DEAR COLLEAGUES:

To be effective, medical publication professionals must stay current with the continuous evolution of guidelines and regulations, occasionally make judgment calls on ethical “grey areas,” and navigate a changing landscape while upholding good publication practices. To help members meet these challenges, this year’s meeting dispenses with the theoretical and focusses on the practical skills that drive successful publication delivery.

Every year, we work hard to retain content that meets with favorable response, discard that which does not, and adapt educational offerings according to member feedback. Thus we have increased the number of roundtable options from two to three, and we are repeating and expanding the popular “speed research” session, where member authors are allowed a minimal amount of time to convey the highlights of their research. The importance of GPP3 cannot be overstated, but as it has been available on-line since August, we are taking a novel approach via relevant case studies and queries inspired by responses to a recent member survey.

We have designed content that reflects the meeting theme, *Publication Planning in Practice: Overcoming Challenges in the Age of Transparency*, in the hope that attendees will leave the 2016 European Meeting of ISMPP with enduring messages and ideas they can apply the day they return to the office. This real-world approach will be carried out over two days of educational programming that covers GPP, RWE, data transparency, journal trends, metrics/altmetrics, peer review, authorship, plagiarism, fraud/redaction, pre-publication, and copyright, and features roundtables, poster and oral presentations, opportunities for collaborative exchange and networking, and exhibits.

We hope that these efforts and this year’s emphasis on the fundamentals of medical publication meet with your approval. ISMPP members have the potential, the vision, the knowledge, the wherewithal and the experience to help ISMPP move successfully into the future. We trust that convening each year in this forum will go a long way toward keeping members proactive, engaged, and eager to help ISMPP shape the future of medical publications.

Sincerely,

Teresa L. (Terry) Peña, PhD, CQE
Executive Director, Global Medical Publications
Bristol-Myers Squibb
Chair, ISMPP Board of Trustees

Fiona Plunkett, PhD, ISMPP CMPP™
Client Services Director, Health Interactions
Chair, European Meeting Programme Committee
PUBLICATION PLANNING IN PRACTICE: OVERCOMING CHALLENGES IN THE AGE OF TRANSPARENCY
<table>
<thead>
<tr>
<th>Time</th>
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<tr>
<td>9:00–10:00</td>
<td>Registration and Continental Breakfast</td>
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<tr>
<td>10:00–10:15</td>
<td>Welcome to the 2016 European Meeting of ISMPP</td>
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<tr>
<td></td>
<td>Fiona Plunkett, PhD, ISMPP CMPP™</td>
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<td></td>
<td>Chair, European Meeting Programme Committee</td>
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<tr>
<td>10:15–10:45</td>
<td>2015: A Year in Review</td>
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<td>A retrospective of key events and emerging issues in the medical publications space throughout the year</td>
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<td><strong>Faculty</strong></td>
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<td>Iain Hrynaszkiewicz, PhD</td>
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<td></td>
<td>Head of Data and Health &amp; Social Sciences Publishing</td>
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<td>Nature Publishing Group/Palgrave Macmillan (UK)</td>
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<td><strong>Moderator</strong></td>
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<td></td>
<td>John Gonzalez PhD, ISMPP CMPP™</td>
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<td>Publications Director, AstraZeneca Pharmaceuticals (UK)</td>
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</table>
**MORNING**

### 10:45–11:45 GPP3: Member-Proposed Case Studies and Panel Discussion

A discussion of the key points included in the recent Good Publication Practice 3 (GPP3) publication and case-based presentations inspired by a recent ISMPP member survey, with a panel comprised of guideline authors, representatives from industry and agencies, and a journal editor.

**Faculty**

- **Dan Bridges, MS, PhD, ISMPP CMPP™**  
  Regional Director-Europe  
  Nucleus Global (UK)

- **Ana Marušić, MD, PhD**  
  Professor of Anatomy, Chair, Department of Research in Biomedicine and Health, University of Split; Editor in Chief, *Journal of Global Health* (Croatia)

- **Elizabeth Wager, MA, PhD**  
  Publications Consultant  
  Sideview (UK)

- **Nicole Rapior, MS, PhD**  
  Head of Global Scientific Publications  
  Boehringer Ingelheim Pharma GmbH & Co. KG (Germany)

**Moderator**

- **Dawn Lobban, PhD, ISMPP CMPP™**  
  Director, Medical Strategy  
  Spirit Medical Communications (UK)

### 11:45-12:15 Real World Evidence and Publications

The relatively new discipline of real world evidence (RWE) is similar to traditional randomized clinical trial programs in that both use large datasets to determine performance of specific drugs. However, although clinical trials usually exclude participation of those not meeting precisely defined criteria, RWE utilizes observational data such as electronic medical records, claims information, and patient feedback to determine how health care professionals use medicines in diverse settings and how patients use them when not constrained by parameters of a controlled environment. Real-world observation offers valuable insights not obtainable via randomized controlled studies. This session explores the risks and benefits of planning and developing publications reporting results of real-world studies, and the similarities and differences vis-à-vis traditional publications stemming from clinical trials. Ample time for Q&A and audience input will conclude the session.

**Faculty**

- **Richard White, MA, PhD**  
  Commercial Director, Oxford PharmaGenesis Ltd (UK)

### 12:15–13:15 Lunch
Tuesday, 19 January 2016

**AFTERNOON**

**13:15-14:45 Roundtables**
Utilizing case studies as a starting point and designed for optimal interaction, this year’s roundtables provide the ideal setting for peer-to-peer engagement and expert-led consideration of issues fundamental to the role of publication professionals. In line with member recommendations, attendees will now be able to explore 3 different topics during the 90-minute session. Many qualify for CMPP recertification credit (check status on Meeting Day), with some especially targeted toward participants with 5 years or fewer of publication experience.

**Table Topics/Moderators:**

- **Best practice on authorship**
  - Angela Cairns, ISMPP CMPP™
  - Ashfield Healthcare Communications
  - Elizabeth Wager, MA, PhD, Sideview

- **Data transparency & consistency**
  - Fergus Sweeney, EMA
  - Laurence Rouxhet, ISMPP CMPP™, GSK

- **Devices/Diagnostics Publications**
  - Patrice Becker, Medtronic

- **HEOR Publications: Why do we need them?**
  - Jasim Uddin, PhD & Sean Walsh, PAREXEL Access Consulting

- **Industry-agency relationships**
  - (Introductory)
  - Tom Grant, PhD, Complete HealthVizion

- **Multidisciplinary working**
  - Kay Koyander, AstraZeneca
  - Steve Winter, PhD, AstraZeneca

- **Patient lay summaries**
  - Rachel Jones, PharmD, AstraZeneca
  - Richard Stephens, Patient Advocate/Blogger

- **Publications metrics based on social media**
  - Ben McLeish, Altmetric
  - Tom Rees, MS, PhD, ISMPP CMPP™, PAREXEL International

- **Publications steering committees**
  - TBC

- **Publications strategy (Introductory)**
  - Ciara O’Donovan, MSc, PhD
  - Actelion
  - Jennifer Van Zwieten, MS, ISMPP CMPP™
  - Succinct Communications

- **Transfer of Value: The EU Perspective**
  - Antonia Panayi, PhD, Shire
  - Andy Powrie-Smith, EFPIA

- **Faculty**
  - Slavka Baronikova, PharmD, PhD, ISMPP CMPP™
    - Publications Lead, Shire (Belgium)
  - Ana Marušić, MD, PhD
    - Professor of Anatomy, Chair, Department of Research in Biomedicine and Health University of Split
    - Editor in Chief, *Journal of Global Health* (Croatia)
  - Andy Powrie-Smith
    - Director of Communications, EFPIA
  - Laurence Rouxhet, ISMPP CMPP™
    - Head of Publications Management & Web Disclosures
    - GlaxoSmithKline Biologicals (Belgium)
  - Fergus Sweeney
    - Head of Inspections & Human Medicines
    - Pharmacovigilance Division
    - European Medicines Agency (EMA)

**14:45-15:15 Afternoon break and visit exhibits**

**15:15-16:45 Data and Financial Transparency Reporting**
Over the last few years, requirements for transparency and data reporting have become more widespread, with potentially substantial consequences for those responsible for scientific publication planning. Recently, the European Medicines Association (EMA) and European Federation of Pharmaceutical Industries and Associations (EFPIA) have implemented significant changes to existing rules and directives. This session features an in-depth discussion of these revised mandates and how they affect publication planning; representatives from EMA, EFPIA and industry will provide perspective. A panel discussion of key issues will conclude the session.

The faculty has asked that members familiarize themselves with the following background information on recent transparency initiatives before attending the session:


**Faculty**

- Slavka Baronikova, PharmD, PhD, ISMPP CMPP™
  - Publications Lead, Shire (Belgium)
- Ana Marušić, MD, PhD
  - Professor of Anatomy, Chair, Department of Research in Biomedicine and Health University of Split
  - Editor in Chief, *Journal of Global Health* (Croatia)
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  - GlaxoSmithKline Biologicals (Belgium)
- Fergus Sweeney
  - Head of Inspections & Human Medicines
  - Pharmacovigilance Division
  - European Medicines Agency (EMA)

**Moderator**

- Thomas Wicks
  - Chief Strategy Officer
  - TrialScope (USA)
16:45-17:00  ISMPP Update

It is a challenging time for the medical publications industry as ISMPP moves into its eleventh year of interpreting and applying evolving standards and guidelines for appropriate scientific exchange. As the society expands into new geographical regions during a time of global transformation, the hope is to continue to convene and bring together inspired publication professionals each year in forums like the 2016 European Meeting. Find out about ISMPP’s 2015 journey, developments within the CMPP program, and aspirations for 2016 in this brief update.

Faculty
John Gonzalez, PhD, ISMPP CMPP™
Publication Director, Global Medical Affairs
AstraZeneca (UK)

Al Weigel, MEd, ISMPP CMPP™
President and COO, ISMPP

17:00–18:30  ISMPP member poster presentation assembly and networking reception

Enjoy wine and hors d’oeuvres while catching up with old friends, making new contacts, and discovering the research of fellow ISMPP members.
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<th>Time</th>
<th>Session</th>
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<td>8:00–9:00</td>
<td><strong>Registration and Continental Breakfast</strong></td>
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<tr>
<td>9:00–10:30</td>
<td><strong>Publishing and Journals: Practical Considerations for Medical Publication Professionals in 2016</strong></td>
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<td>The models, publication offerings and concerns of journals and their publishers continue to evolve. Social media, altmetrics, digital offerings and mega-journals provide publication planners and authors with new features not available in the past. Open access and peer review models have been continuously enhanced and adapted. Many of these novel features are only possible because of the benefits associated with our new digital age. However, this digital era also brings its own challenges. Fraud and plagiarism are on the increase, and a new phenomenon – the “predatory journal” – has arisen in recent years. Additionally, authors now have the opportunity to communicate research online prior to publication. This session provides a practical guide for navigation of these often complicated issues. Part 1 offers an overview of factors to consider when choosing a journal in 2016. Part 2 is a discussion of key considerations affecting publishers/editors as we embark on the new year, with a focus on implications for medical publication professionals. The session will wrap up with an undoubtedly lively Q&amp;A and panel discussion.</td>
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<td><strong>Faculty:</strong></td>
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<td></td>
<td>Amy Bourke-Waite</td>
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<td>Tom Rees, MS, PhD, ISMPP CMPP™</td>
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<td>Senior Communications Manager</td>
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<td>Scientific Strategy Advisor</td>
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<td>Springer Nature (UK)</td>
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<td>PAREXEL International (UK)</td>
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<td>Maria Kowalczuk, PhD</td>
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<td>Anna Sharman, PhD</td>
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<td>Biology Editor, Research Integrity Group</td>
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<td>Founder, Cofactor Ltd (UK)</td>
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<td>BioMed Central (UK)</td>
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<td><strong>Moderator:</strong></td>
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<td></td>
<td>Elizabeth Wager, MA, PhD</td>
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<td></td>
<td>Publications Consultant, Sideview (UK)</td>
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<td>10:30–11:00</td>
<td><strong>Morning break and visit exhibits</strong></td>
</tr>
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Wednesday, 20 January 2016

**MORNING**

11:00-Noon  “**Speed**” Research

An encore of last year’s popular member presentation session, whereby authors of abstracts selected by blinded peer review must present their research in 8 minutes or less. Moderated Q&A follows each presentation.

**Presenters:**

- **Sana Eljamel**
  Costello Medical Consulting Ltd (UK)
  Are we there yet? Does current practice in acknowledging professional medical writing support meet the requirements of GPP3?

- **Will Gattrell, PhD**
  Research Evaluation Unit, Oxford PharmaGenesis Ltd (UK)
  Department of Mechanical Engineering & Mathematical Sciences, Oxford Brookes University
  Does professional medical writing support increase the impact of articles reporting randomized controlled trials?

- **Bernard Kerr**
  Succinct Medical Communications (UK)
  Reporting of positive and negative clinical trial results in the age of mandatory clinical trial registration

- **Andrew Desson, MS, ISMPP CMPP™**
  Shire (Switzerland)

- **Christopher Winchester, PhD**
  Research Evaluation Unit, Oxford PharmaGenesis (UK)
  Journal choice: Which factors do you value when submitting a manuscript?

- **Daniel Portsmouth**
  Boehringer Ingelheim Pharma GmhH & Co. KG (Germany)
  Benchmarking of publicly disclosed clinical trial publication policies among pharmaceutical companies

**Moderator:**

- **Ryan Woodrow, ISMPP CMPP™**
  Director, Aspire Scientific Ltd (UK)

Noon-13:00  Lunch
Wednesday, 20 January 2016

**AFTERNOON**

13:00-14:30  **Parallel Sessions: Other Guidelines and Regulations Impacting Publication Planners**

Attendees can choose 2 of 3 available topics that are of most interest and applicability to their publications roles: (1) Corporate Integrity Agreements, (2) Copyright, and (3) EQUATOR. Presenters will take a practical approach, sharing their personal experiences and using real-world examples to offer comprehensive definitions and evidence as to how and why publication professionals need to have more than a passing knowledge of each concept. Each session is 45 minutes long, with plenty of time for audience participation and Q&A.

**Faculty:**
- Gina D’Angelo, MBA, PharmD, ISMPP CMPP™
  Director, Global Scientific Publications, Shire (USA)
- Jesper Konradsen, Candidatus magisterii
  Global Publications Director
  Novo-Nordisk Health Care AG (Switzerland)
- Jackie Marchington, PhD, ISMPP CMPP™
  Director of Operations, General Manager
  Caudex (UK)
- Ana Marušić, MD, PhD
  Professor of Anatomy; Chair,
  Department of Research in Biomedicine and Health
  University of Split; Editor in Chief, *Journal of Global Health* (Croatia)
- John McConnell
  Editor, *The Lancet* (UK)
- Abbie Pound
  Head of Medical Communications
  Sudler & Hennessy (UK)
- Iveta Simera, PhD
  Deputy Director, EQUATOR Network (UK)
- Elizabeth Wager, MA, PhD
  Publications Consultant, Sideview (UK)

**Moderators:**
- Margaret Haugh, PhD, ISMPP CMPP™
  President
  MediCom Consult (France)
- Sophie Inwood
  Account Director, Client Services
  Succinct Medical Communications (UK)
- Laura McGovern, ISMPP CMPP™
  Associate Editorial Director, Scientific Services
  Cognito Medical (UK)

14:30-15:00  **Afternoon break and visit exhibits**

15:00-15:45  **Keynote Address: Publications: Where do we go from here?**

Vitek Tracz, Chairman of the Science Navigation Group, founder of BioMed Central

15:45-16:00  **Awards, exhibitor passport raffle**

16:00-16:10  **Closing comments, meeting adjourns**
Are clinical trial data published in a timely manner?
James Wallis, Amy MacLucas, & Nina C Kennard
iS LifeScience, Farnham, UK

Are we there yet? Does current practice in acknowledging professional medical writing support meet the requirements of GPP3?
Sana Eljamel & Simon Page
Costello Medical Consulting Ltd, Cambridge, UK

Benchmarking of publicly disclosed clinical trial publication policies among pharmaceutical companies
Daniel Portsmouth, David Haworth, & Elizabeth Ward
*Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany; AAshfield Healthcare Communications, Macclesfield, Cheshire, UK

Copyright infringement: A case study
Manon Boisclair, Robert Mathies, Keisha Peters, Adriana Star, Niina Nuottamo, & Anna Georgieva
*Celgene Corporation, Summit, NJ, USA; **Excerpta Medica, Amsterdam, The Netherlands

Current medical writing practices: Identifying the optimal model for effective and timely publications
Susan Pacconi, Dan Bridges, & Robert Mathies
*Celgene Corporation, Summit, NJ, USA; **Nucleus Global, London, UK

Does professional medical writing support increase the impact of articles reporting randomized controlled trials?
William Gattrell, Paul Farrow, Elizabeth Costigan, Catherine Sheard, Richard White, & Christopher Winchester
*Research Evaluation Unit, Oxford PharmaGenesis Ltd, Oxford, UK; **Department of Mechanical Engineering & Mathematical Sciences, Oxford Brooks University, Oxford, UK; **Department of Zoology, University of Oxford, Oxford, UK

Do patients have a voice in medical journals?
Amy MacLucas & Nina C Kennard
iS LifeScience, Farnham, UK

The impact of data extrapolation on publication plans for biosimilars
Holly Kramer, Tony Reardon, & Fiona Bolland
Spirit Medical Communications Ltd, Cambridge, UK

Is there a need for uniform poster presentation guidelines across conferences?
Kunbi Ayo-Okanlawon, Amy MacLucas, & Nina C Kennard
iS LifeScience, Farnham, UK

Journal choice: Which factors do you value when submitting a manuscript?
Noëlle L O’Regan, Andrew Desson, Catherine Hill, Antonia Panayi, Christopher Winchester, & Slavka Baronikova
*Research Evaluation Unit, PharmaGenesis London, UK; **Shire, Nyon, Switzerland; **Research Evaluation Unit, Oxford PharmaGenesis, Oxford, UK; **School of Medicine, Pharmacy & Health, Durham University, UK

Journal preferences and changing views about open access: Results from the 2015 Author Insights survey
Neil Adams, Kathleen Lyons, Dan Penny, Katie Allirr, & Alison Wrigley
**Nature Publishing Group, New York, USA; **Nature Publishing Group, London, UK

Reporting of positive and negative clinical trial results in the age of mandatory clinical trial registration
Bernard Kerr, Elin Siddall, André da Luz, Veronique Buchanan, Radha Tailor, Rajpreet Grewal, Sara Black, & Rachel Spice
**Succinct Medical Communications, Marlow, UK; **Succinct Medical Communications, London, UK

Systematic Literature Reviews in Oncology: A Cross-Sectional Analysis of Ambiguity in Publication Practice
Carole Jones, Robyn Fowler, Sadiq Lula, Rebecca McCracker, & Karen Smoyer
**Envision Pharma Group, London, UK; **Envision Pharma Group, Southport, CT, USA; **Envision Pharma Group, Philadelphia, PA, USA

Systematic versus narrative reviews: How do they compare, and what does that tell us about their role in scientific exchange?
Tom Rees, Shweta Takvari, Debbie Sherwood, Shelley Lindley, & Manu Seghal
**PAREXEL International Medical Communications, Worthing, UK; **PAREXEL HERON Commercialization, Chandigarh, India; **PAREXEL International Medical Communications, Uxbridge, UK

Use of reporting standards for consistent reporting in medical publications
Matthew Booth, Natalie Dennis, Leigh Prevost & Carol Richter
PAREXEL, Worthing, UK

Use of supplementary materials in the era of data transparency
Lynda Chang, Glynis Davies, Tom Graney, & Lianne Young
*Complete HealthVizion, Glasgow, UK; **Complete HealthVizion, Macclesfield, UK

Poster Presentations

Systematic versus narrative reviews: How do they compare, and what does that tell us about their role in scientific exchange?
Tom Rees, Shweta Takvari, Debbie Sherwood, Shelley Lindley, & Manu Seghal
**Envision Pharma Group, London, UK; **Envision Pharma Group, Southport, CT, USA; **Envision Pharma Group, Philadelphia, PA, USA

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**Envision Pharma Group, London, UK; **Envision Pharma Group, Southport, CT, USA; **Envision Pharma Group, Philadelphia, PA, USA
ISMPP would like to express its sincere appreciation to the exhibitors and sponsors of the 2016 European Meeting of ISMPP.
If you are interested in learning about the ISMPP Corporate Sponsorship programs that are available, please email ISMPP at ismpp@ismpp.org.
ISMPP expresses its sincere appreciation to the following, and to all others who have provided support for a successful European Meeting.

Programme Committee
Dan Bridges
John Gonzalez
Margaret Haugh
Gillian Hill
Sophie Inwood
Dawn Lobban
Laura McGovern
Louise Norbury
Anne Ozog
Antonia Panayi (Vice Chair)
Fiona Plunkett (Chair)
Susan Scott
Joanne Walker
Ryan Woodrow

Abstract Subcommittee
Jason Gardner
Margaret Haugh
Gillian Hill
Dawn Lobban
Susan Scott
Ryan Woodrow (Chair)

ISMPP also thanks its dedicated staff for their contributions to the 2016 European Meeting of ISMPP, and acknowledges the following:
Neil Thompson, Managing Director, Red White Blue Ltd. – overall meeting and logistic support
Creative Department, MedErgy – graphic support

See you in January 2017 for the next European Meeting of ISMPP!
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And, be sure to share your key takeaways and spur discussions through our ISMPP LinkedIn Group!
PUBLICATION PLANNING IN PRACTICE:
OVERCOMING CHALLENGES IN THE AGE OF TRANSPARENCY