Ide Mills, CSW, Principal, Strategic Healthcare Communications

Optimizing Patient-Centered Outcomes Research
- Jean R. Slutsky, PA, MSPH, Chief Engagement and Dissemination Officer, PCORI

The Patient Voice: How is Industry Leveraging the Patient Perspective to Inform Development Plans and Optimize Treatment Decisions?
- Patricia Comet, MA, Associate Director Advocacy, Diversity & Patient Engagement, Global Development, Operations, R&D, BMS
- Ide Mills, CSW, Principal, Strategic Healthcare Communications
- Mary Uhlenhopp, RN, MS, MPH, Advocacy & Ally Development Lead, Amgen (Europe) GmbH
- **Moderator:** Diane Moniz Reed, PharmD, CMPP™, Head, Oncology Medical Publications, BMS

Patient Lay Summaries: Internal Coordination of Scientific Communications
- 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, CISCRP

Patient Participatory Model: A New Paradigm for Medical Journals?
- Daniel Shanahan, MA, MSc, Associate Publisher, BioMed Central
- **Moderator:** Neil Adams, ISMPP CMPP™, Publishing Manager, Nature Publishing Group
Patient Engagement

• Scientific exchange increasingly moving towards being more patient-centric

• Opportunities for patients to be involved in processes they recently did not have access to, many which will directly or indirectly effect medical pubs:
  – Clinical trial design
  – Scientific funding/grant review
  – Scientific manuscript peer review

• Regulatory and ethical obligations to communicate openly with patients
  – Clinical trial lay summaries
**Escalating Demands for Clinical Trial Transparency**

- **EU CTR Requirement** effective in 2016 to post summaries and layperson’s summaries to EU Portal

- “All medical research subjects should be given the option of being informed about the general outcome and results of the study”

- **2011:** EU public register of clinical trials launched online
  - US requires disclosure of results notification process during informed consent (into effect 2012)

- **2012:** US TEST Act introduced in the HoR to expand requirements – not enacted

- **2013:** Dec. of Helsinki revised Article 26 ‘Option to be informed about results for all medical research subjects’

- **2014:** EMA policy 70 on proactive publication and access to CT data effective 1 Jan 2014
  - New EU CTR introduced requirement effective in 2016 to post summaries and layperson’s summaries to EU Portal

- **2015:** Mar - MRCT at Harvard finalized guidance doc and toolkit on return of results to CT participants (input from EMA/FDA)
  - Mar - TransCelerate workstream kicked off to develop template and options for distribution of lay summary results (based on MRCT doc)

Presented by 4.27.15 by J. Cole @ the 11th Annual Mtg of ISMPP
Evolution of Patient Engagement with Industry: Getting to Partnership

Presented by 4.27.15 by D. Moniz-Reed @ the 11th Annual Mtg of ISMPP
Why Engage with Patients?

• Patient engagement in the design and conduct of research offers a greater likelihood of:
  – Influencing research to be patient centered, useful, and relevant
  – Establishing trust and a sense of legitimacy in its findings
  – Successful use and uptake of research results by the patient community
### Lay Summaries for Patients: Do They Care?

<table>
<thead>
<tr>
<th>Patients/Study Volunteers</th>
<th>Research Professionals</th>
</tr>
</thead>
<tbody>
<tr>
<td>90% want to know the results of their clinical trial&lt;sup&gt;1&lt;/sup&gt;</td>
<td>98% of study staff would like to provide results to their volunteers&lt;sup&gt;4&lt;/sup&gt;</td>
</tr>
<tr>
<td>91% never hear back from study staff or sponsor&lt;sup&gt;2&lt;/sup&gt;</td>
<td>95% of research ethics board chairs strongly support (Canadian survey)&lt;sup&gt;5&lt;/sup&gt;</td>
</tr>
<tr>
<td>If not informed, 68% would not participate in future trials&lt;sup&gt;3&lt;/sup&gt;</td>
<td>PhRMA and EFPIA: Principles for Responsible Data Sharing (2013)</td>
</tr>
</tbody>
</table>


Presented by 4.27.15 by J. Cole @ the 11<sup>th</sup> Annual Mtg of ISMPP
Lay Summaries May Impact Clinical Trial Participation

How Important Were the Following Factors in Your Choosing to Participate in a Clinical Research Study?

<table>
<thead>
<tr>
<th>Percent of Respondents</th>
<th>GENDER</th>
<th>REGION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Percent rating “Somewhat/Very Important”</strong></td>
<td>OVERALL</td>
<td>FEMALE</td>
</tr>
<tr>
<td>Quality medical care</td>
<td>85%</td>
<td>90%</td>
</tr>
<tr>
<td>Access to medical professionals</td>
<td>83%</td>
<td>88%</td>
</tr>
<tr>
<td>Learn about my disease</td>
<td>79%</td>
<td>83%</td>
</tr>
<tr>
<td>Receive regular updates about the research while I’m enrolled</td>
<td>68%</td>
<td>70%</td>
</tr>
<tr>
<td>Receive information about the results after the study has ended</td>
<td>71%</td>
<td>73%</td>
</tr>
<tr>
<td>Feel part of a community</td>
<td>61%</td>
<td>65%</td>
</tr>
</tbody>
</table>

Base: Have Participated

Presented by 4.27.15 by J. Cole @ the 11th Annual Mtg of ISMPP

www.ciscrp.org

The Center for Information & Study on Clinical Research Participation (CISCRP)
Challenges for Sponsor Companies

• Ensuring non-promotional content
  – US Regulators: “It is necessary to demonstrate that narrative summaries of applicable clinical trials can be consistently produced in a way that will not be misleading or promotional”
  – Patients: “I want whoever wrote this report to be a government or a non-profit agency”

• Aligning timelines and workflows
  – EU requirement: “Within one year from the end of a clinical trial”
  – Remember the patient’s current post-trial experience: “They kept us in the dark”

• Cost considerations and patient engagement
  – Regulations only require posting to EU database
  – Most patients (90%) prefer printed format delivered via investigative site
  – Translations into patient languages of great value
How might this evolve?

- Paper
- Digital
- Text
- Multimedia
- Intermediary
- Self Service
- Summaries
- Individual

Presented by 4.27.15 by J. Cole @ 11th the Annual Mtg of ISMPP
Patient Peer Review – A New Paradigm?

• BMJ and BioMed Central embedding patient review of papers in the standard peer review processes
  – Believe patients can best help address question of clinical relevance & potential real world effect
  – Overwhelming patient response
  – Authors very positive to reviews received
  – Publishers have mixed reaction
    • Waiting to see effect on internal processes and turn-around times
    • Gauging reception from more established researchers
Guidance for Reviewers

• Is the rationale for what the author(s) have done clearly demonstrated?
• Have all methods been described in sufficient detail to allow others to evaluate and/or reproduce the work in similar circumstances?
• Is the interpretation (discussion and conclusion) of the article, well balanced and supported by what was done and/or seen?
• Has sufficient attention been given to ethical considerations and how these were managed?
• Can the writing, organization, tables and images be improved?
Patient Peer Review Resources

• Resources
  - INN Interview with Daniel Shanahan
    • https://www.youtube.com/watch?v=9Vgchwjio2E
  - Guidance for BMJ Patient Peer Reviewers
    • http://www.bmj.com/about-bmj/resources-reviewers/guidance-patient-reviewers
  - Research Involvement and Engagement journal
    • http://www.researchinvolvement.com/

INN = Interactive News Network
Key Takeaways - 360 View

• Patient engagement/involvement in scientific exchange is here to stay
• Patient engagement can serve as a path to useful, high-quality research
• Industry is working with patient organizations on new and innovative concepts that will ensure more active involvement of patient experts in R&D and HTA
• Regulatory environment is in support of lay summaries for patients
• Increased patient involvement is impacting medical journal processes and decision-making; patient peer review may be the wave of the future
DATA, DATA, AND MORE DATA

Donna Simcoe, MS, MS, MBA, ISMPP C MPP™
Medical Publication Consultant, Simcoe Consultants, Inc.
# Data-Focused Presentations

## Tuesday Keynote: Clinical Data Disclosure: The Five P’s
- Iain Hrynaszkiewicz, MA, Head of Data and Humanities & Social Sciences Publishing, Nature Publishing Group & Palgrave Macmillan

## The Democratization of Healthcare Information via Social Media
- 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

## Health Economics and Outcomes Research (HEOR): Roadmap of Top 10 Principles to Follow When Developing HEOR Publications
- **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

## Data Sharing Partnerships: Impact on Future Research and Publishing
- Karla Childers, MS, Director, Strategic Projects, Johnson & Johnson, Office of the Chief Medical Officer

## “Negative” or Non Confirmatory Data Publications: Practical Approaches to Getting Published
- 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
Data-Focused Presentations (cont)

Building a Publishing Partnership
- 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 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

Medical Publishing Insights and Practices Initiative (MPIP): Defining Best Practice For Adverse Event Reporting With Industry-sponsored Clinical Trial Manuscripts
- Susan Glasser, PhD, Senior Director, Scientific & Medical Publications, Reg MW Company, Janssen Research & Development, LLC

Rare Diseases and Orphan Drugs: Publications and Perspectives
- Johnathan Goldsmith, MD, FACP, Acting Associate Director, Rare Diseases Program, Office of New Drugs, Center for Drug Evaluation and Research, FDA
- 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
- **Moderator:** Christine Gatchalian, PhD, Director, Global Medical Writing, Amgen

Real-World Evidence
- Alexander Liede, MSc, PhD, Director, Center for Observational Research, Amgen, Inc.
- Robert LoCasale, PhD, Director of Quality, Design & Analytics in Medical Evidence and Observational Research, AstraZeneca
- **Moderator/Faculty:** Mariam Bibi, PhD, Director Of Real-World Evidence, Complete True Life
An Increasingly Data-Rich World

Patient registries
Pharmacoeconomics
Patient-reported outcomes
REAL WORLD EVIDENCE
Negative/Null data
Big Data
HEOR
RCTs
Social media
Number of Factors Aligned to Make Real World Data an Integral Component of Evidence Generation

- Healthcare systems having to derive increased value from medicines in targeted patient populations to maximize healthcare resources while providing optimal patient outcomes
- Innovative high-cost technologies
- Stakeholders’ appetite for data beyond efficacy and safety
- Advances in technology have allowed easier, faster access to multiple data sources
What’s driving data transparency?

- Funder policy and mandates\(^1\)
- Regulatory agencies (EMA)
- Legislation (FDAAA)
- Non-governmental/academic (IOM, YODA)
- Industry (CSDR)
- Journals and ICMJE\(^2\)

Data Sharing: Landscape Still Fairly Divergent

**Past**
Individual companies responded to requests and made decisions about sharing.

**Present**
Various models exist – with some sponsors of clinical research not participating at all.

**Future**
Can we envision a system that uses a completely independent custodian managing the process across a range of sponsors and all stakeholders?

Presented by 4.28.15 by K. Childers @ the 11th Annual Mtg of ISMPP
One Example: YODA (Yale University Open Data Access) Project

Commitment to review all requests and try to fulfill if consistent with YODA principles, irrespective of when studies conducted

**YODA will:**
- Interact with requestors (single point of contact)
- Have an advisory Steering Committee
- Engage external experts at their discretion
- Have final decision-making authority

**Requestors must:**
- Provide specific details about themselves and the research to be conducted, including a statistical analysis plan
- Submit a plan for publication of research
- Sign a Data Use Agreement

Presented by 4.28.15 by K. Childers @ the 11th Annual Mtg of ISMPP
Publication considerations in data sharing

What are the considerations in determining timing of publications?

How should teams react to the knowledge that a particular analysis is being done?

Timing for sharing data from primary publications

Checks on publications from secondary research

Impact on publication strategy

Incentives for data sharing

How can we support productive dialogue about results?

How do we give credit for secondary research to encourage participation?

Presented by 4.28.15 by K. Childers @ the 11th Annual Mtg of ISMPP
Data Sharing Challenges for editors and publishers

- Hosting vs. linking to data
- Finding suitable repositories
- Peer review of data
- Extra resources – enforcing policy
- Incentivising compliance
- Link decay
Key Takeaways - 360 View

Real World Evidence (RWE)

• RWE is not a temporary nor new phenomena
• Real world data are underutilized
• Companies are investing heavily to build RWE capability
• Publication professionals are critical in assisting the RWE scientists in getting the evidence out to the right audience in time and at the right time
Key Takeaways - 360 View

Data Sharing

• Data sharing is part of increasing reliability and reproducibility
• Timing of publications is becoming an increasing focus of discussion
• Data sharing can have an effect on internal publication planning
• We need productive dialogue about the results of secondary research
• Medical publishing is changing – digital landscape can reach more people, more quickly and shorten the window between acquisition of knowledge and clinical translation
Data Resources

• Resources
  – INN interview with Keynote Iain Hynaskiewicz (open publishing/data sharing)
    • https://www.youtube.com/watch?v=g0M1sKALOZs
  – INN Interview with Karla Childers (data sharing)
    • https://www.youtube.com/watch?v=OBApE-69IoY
  – INN interview with Paul Tunnah (social media)
    • https://www.youtube.com/watch?v=KOR_bKACLE
  – INN interview with MPIP (Adverse Events Research Project)
    • https://www.youtube.com/watch?v=qNsEllMLmEc

INN = Interactive News Network
CURRENT/FUTURE LOOKING...

Jennifer Ciafullo, MPH, ISMPP C MPP™
Education Content Manager
ISMPP
Wednesday Keynote: DC Update: What’s Happening In Medical Communication & Marketing And What We Can Do About It
• John Kamp, PhD, JD, Executive Director, Coalition for Healthcare Communication

The Sunshine Act, Medical Publications, and Authors: Results of the ISMPP Survey
ISMPP Sunshine Act Task Force Members
• Robert J. Matheis, PhD, ISMPP CMPP™ (Chair); Executive Director, Global Scientific Communications, Celgene Corporation; President, ISMPP (2011-2012)
• Moderator/Faculty: Kim Pepitone, BA, ISMPP CMPP™ (Vice Chair); 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

Innovation in Metrics: Capturing the Full Impact of Publications
• 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

Practical Implications of GPP3: Are You Prepared?
• Teresa L. (Terry) Peña, PhD, CQE, Executive Director, Global Medical Publications, BMS
Patient Involvement

Current/Future Looking Presentations (cont)

**Medical Fellows: Insights and Opportunities**
- Darshan Doshi, MD, Cardiology Fellow, Columbia University Medical Center
- Anuj Gupta, MD FACC, FSCAI, Assistant Professor of Medicine, Division of Cardiovascular Medicine, University of Maryland School of Medicine; Director, Cardiac Catheterization Lab; Governor-Elect, Maryland ACC
- **Moderator/Faculty:** Gaby Weissman, MD, Director, Cardiology Fellowship Program, Washington Hospital Center

**Collaborative Technology Real-World Case Studies**
- 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, Bi 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

**Research Technology Real World Case Studies**
- 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

**Medical Journalism and ISMPP: What Level of Engagement is Best for Scientifically Sound Reporting?**
- 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
Major Marking Issues Brewing in 2015

• Tax reform and deductibility of marketing costs
• Privacy legislation supported by Obama Administration
• Path to 21st Century Cures
  – HR 293 Exempting Textbooks & Reprints from Sunshine
  – Off Label Communications
  – One Click Away/Twitter
• HHS/CMS Policies on Sunshine
• FDA Marketing Regulation
• FDA Drug Approvals

Presented by 4.29.15 by J. Kamp @ the 11th Annual Mtg of ISMPP
GPP3 Participants

• Steering Committee
  – 19 qualified
  – Globally diverse group and perspectives from across the profession from seven countries representing:
    • Industry (pharma and device)
    • Medical communication companies
    • Freelance writers
    • Journal editors
    • Publishers
  – Breakdown by country: US (10); Netherlands (1); UK (3), Denmark (1); Aus/NZ (3), Japan (1)

• Reviewer panel
  – 174 approached and 94 confirmed reviewers, mainly from pharmaceutical/device industries and medical communication agencies; included 21 journal editors

Presented by 4.29.15 by T. Peña @ the 11th Annual Mtg of ISMPP
# What’s new in GPP3?

<table>
<thead>
<tr>
<th>New elements include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Guidance on updated ICMJE 2014 authorship criteria</td>
</tr>
<tr>
<td>2. Guidance on common issues regarding authorship</td>
</tr>
<tr>
<td>3. Guidance and improved clarity on author payment and reimbursement</td>
</tr>
<tr>
<td>4. Additional clarity on what constitutes ghost or guest authorship</td>
</tr>
<tr>
<td>5. Expanded information on the role and benefit of professional medical writers</td>
</tr>
<tr>
<td>6. Guidance for appropriate data sharing</td>
</tr>
<tr>
<td>7. Overall simplification of language and format with a new guiding principles section and quick reference tables addressing guidance on authorship criteria and common authorship issues</td>
</tr>
</tbody>
</table>

Presented by 4.29.15 by T. Peña @ the 11th Annual Mtg of ISMPP
Predicting the impact

New elements include:

1. Guidance on updated ICMJE 2014 authorship criteria
2. Guidance on common issues regarding authorship
3. Guidance and improved clarity on author payment and reimbursement
4. Additional clarity on what constitutes ghost or guest authorship
5. Expanded information on the role and benefit of professional medical writers
6. Guidance for appropriate data sharing
7. Overall simplification of language and format with a new guiding principles section and quick reference tables addressing guidance on authorship criteria and common authorship issues
Education & training pyramid

Senior Leaders

Authors, agency partners, publication teams, cross-functional stakeholders & partners

Publication, compliance & legal teams

1st line communication & education on business impact

2nd line education & training

1st line education & training

Focused & customized training

High detail & depth

Presented by 4.29.15 by T. Peña @ the 11th Annual Mtg of ISMPP
Next Steps for GPP3

• Begin parallel activities
  – Update GPP website on ISMPP site content to include GPP3
    • Steering committee member list
    • ‘GPP3 for authors’ checklist - practical tool
    • FAQ document
    • GPP3 process summary
  – Establish GPP3 sub-committee to monitor and respond to FAQs
  – Explore GPP3 sessions at ISMPP Annual Meetings
    • September 2015; Tokyo & Beijing

• Post acceptance activities
  – Organization outreach for GPP3 endorsement to include AMWA, EMWA, COPE and others…
  – Guideline translations in Japanese and Chinese
  – Download access to GPP3
  – Archive of GPP2 information
Key Takeaways - 360 View

• A number of US-regulatory issues brewing that will potentially impact:
  – Journal advertising
  – Sunshine reporting in relation to medical publications/reprints
  – Manufacturer communication of new scientific developments including (potentially) off-label results
  – Social media communications to patients

• GPP3 will soon be published in Annals of Internal Medicine – start to educate internal and external stakeholders
Current/Future Looking Resources

• Development of GPP3 & how it will affect publications practice:
  – INN interview with Chris Carswell, MSc, Editor-in-Chief, *Pharmacoconomics*, Springer Science and Business Media, LLC
    • [https://www.youtube.com/watch?v=VlWqr60jshw](https://www.youtube.com/watch?v=VlWqr60jshw)
  – INN Interview with Angela Cairns, SVP, Global Compliance Team Leader, Executive Management, Ashfield Communications
    • [https://www.youtube.com/watch?v=jHz0ZKWEUKw](https://www.youtube.com/watch?v=jHz0ZKWEUKw)
  – INN interview with Grannum Sant, MD, Tufts University
    • [https://www.youtube.com/watch?v=znj0Z1EqYHg](https://www.youtube.com/watch?v=znj0Z1EqYHg)
  – INN interview with John Gonzalez, PhD, Publications Director, AstraZeneca
    • [https://www.youtube.com/watch?v=t9p08MyTgrU](https://www.youtube.com/watch?v=t9p08MyTgrU)
  – INN interview with Dan Bridges, PhD, Europe Regional Director at Nucleus Global
    • [https://www.youtube.com/watch?v=v9-NIClB4tU](https://www.youtube.com/watch?v=v9-NIClB4tU)

INN = Interactive News Network
### Regulatory Environment/Good Practice-Focused Presentations

#### Advancing Good Publication Practices in the Asia-Pacific Region: Focus on India
- 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

#### Sunshine Act: Examination of the Open Payments Database
- Laura C. Conway, JD, Director, Regulatory and Compliance Services, Porzio Life Sciences
- **Moderator:** Larry Kovalick, Director, Medical Writing, Amgen

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

#### Making the Most of Your ISMPP Certified Medical Publication Professional™ (CMPP) Credential
- 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, ISMPP
Regional Challenges in Publication Planning

- Manon Boisclair, MS, (RN), ISMPP CMPP™, Director, Global Publication Operations, Celgene
- Rhiannon Meaden, PhD, Director, Global Business Development, Adelphi Communications
- Jorge Moreno-Cantu, MS, PhD, ISMPP CMPP™, Global Scientific and Medical Publications Director, Merck
- Jill Sanford, MS, Director, Global Scientific Communications, Celgene

Moderator/Faculty: Paul O’Grady, PhD, Senior Director, Global Scientific Communications, Novartis

Rare Diseases and Orphan Drugs: Publications and Perspectives

- Johnathan Goldsmith, MD, FACP, Acting Associate Director, Rare Diseases Program, Office of New Drugs, Center for Drug Evaluation and Research, FDA
- 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

Moderator: Christine Gatchalian, PhD, Director, Global Medical Writing, Amgen

Practical Implications of GPP3: Are You Prepared?

- Teresa L. (Terry) Peña, PhD, CQE, Executive Director, Global Medical Publications, BMS
### APAC-Focused Presentations

#### Advancing Good Publication Practices in the Asia-Pacific Region: Focus on India
- 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

#### Regional Challenges in Publication Planning
- Manon Boisclair, MS, (RN), ISMPP CMPP™, Director, Global Publication Operations Celgene
- Rhiannon Meaden, PhD, Director, Global Business Development, Adelphi Communications
- Jorge Moreno-Cantu, MS, PhD, ISMPP CMPP™, Global Scientific and Medical Publications Director, Merck
- Jill Sanford, MS, Director, Global Scientific Communications, Celgene
- **Moderator/Faculty:** Paul O’Grady, PhD, Senior Director, Global Scientific Communications, Novartis

#### Special Presentation
Establishing trust, demonstrating knowledge and gaining respect are key to building the foundation for good publication practice in the Asia-Pacific region: the ISMPP Asia-Pacific Education Task Force
Julliana Newman, Balaji Ganesan, Tim Collinson, Rebecca Lew, Bruce Shao, Kanaka Sridharan and Eric Yu

#### Poster #2: Awareness of international publication guidelines in Asia
Suchita Nath-Sain and Namita Bose

#### Poster #9: Trends in Southeast Asian articles in top-tier journals
Catherine Rees, Nicola Ryan, Thomas Drain, Kirandeep Perhar and Jiayang Chen

#### Poster #25: Adherence to Consolidated Standards of Reporting Trials (CONSORT) guidelines in manuscripts published from the Asia-Pacific region
Shruti Shah, Madhavi Patil, Vishal Goriya, and Vatsal Shah
POSTER WINNERS
Special Thanks - 11th Annual Meeting
Abstract Subcommittee

- Marc Eisenberg
- James Gurr
- Bhakti Kshatriya
- Sharon Suntag
- Holly Zoog

Record number of abstract submissions this year - 60!

40+ hours!
11th Annual Meeting Oral Presentations

Copyright Infringement: A Case Study
Manon Boisclair, MSc, (RN), ISMPP CMPP™, Director, Global Publication Operations, Celgene

Optimizing Scientific Poster Production
Joelle McCaslin, MA, ISMPP CMPP™, Associate Director, Medical Publications, Biogen

Monitoring Adherence to Good Publication Practices (GPP): Insights from a Global Biopharmaceutical Company
Sonia A. Schweers, PharmD, ISMPP CMPP™, Global Publication Practices Monitor, Medical Publications, Bristol-Myers Squibb
11th Annual Meeting Poster Winners

**BEST PRACTICE**

*Current medical writing practices: Identifying the optimal model for cost-effective and timely publications (Poster #11)*
Susan Pacconi, Dan Bridges and Robert Matheis

**ORIGINAL RESEARCH – TIE**

*Clinical trials: do the patients get the thanks they deserve? (Poster #5)*
Radhika Bhatia and Barrie Anthony

*Professional medical writing support improves the quality of reporting of randomized controlled trials (Poster #36)*
William Gattrell, Sally Hopewell, Kate Young, Stephen Lang, Paul Farrow, Richard White, Elizabeth Wager and Christopher Winchester

**VISUAL COMMUNICATION**

*Publication contracting made simple (Poster #14)*
George Samman and Jessica Bowler
CURRENT MEDICAL WRITING AND OPTIMAL PRACTICES: IDENTIFYING COST-EFFECTIVE AND TIMELY PUBLICATIONS

Susan Pacconi
Celgene Corporation
Senior Manager, Strategic Planning
Global Medical Affairs

Co-authors:
Susan Pacconi,1 Dan Bridges,2* Robert Matheis1
1. Celgene Corporation, Summit, NJ, USA; 2 Nucleus Global, London, UK; *DB conducted part of this research while employed by apothecom scopemedical, London, UK
Why Evaluate the Benefits and challenges of Differing Medical Writing Organizational Models?

• To understand current practices in medical writing across a broad range of pharmaceutical, biotech and device companies
• To assess the potential benefits of different medical writing models on key publication outcomes, including:
  • Control of deliverables/timelines
  • Flexibility and efficiency
  • Experience and continuity
  • Resources and volume of work
The Market Research

- We contacted publication directors and/or managers responsible for publication planning at **14 pharmaceutical, biotech and device companies** inclusive of Amgen, A-Z, J&J, Novartis Vaccine, Novo Nordisk, Pfizer, Roche, Sanofi and Vertex.

- The results: **9 (64%) participated** in live discussions including 3 responders sharing additional perspectives as part of a subsidiary, allowing for a maximum of **12 organizations providing data**.
**Data Points Collected**

The most important skills identified for internal medical writers were interpersonal stakeholder management, writing ability, scientific ability/knowledge and compliance knowledge.

Internal writers were most often used for supporting internal department publications, small projects, and business-critical publications.

<table>
<thead>
<tr>
<th>Skill</th>
<th>Company</th>
<th>Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliance knowledge</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Interpersonal/stakeholder management</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Pharma experience</td>
<td>✔️</td>
<td></td>
</tr>
<tr>
<td>Project management</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Scientific ability</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Therapeutic knowledge</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Writing ability</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>
The Results

This research demonstrates that a variety of medical writing models have evolved across organizations.
There is broad consensus that a hybrid model may provide the most effective approach.
Assessing the challenges and cost of implementing a hybrid model would need discussion and review by each organization.
Thank You

Susan Pacconi
Contact information:
spacconi@celgene.com
908.673.2374
Professional medical writing support improves the quality of reporting of randomized controlled trials

William Gattrell, Sally Hopewell, Kate Young, Stephen Lang, Paul Farrow, Richard White, Elizabeth Wager and Christopher Winchester
Disclosures

• Study funded by Oxford PharmaGenesis
• W Gattrell, K Young, P Farrow, R White and C Winchester are employees of Oxford PharmaGenesis, and P Farrow, R White and C Winchester are shareholders
• S Hopewell is a member of the Consolidated Standards of Reporting Trials (CONSORT) group
• S Lang is a former employee of Oxford PharmaGenesis
• E Wager is the owner of Sideview, which provides training and consultancy in medical writing
Medical writing is misunderstood and sometimes gets bad press
Our industry bodies say ...

“...medical writers can often improve the efficiency and effectiveness of manuscript preparation by working with the research team to develop clear and concise manuscripts in a timely fashion”\(^1\)

“...involving medical writers may therefore raise the standard of publications and accelerate the writing and publication process”\(^1\)

... but is there any evidence to support these statements?

Currently available evidence

“...When professional medical writers help authors prepare manuscripts, these manuscripts are less likely to be retracted for misconduct, are more compliant with best-practice reporting guidelines, and are accepted more quickly for publication.”

Woolley KL et al. Poor compliance with reporting research results – we know it’s a problem ... how do we fix it? *Curr Med Res Opin* 2012;28:1857–60


Identification and review of articles

With acknowledged medical writing support (n = 110)

BioMed Central articles describing RCTs

Quality of reporting¹,²

Quality of written English

Speed of acceptance

Is there a difference?

Without acknowledged medical writing support, random subset (n = 123)

RCT, randomized controlled trial
Higher rate of reporting of CONSORT items with medical writing support…

**CONSORT item (number)**

- Pre-defined primary outcome (6a)
- How sample size was determined (7a)
- Method used to generate random allocation (8a)
- Type of randomization (8b)
- Mechanism to implement random allocation sequence (9)
- Who generated the allocation sequence (10)
- Who was blinded (11a)
- Description of similarity of interventions (11b)
- Participant flow diagram (13)
- Dates defining recruitment and follow-up (14a)
- Trial registration (23)
- Access to study protocol (24)

**Relative risk (95% CI)**

- 1.77 (1.47–2.13)
- 1.39 (1.10–1.75)
- 0.97 (0.72–1.32)
- 2.03 (1.17–3.53)
- 0.99 (0.60–1.63)
- 1.16 (0.72–1.88)
- 1.24 (0.84–1.84)
- 1.96 (1.48–2.61)
- 2.04 (1.32–3.17)
- 1.64 (1.34–2.01)
- 7.83 (0.98–62.62)

**Items were chosen that are often poorly reported**

CI, confidence interval; CONSORT, Consolidated Standards of Reporting Trials; MW, medical writer
Irrespective of funding source

- Medical writing support was associated with enhanced reporting of CONSORT checklist items (≥ 50%) versus no medical writing support
  - Irrespective of industry funding
Improved quality of written English

- Medical writing support was associated with significantly better written English, as judged by peer reviewers:
  - Acceptable
  - Needs some language corrections before being published
  - Not suitable for publication unless extensively revised

MW, medical writer
Slight reduction in speed of acceptance

- Median time from submission to acceptance was longer for articles with medical writing support than for those without:
  - 23.9 versus 19.4 weeks ($p < 0.01$)
  - Attributable to increased time for peer review and responding to reviewers

![Diagram showing time (days) for different stages of article processing with and without medical writing support.](chart.png)

MW, medical writer
Conclusions

• Declared medical writing support was associated with higher quality reporting of RCTs in articles, compared with no writing support
  – Differences between the study groups, such as differences in funding source and publication year, do not explain our findings
• First study to demonstrate convincingly the value of medical writing support
• Full manuscript drafted

RCT, randomized controlled trial
BACK-UP SLIDE
**Study design**

**Search string:**
```
```

Search conducted 16 July 2014

**AND**
```
"medical writer" OR "medical writing" OR "editorial assistance"
```

- **n = 305**

**Remove duplicates**
- Exclude: study protocols, reviews, post hoc analyses, non-pharmacological interventions

**Check article to confirm medical writer involvement**

**Medical writer group (n = 110)**

**NOT**
```
"medical writer" OR "medical writing" OR "editorial assistance"
```

- **n = 10,688**

**Remove duplicates**
- Exclude: study protocols, reviews, post hoc analyses, non-pharmacological interventions

**Check article to confirm no medical writer involvement**

**No medical writer group (n = 123)**
11TH ANNUAL MEETING RESOURCES: WHERE TO FIND THEM
11th Annual Meeting Archives

1. Go to www.ISMPP.org, click on Education tab, then click on “Annual Meeting” in the drop box.

2. Click on “Members Only: Annual Meeting Archive”

3. Choose “11th Annual Meeting of ISMPP” from the Archives
Additional Meeting Resources

• ISMPP Interactive News Network: https://www.youtube.com/results?search_query=ismpp+2015
• Twitter hashtag: #ISMPP
• Current Medical Research and Opinion supplement: http://informahealthcare.com/loi/cmo/
  – Member abstracts from 11th Annual Meeting of ISMPP and 2015 European Meeting of ISMPP
  – Editorial by BOT Chair Terry Peña
It Takes a Village…

ISMPP Staff

Program & Workshop Committees

ISMPP BOT

ISMPP Members!
12th Annual Meeting of ISMPP
April 11 - 13, 2016

Gaylord National Resort & Convention Center
National Harbor, MD, USA
THANK YOU
• To ask a question, please type your query into the Q&A box.

• To ensure anonymity, before sending please choose the drop-down box option, "Hosts, Presenters and Panelists." Otherwise, **ALL** audience members will be able to see your submitted question.

• Due to the nature of this particular ISMPP U topic and the fact that it is an overview of many individual presentations, we may not be able to answer all questions. We are happy to follow up with specific faculty after the ISMPP U if needed.
UPCOMING ISMPP U'S

• **July 22, 2015**
  • Topic: Real World Evidence
  • Presenters:
    • Richard White, MA, PhD, Commercial Director, Oxford PharmaGenesis Ltd
    • Timothy Koder, PhD, Account Director, Oxford PharmaGenesis Ltd

• **September 23, 2015**
  • Topic: Predatory Journals
  • Presenter:
    • Jeffrey Beall, MA, MSLS, Scholarly Initiatives Librarian/Associate Professor, Auraria Library, University of Colorado, Denver, Colorado
Upcoming APET ISMPP U

- **July 14, 2015 – 7:30am India-IST**
  - Topic: Waking the Sleeping Tiger: Overview of Clinical and Publications Practices in India
  - Presenter:
    - Ajit Nair – Head Global Medical and Clinical Services, Novartis Healthcare Pvt Ltd., India

<table>
<thead>
<tr>
<th>US (West)</th>
<th>US (East)</th>
<th>UK</th>
<th>India</th>
<th>China</th>
<th>Japan, Korea</th>
<th>Australia (East)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 pm</td>
<td>10 pm</td>
<td>2:00 am</td>
<td>7:30 am</td>
<td>10:00 am</td>
<td>11:00 am</td>
<td>1:00 pm</td>
</tr>
<tr>
<td>Monday July 13</td>
<td>Monday July 13</td>
<td>Tuesday July 14</td>
<td>Tuesday July 14</td>
<td>Tuesday July 14</td>
<td>Tuesday July 14</td>
<td>Tuesday July 14</td>
</tr>
</tbody>
</table>
THANK YOU FOR ATTENDING!

• We hope you enjoyed today’s presentation. Please take a few moments to complete the survey that will appear on your screen immediately after the presentation. We depend on your valuable feedback and take it into account as we develop future educational offerings.