# ISMPP:
# A Decade of Achievements

## 2005–2015

# Table of Contents

# 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

# Introduction to ISMPP

# Founding Corporate Sponsors

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

| Timothy D. Bacon | Ross A. Baker | Carolyn S. Clark |
|---|---|---|
| Joanne Conaty | Elizabeth Faust | Elizabeth Field |
| Stan Heimberger | Laurence J. Hirsch | Richard F. Lamb |
| Gary McQuarrie | Robert Norris | Gene P. Snyder |

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 |
|---|---|---|---|---|
| **2005** | **2006** | **2007** | **2008** | **2009** |
| Joint Position papers on Clinical Trial Information | Open peer review | Clinicaltrials.gov FDAAA | Senator Grassley's ghostwriting accusations | GPP2 and ISMPP CMPP™ |
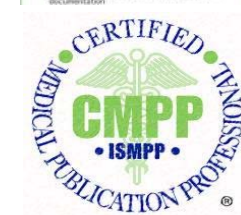


US: Senator Grassley's investigation and report into off-label use and promotion

# 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 | 2011 | 2012 | 2013 | 2014 |

**2010**

Revised ICMJE guidelines

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

US Sunshine Act

**2011**

EudraCT confidentiality lifted, launch of current database

**2012**

*BMJ* Data Sharing Campaign

**2013**

ICMJE recommendations

GSK opens patient-level data to external researchers

AllTrials Campaign

PhRMA/EFPIA Principles on Responsible Data Sharing

**2014**

PLOS journals require authors to provide data availability statement
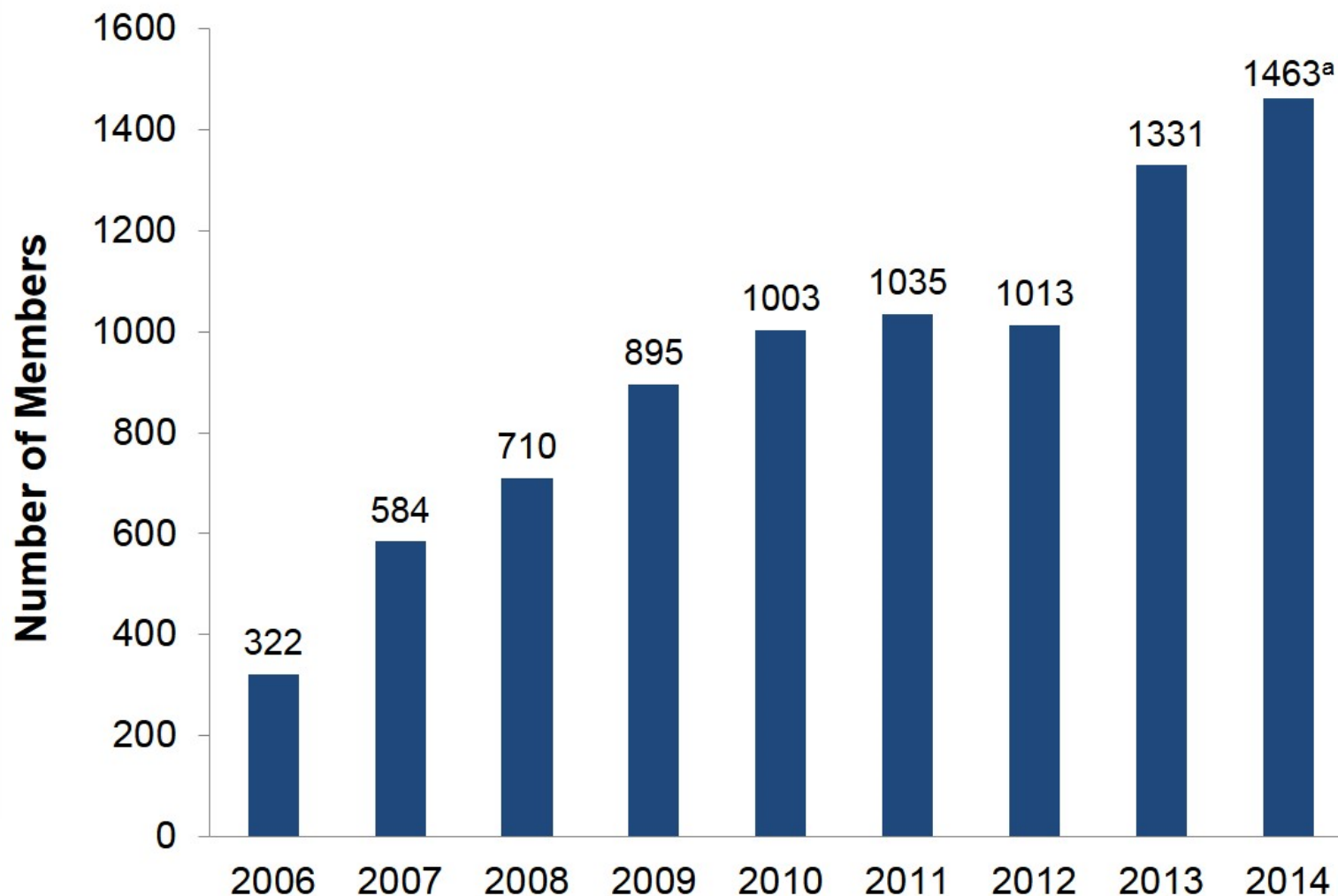
New BMJ policy institutes patient-centric approach to publications

ISMPP Today:
Facts and Figures

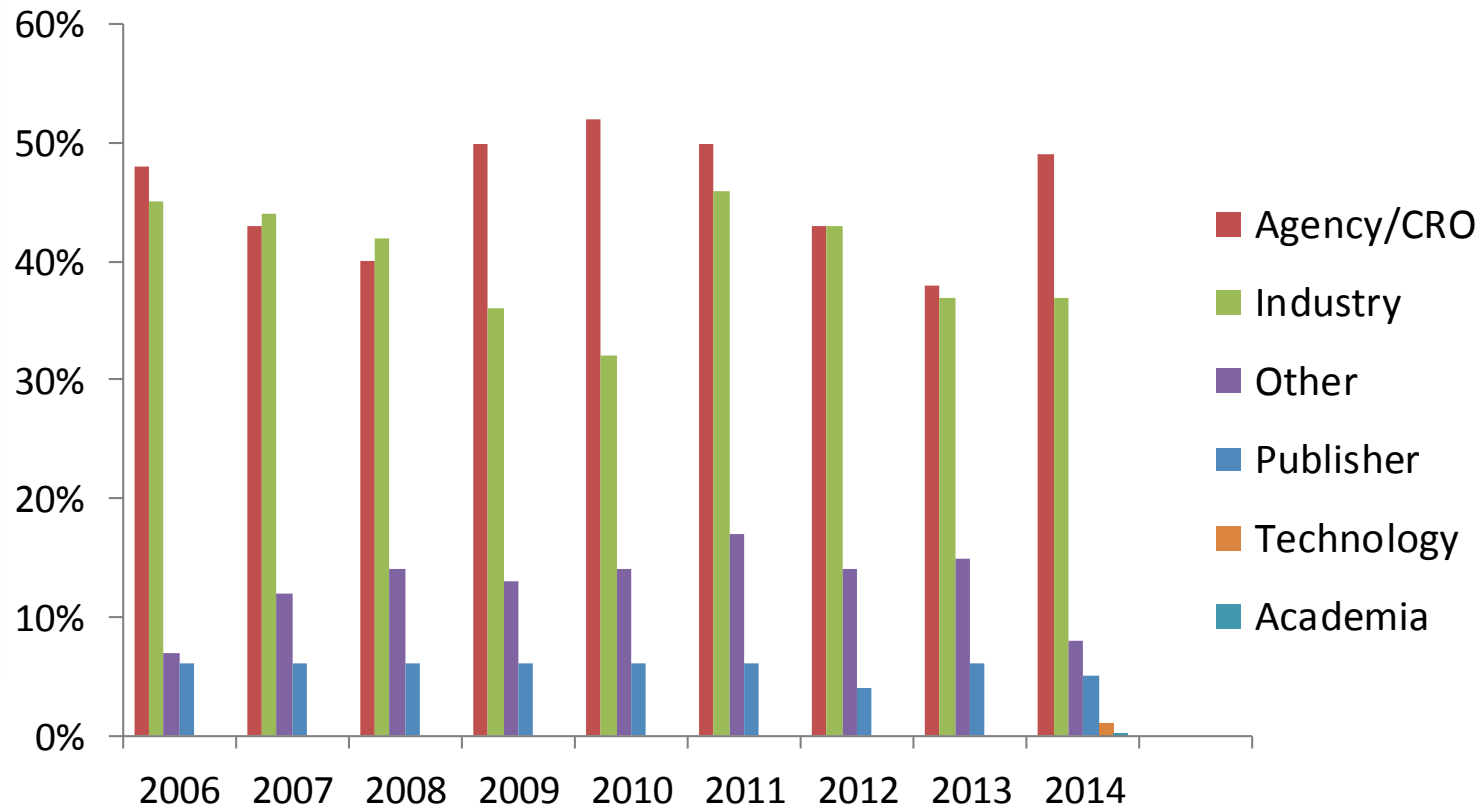# A Growing Membership



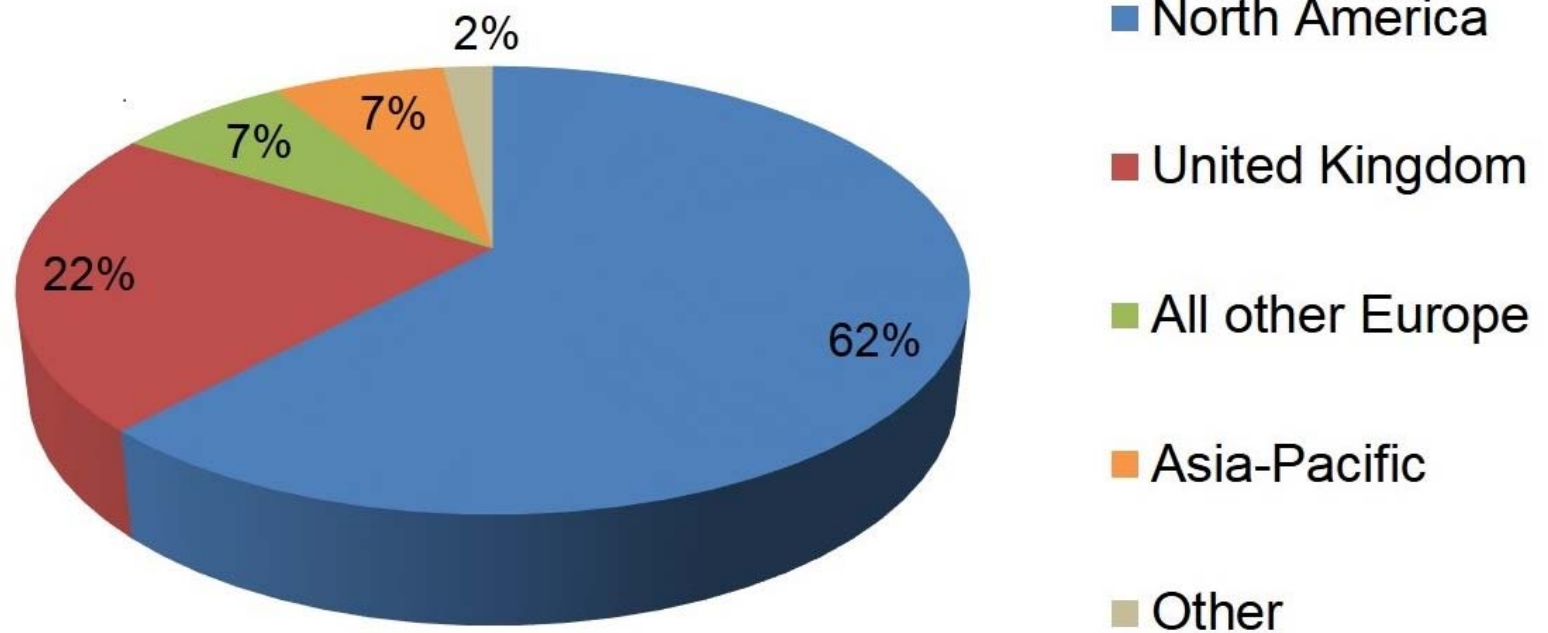a2014 figures through April 13, 2015.

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# Membership Trends by Sector

Industry and Agency continue to dominate membership

- Agency/CRO: 49%
- Industry: 37%

- Other: 8%
- Publisher: 5%

- Technology: 1%
- Academia: <1%

# International Membership



Pie chart legend:
- North America — 62%
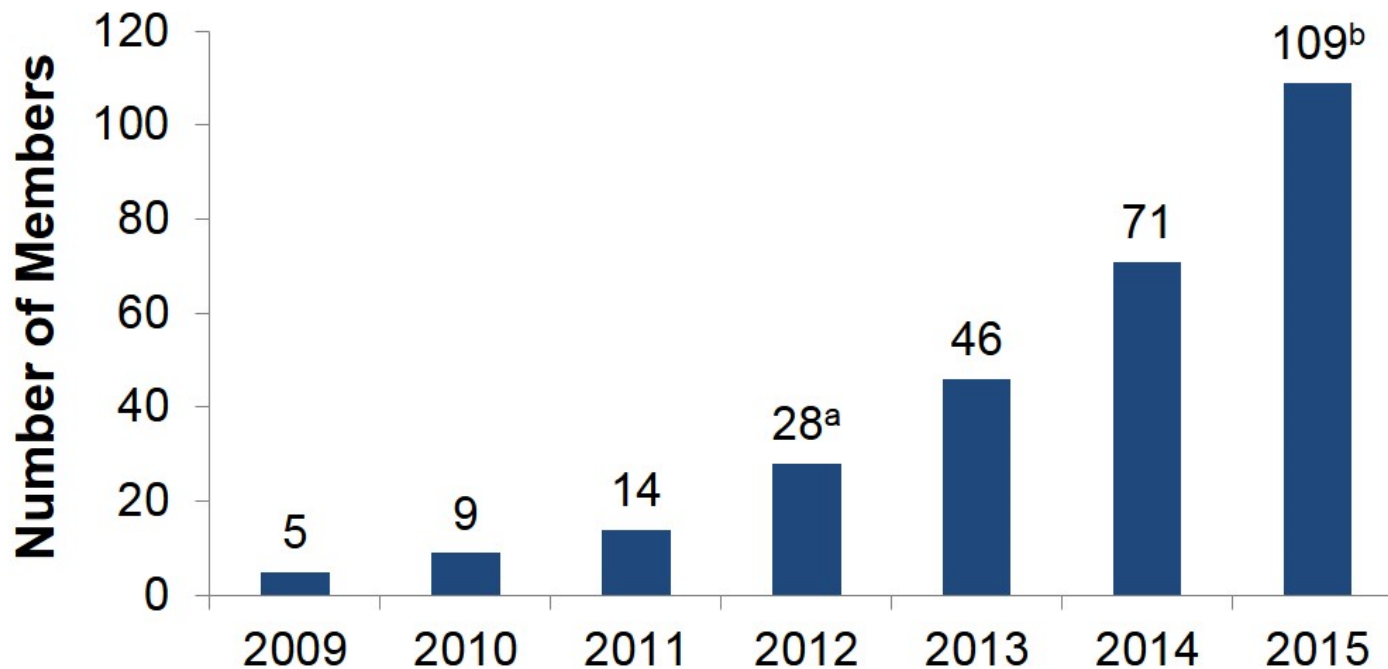- United Kingdom — 22%
- All other Europe — 7%
- Asia-Pacific — 7%
- Other — 2%

# 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)



[a]Associate Member dues adopted October, 2012 ($95 USD).
[b]As of March 17, 2015.

# Reasons for Joining ISMPP
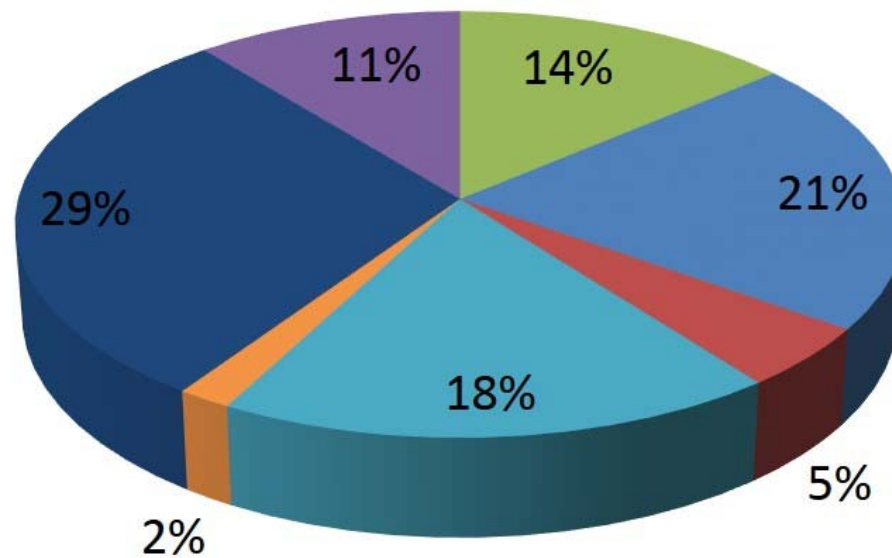


Legend:
- Ability to register for ISMPP annual meetings
- Access to monthly ISMPP U
- Access to ISMPP Archives
- Networking
- Other
- Professional development
- To serve/advance the profession

Pie chart values: 14%, 21%, 5%, 18%, 2%, 29%, 11%

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

# GPP: Establishing Standards

Good publication practice for pharmaceutical companies

Elizabeth Wager[1], Elizabeth A. Field[2] and Leni Grossman[3]

*Current Medical Research and Opinion.* 2003;19(3):149-154.

- <u>Prior to ISMPP</u>, 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."

# GPP2: Evolving Requirements

## RESEARCH METHODS & REPORTING

### Good publication practice for communicating company sponsored medical research: the GPP2 guidelines

Chris Graf,[1] Wendy P Battisti,[2] Dan Bridges,[3] Victoria Bruce-Winkler,[4] Joanne M Conaty,[5] John M Ellison,[6] Elizabeth A Field,[7] James A Gurr,[8] Mary-Ellen Marx,[9] Mina Patel,[10] Carol Sanes-Miller,[5] Yvonne E Yarker,[11] for the International Society for Medical Publication Professionals

- 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](http://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

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

- Generate and disseminate research
- Share best practices
- Forum for professional collaboration

# Annual Meeting – Topics

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

# EU Meeting – Topics

| Year | Program Title |
|------|---------------|
| 2015 | Medical Publications for Better Patient Care: Integrity, Innovation, and Impact |
| 2014 | A New Era in Global Medical Publications |
| 2013 | Doing the Right Thing and Doing Things Right |
| 2011 | Trends, Transparency and Trust: From Insights to Action |
| 2010 | Inaugural European Meeting of ISMPP |

# 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

- Chipperfield L, et al. Authors' submission toolkit: a practical guide to getting your research published. Curr Med Res Opin. 2010;26:1967-1982.

- Clark J, et al. Enhancing transparency and efficiency in reporting industry-sponsored clinical research: report from the Medical Publishing Insights and Practices initiative. Int J Clin Pract. 2010:64:1028-1033.

- Mansi B, et al. Ten recommendations for closing the credibility gap in reporting industry-sponsored clinical research: a joint journal and pharmaceutical industry perspective. Mayo Clinic Proc. 2012;87:424-429.

- Marušić A, et al. Five-step authorship framework to improve transparency in disclosing contributors to industry-sponsored clinical trial publications. BMC Medicine. 2014;12:197.

- 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)

- Woolley K, Gertel A, Hamilton C, Jacobs A, Snyder G; Global Alliance of Publication Professionals (www.gappteam.org). Don't be a fool-- don't use fool's gold. Am J Med. 2012 Oct;125(10):e21-2.

- Hamilton CW. Differential diagnosis: distinguishing between ghostwriting and professional medical writing in biomedical journals. JAMA Intern Med. 2013 Dec9-23;173(22):2091-2.

- Woolley KL, Gertel A, Hamilton CW, Jacobs A, Snyder GP; Global Alliance of Publication Professionals. Time to finger point or fix? An invitation to join ongoing efforts to promote ethical authorship and other good publication practices. Ann Pharmacother. 2013 Jul-Aug;47(7-8):1084-7.

- Global Alliance of Publication Professionals (GAPP):, Woolley KL, Gertel A, Hamilton C, Jacobs A, Snyder G. Poor compliance with reporting research results - we know it's a problem … how do we fix it? Curr Med Res Opin. 2012 Nov;28(11):1857-60.

- Hamilton C, Woolley K, Gertel A, Jacobs A, Snyder GP. Letter to the editors. Bioethics. 2014 Nov;28(9):500.

# 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
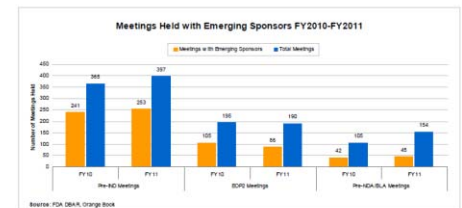
# Summary and Take-away Messages

# 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

- Norris R, Bowman A, Fagan JM, et al. International Society for Medical Publication Professionals (ISMPP) position statement: the role of the professional medical writer. Curr Med Res Opin. 2007;23(8):1837-1840.

- Graf C, Battisti WP, Bridges D, et al. for the International Society of Medical Publication Professionals. Good Publication Practice for Communicating Company-Sponsored Medical Research: the GPP2 Guidelines. BMJ 2009;339:b4330.

- 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.

- ISMPP Issues and Actions Committee position paper on "The Rationale and Value of Medical Publications". http://www.ismpp.org/assets/docs/Inititives/advocacy/the_rationale_and_value_of_medical_publications.pdf

- ISMPP Issues and Actions Committee position paper on "Ghostwriting and the Professional Medical Writer". 2011. http://www.ismpp.org/assets/docs/Inititives/advocacy/ismpp_ghost_writing_vs_professional_medical_writing_oct_2011.pdf

- Pepitone K, Weigel A. Transparency and the Healthcare Industry: The Sun is Shining. Medical Writing 2013;22:243-247.