ISMPP: A Decade of Achievements

2005–2015
Table of Contents

- Objectives
- Introduction to ISMPP
- ISMPP History and Important Milestones
- ISMPP Today: Facts and Figures
- Integrity and Transparency
- Standards and Best Practices
- Education, Advocacy, and Professional Collaboration
- Future Goals and Plans
- Summary and Take-away Messages
Objectives

• Document ISMPP’s achievements over the past 10 years

• Provide ISMPP members with a resource to reinforce requests to their management for membership, meeting attendance, and/or sponsorship support
ISMPP was founded in 2005 as a nonprofit professional membership organization dedicated to advancing the professional field of publication planning and other aspects of the publication of biomedical research

www.ismpp.org

<table>
<thead>
<tr>
<th>Timothy D. Bacon</th>
<th>Ross A. Baker</th>
<th>Carolyn S. Clark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joanne Conaty</td>
<td>Elizabeth Faust</td>
<td>Elizabeth Field</td>
</tr>
<tr>
<td>Stan Heimberger</td>
<td>Laurence J. Hirsch</td>
<td>Richard F. Lamb</td>
</tr>
<tr>
<td>Gary McQuarrie</td>
<td>Robert Norris</td>
<td>Gene P. Snyder</td>
</tr>
</tbody>
</table>

Supported by Kimberly Goldin, now General Manager of ISMPP
ISMPP Mission and Vision

**Mission Statement**
Advance the medical publication profession globally through:

- Enhanced integrity and transparency in medical publications
- Improved standards and best practices
- Education, advocacy, and professional collaboration

**Vision**
To become the leading global authority on the ethical and effective publication of medical research to inform treatment decisions
ISMPP Strategic Imperatives 2014-2015

1. Evolve and visibly advocate best practices
2. Broaden global presence and outreach
3. Collaborate and build relationships with key external stakeholders
4. Increase membership and sponsors, effectively supporting their current and future needs
5. Align internal infrastructure, resources and processes with evolving requirements
ISMPP History and Important Milestones
Practice-Changing Events

**Driving the Value of Publications: An Integrated Approach**

**Setting the Course: Navigating Today's Current Publications Landscape**

**Ensuring Integrity in Medical Publications: Conflicts, Credibility and Collaboration**

**Mapping Success: New Rules of the Road for Medical Publications**

**Defining Professionalism in Medical Publications: Transparency, Objectivity, and Ethics**

<table>
<thead>
<tr>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joint Position papers on Clinical Trial Information</td>
<td>Open peer review</td>
<td>Clinicaltrials.gov FDAAA</td>
<td>Senator Grassley’s ghostwriting accusations</td>
<td>GPP2 and ISMPP CMPP™</td>
</tr>
</tbody>
</table>

US: Senator Grassley’s investigation and report into off-label use and promotion
And the Beat Goes On…

Delivering Value and Driving Advocacy in Medical Publications

Anticipating Change in Medical Publications: Leading Now for the Future

Practical Solutions for a Complex Medical Publications World

Empowering the Medical Publication Community to Advance the Profession

Leading Through Collaboration

2010
Revised ICMJE guidelines

ICMJE

Joint Position on Publication of Clinical Trial Results in the Scientific Literature

US Sunshine Act

2011
EudraCT confidentiality lifted, launch of current database

BMJ Data Sharing Campaign

2012
ICMJE recommendations

GSK opens patient-level data to external researchers

AllTrials Campaign

2013
PLOS journals require authors to provide data availability statement

New BMJ policy institutes patient-centric approach to publications

PhRMA/EFPIA Principles on Responsible Data Sharing

2014

Practical Solutions for a Complex Medical Publications World

Empowering the Medical Publication Community to Advance the Profession

Leading Through Collaboration
ISMPP Today:
Facts and Figures
A Growing Membership

Number of Members

2006: 322
2007: 584
2008: 710
2009: 895
2010: 1003
2011: 1035
2012: 1013
2013: 1331
2014: 1463

*a2014 figures through April 13, 2015.*
Membership Trends by Sector

Industry and Agency continue to dominate membership

- Agency/CRO: 49%
- Industry: 37%
- Other: 8%
- Publisher: 5%
- Technology: 1%
- Academia: <1%

![Graph showing membership trends by sector from 2006 to 2014.](image-url)
International Membership

- North America: 62%
- United Kingdom: 22%
- All other Europe: 7%
- Asia-Pacific: 7%
- Other: 2%
Asia-Pacific Membership

- Successful outreach to Asia-Pacific region
- AP Leadership Summits in August 2014:
  - Tokyo, Japan and Beijing, China
  - In concert with Asia Pacific Advisory Committee (APAC)

![Bar Chart]

Number of Members

- 2009: 5
- 2010: 9
- 2011: 14
- 2012: 28\(^a\)
- 2013: 46
- 2014: 71
- 2015: 109\(^b\)

\(^a\) Associate Member dues adopted October, 2012 ($95 USD).

\(^b\) As of March 17, 2015.
Reasons for Joining ISMPP

- Ability to register for ISMPP annual meetings: 29%
- Access to monthly ISMPP U: 11%
- Access to ISMPP Archives: 14%
- Networking: 21%
- Other: 18%
- Professional development: 5%
- To serve/advance the profession: 2%

N = 339
Feb-July 2013
Corporate and In-Kind Sponsors

- Comprehensive and multi-tiered ISMPP Corporate Sponsorship Program, which provides substantial benefits at every level
  - Titanium, enhanced Platinum, Platinum, Gold, Silver, and Bronze levels

- 30 corporate sponsors
  - Pharmaceutical companies
  - Medical communications agencies
  - Biotech/device companies
  - Publishers

- 3 In-Kind Sponsors
  - Medical communication agencies
Integrity and Transparency
Prior to ISMPP, the landmark guidelines on Good Publication Practice (GPP) were developed with the aim of ensuring that “clinical trials sponsored by pharmaceutical companies are published in a responsible and ethical manner.”

Good publication practice for pharmaceutical companies

Elizabeth Wager¹, Elizabeth A. Field² and Leni Grossman³

GPP2: Evolving Requirements


- To address legislative, guidance, and ethical developments since 2003, and to reinforce the aims of the 2003 GPP publication, ISMPP convened a Steering Committee to develop a revised Good Publication Practice document, which is now known as GPP2.
GPP2 → GPP3

**Integrity in Publication Planning**

- **GPP2** provided guidance on the following:
  - Roles of authors, sponsors, and other contributors
  - Reimbursement and honoraria
  - How to establish a publication steering committee
  - Role of professional medical writers
  - Recommendations for publication planning and documentation

- **GPP3** is in progress
  - Submitted in February 2015
The Sunshine Act Task Force

• The Sunshine Act Task Force was established by ISMPP to:
  – Follow the financial and transparency issues in both the US and globally
  – Understand the details and requirements of the US National Physician Payment Transparency Program: Open Payments
  – Provide information and tools to our membership with respect to the implications of the Sunshine Act on medical publications
Standards and Best Practices
Code of Ethics

- ISMPP promotes high standards for professional ethics and practices and encourages members to meet such standards.

- Members should act in a manner that promotes integrity and reflects positively on the individual professional, ISMPP, and the medical publication profession, consistent with accepted ethical and legal principles.

- Current Code of Ethics released in 2011 (www.ismpp.org/ethics)
Certification Program

• The Certified Medical Publication Professional (CMPP) credential certifies the following:
  – 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

• Members have provided feedback on the importance of certification in a profession that is under intense scrutiny

• Code of Conduct introduced in 2014 (www.ismpp.org/code-of-conduct)

• Increasingly, organizations are adding the CMPP credential to their employment requirements
Ongoing Development for CMPP

- As of December 31, 2014 there were 971 CMPPs
  ~75% of the ISMPP membership are CMPPs
  ~5% of CMPPs are from Asia-Pacific (and growing)

- Accreditation
  - Multi-year effort to achieve accreditation from the National Commission for Certifying Agencies (NCCA)
  - Identify and document compliance with each standard
  - Writing teams forming to develop the necessary narratives
  - Pending application submission
Education, Advocacy, and Professional Collaboration
# ISMPP Educational Activity

<table>
<thead>
<tr>
<th>Activity</th>
<th>Program</th>
<th>Attendance</th>
<th>Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Meeting</td>
<td>Sessions, panels, and roundtable discussions on key issues</td>
<td>~500</td>
<td>Since 2005</td>
</tr>
<tr>
<td>European Meeting</td>
<td>Similar in scope to the Annual Meeting with a focus on European publication practices</td>
<td>~200</td>
<td>Since 2010</td>
</tr>
<tr>
<td>Workshops</td>
<td>Given at the Annual/European Meeting</td>
<td>Depends on the topic</td>
<td>Ongoing</td>
</tr>
<tr>
<td>ISMPP U</td>
<td>Monthly webinars on timely issues; audio/slides available via ISMPP Archive</td>
<td>&gt;200</td>
<td>Ongoing</td>
</tr>
<tr>
<td>ISMPP U Asia-Pacific</td>
<td>FREE quarterly time zone-friendly webinars on issues relevant to the Asia-Pacific region</td>
<td>&gt;100</td>
<td>Since 2014</td>
</tr>
</tbody>
</table>

- Generate and disseminate research
- Share best practices
- Forum for professional collaboration
# Annual Meeting – Topics

<table>
<thead>
<tr>
<th>Year</th>
<th>Program Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>Optimizing Scientific Values: Smart and Systemic Approaches to Medical Publications</td>
</tr>
<tr>
<td>2014</td>
<td>Leading Through Collaboration</td>
</tr>
<tr>
<td>2013</td>
<td>Empowering the Medical Publication Community to Advance the Profession</td>
</tr>
<tr>
<td>2012</td>
<td>Practical Solutions for a Complex Medical Publications World</td>
</tr>
<tr>
<td>2011</td>
<td>Anticipating Change in Medical Publications: Leading Now for the Future</td>
</tr>
<tr>
<td>2010</td>
<td>Delivering value and driving advocacy in medical publications</td>
</tr>
<tr>
<td>2009</td>
<td>Defining Professionalism in Medical Publications: Transparency, Objectivity, and Ethics</td>
</tr>
<tr>
<td>2008</td>
<td>Mapping Success: New Rules of the Road for Medical Publications</td>
</tr>
<tr>
<td>2007</td>
<td>Ensuring Integrity in Medical Publications: Conflicts, Credibility &amp; Collaboration</td>
</tr>
<tr>
<td>2006</td>
<td>Setting the Course: Navigating Today’s Current Publications Landscape</td>
</tr>
<tr>
<td>2005</td>
<td>Driving the Value of Publications: An Integrated Approach</td>
</tr>
</tbody>
</table>
## EU Meeting – Topics

<table>
<thead>
<tr>
<th>Year</th>
<th>Program Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>Medical Publications for Better Patient Care: Integrity, Innovation, and Impact</td>
</tr>
<tr>
<td>2014</td>
<td>A New Era in Global Medical Publications</td>
</tr>
<tr>
<td>2013</td>
<td>Doing the Right Thing and Doing Things Right</td>
</tr>
<tr>
<td>2011</td>
<td>Trends, Transparency and Trust: From Insights to Action</td>
</tr>
<tr>
<td>2010</td>
<td>Inaugural European Meeting of ISMPP</td>
</tr>
</tbody>
</table>
ISMPP University

• Monthly webinars, free to ISMPP members

• Topics are chosen to appeal to a broad range of membership sectors
  – Academics, journal editors/publishers, HEOR groups, CROs
  – Topics specific to geographic regions (eg, Asia-Pacific)

• Webinars also available to select invited groups
  – For example, those involved in Patient-reported outcomes, epidemiologic research, diagnostics/medical devices, vaccines, consumer health, aesthetics

• Presenters may be internal ISMPP members or external experts
Advocacy and Collaborations

• The ISMPP Advocacy initiative seeks to improve understanding on:
  – The essential value of medical publications in making medical research public, and ultimately advancing healthcare
  – The appropriate role and underlying value of medical publication professionals in this process

• ISMPP Outreach activities include:
  – Approaching industry societies (eg, ABPI, PhRMA, BIO, Advamed) to determine common goals
  – Undertaking collaborations with related professional organizations (eg, AMWA, EMWA, ISPOR, and others) to strengthen education and best practice initiatives
Medical Publishing Insights and Practices Initiative (MPIP)

- The MPIP initiative was founded in 2008 by members of the pharmaceutical industry and ISMPP (www.mpip-initiative.org)

- Vision
  - To develop a culture of mutual respect, understanding, and trust between journals and pharma that will support more transparent and effective dissemination of results from industry-sponsored trials

- Goals
  - Understand issues and challenges in publishing industry-sponsored research
  - Identify potential solutions to increase transparency and trust
  - Promote more effective partnership between sponsors and journals to raise standards in medical publishing and expand access to research results
MPIP Initiative: Publications


• Free access to these publications and more information on MPIP is available at www.mpip-initiative.org
The Global Alliance of Publication Professionals (GAPP)

• Established in January 2012
  – 5 volunteers from Europe, North America, and Asia-Pacific
  – Each has held a leadership role in professional associations (eg, AMWA, EMWA, ISMPP)

• GAPP is an advocate for ISMPP members
  – Strives to provide timely and credible responses to influential stories that affect medical publication professionals

• GAPP has had 25+ articles (1 every 4-8 weeks) published in high-ranking peer-reviewed journals, mainstream media, and social media

• ISMPP members can use GAPP articles to reinforce the value and ethics of publication professionals

• More information is available at www.gappteam.org
GAPP: Publications (examples)


Future Goals and Plans
The Future

- ISMPP continues to educate, advocate, and set standards for medical publication professionals
- ISMPP is leading research efforts with the goal to establish Best-practice Publishing Guidelines

Many issues to address
- Increased calls for data transparency
  - At the patient level; original case report forms
  - Retrospective period (how far to go back)
  - Disclosures beyond regulators and scientists to the public
- Emerging Sponsor solutions
- Response to the US Sunshine Act and other moves towards transparency
Summary and Take-away Messages
Key Takeaways

- ISMPP has made significant progress since its inaugural Annual Meeting
- ISMPP advances the medical publication profession through driving integrity, improving standards and best practices, and providing education and advocacy
- ISMPP contributes to our identity and authority
- In this era of increasing transparency and data sharing, collaborations are more important than ever, and **ISMPP leads the way!**
Publications and Position Papers


• Marchington J, on behalf of ISMPP Issues and Actions Committee. ISMPP and advocacy for the medical publication professional. Curr Med Res Opin. 2011;27(suppl 1):s5-s6.

