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

ISMPP International Society for Medical Publication Professionals™

PRACTICAL IMPLICATIONS OF GPP3: ARE YOU PREPARED?

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Executive Director, Medical Publications
Bristol-Myers Squibb

April 29, 2015

ISMPP International Society for Medical Publication Professionals™

Session Goal

- Overview of reviewer input
- Key areas of change in GPP3
- How to prepare your organization for GPP3

Disclaimer

The opinions expressed are my own and do not necessarily reflect those of my individual employer or of ISMPP

GPP3 STEERING COMMITTEE

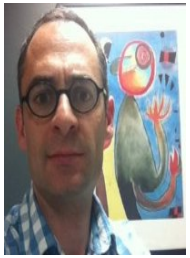
Meet the faces behind the update

GPP3 Steering Committee

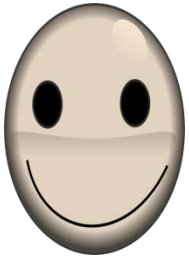








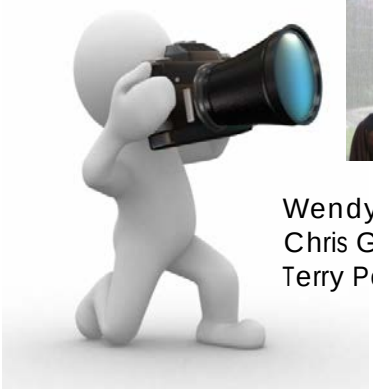












Wendy Battisti, PhD, Lise Baltzer, Dan Bridges, PhD, Angela Cairns, Christopher Carswell, MSc, Leslie Citrome, MD, MPH
Chris Graf, James Gurr, PhD, LaVerne Mooney, DrPH, Carol Sanes-Miller, MS, Jane Moore, MS , Mina Patel, PhD
Terry Peña, PhD, Aya Tokaji, Keith Veitch, PhD, Elizabeth Wager, PhD, Karen Woolley, PhD, Yvonne Yarker, PhD

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

GPP3 process – four key steps

ISMPP

- ISMPP emails >3000 invitations to members, editors and previous GPP2 reviewers (**Sept 2013**)
  - Steering Committee (n=18) selected from applicants (N=118)
  - External reviewer panel (n=153) selected. Additional targeted outreach to editors: 21 agreed

Steering committee

- Reviewed earlier GPP guideline and literature; collated all comments for proposed changes (**Dec 2013 – Feb 2014**)
- Confirmed scope, title, and direction for GPP3 via repeated survey process of committee members (**Jan-Feb 2014**)
- Prepared outline (**March 2014**)
- Formed subcommittees to update or write each section (**April–June 2014**)
- First draft assembled and edited; reviewed by full SC, and draft finalized (**Aug 2014**)

Reviewer panel

- Finalized draft (2nd draft) sent to reviewers (N=174) **Aug 2014**
- Reviewers allowed 5 weeks to comment via Excel spreadsheet.
- Comments captured by section heading and line number.
- Reviewers (n=94) provided comments.

Steering committee

- Review and rank comments (**mid Sept-Oct)** from reviewer panel by:
  - Frequency,
  - Rating, and
  - Individual judgment
- SC reviewed all comments and identified top issues and resolution needed
- Subcommittees address comments; guidelines finalized for submission to *Annals of Internal Medicine* (**Jan 2015**)

GPP3 subcommittees

Section	Subcommittee members
Principles of Publications	**Liz Wager (Lead)**; Karen Woolley; James Gurr
Aims & Scope	Wendy Battisti
Methods	Wendy Battisti
Section 1. Publication Processes • Section 1.1. Publication Planning • Section 1.2. Publication steering committees and writing groups	**Keith Veitch (Lead)**; Jane Moore; Dan Bridges; Aya Tokaji **Jim Gurr (Lead)**; Yvonne Yarker; Mina Patel; Carol Sanes Miller; Lise Baltzer; Les Citrome; Laverne Mooney
Sections 1.3 -1.8. **(What should be published, Premature publication, Redundant or duplicate publication, Plagiarism, Trial registration and public posting of data, Documentation)** *formerly – "Planning, registering, posting, and documenting"*	**Keith Veitch (Lead)**; Jane Moore; Dan Bridges; Aya Tokaji

GPP3 subcommittees

Section	Subcommittee members
Section 2.0. Roles and responsibilities • 2.1 Written agreement • 2.2 Authors Access to data	**Dan Bridges (Lead)**; Jim Gurr; Liz Wager; Angela Cairns; Les Citrome
Section 2.3. Authorship	**Chris Carswell (Lead)**; Keith Vetch; Liz Wager; Angela Cairns ; Les Citrome; Wendy Battisti; Carol Sanes-Miller
Section 2.4. Professional medical writers	**Karen Woolley (Lead)**; Keith Veitch; Jim Gurr; Ange Cairns; Yvonne Yarker; Jane Moore; Liz Wager
Section 2.5. Contributorship and acknowledgments	**Angela Cairns (Lead)**; Jane Moore; Mina Patel; Jim Gurr
Section 2.6. Disclosures	**Les Citrome (Lead)**; Terry Peña; Angela Cairns; Carol Sanes Miller
Section 3.0: Recommendations for specific types of articles and presentations	**Lise Baltzer (Lead)**; Yvonne Yarker; Liz Wager
Sections 4.0 – 5.0. (Reporting standards, Data sharing)	**Laverne Mooney (Lead)**; Terry Peña; Aya Tokaji; Chris Carswell; Keith Veitch
Section 6.0. Future Directions	Liz Wager

NOTE! GRAB YOUR TECHNOLOGY!

This presentation contains polling questions

PRACTICAL IMPLICATIONS OF GPP3

Question: In your opinion, how well informed are you on the development of GPP3?

- Potential answers
  - **Very informed**, heard updates at several publication meetings 48% (29/60)
  - **Somewhat informed**, heard update at a single publication meeting 30% (18/60)
  - **Not informed**, have not heard a thing 22% (13/60)

60 Respondents

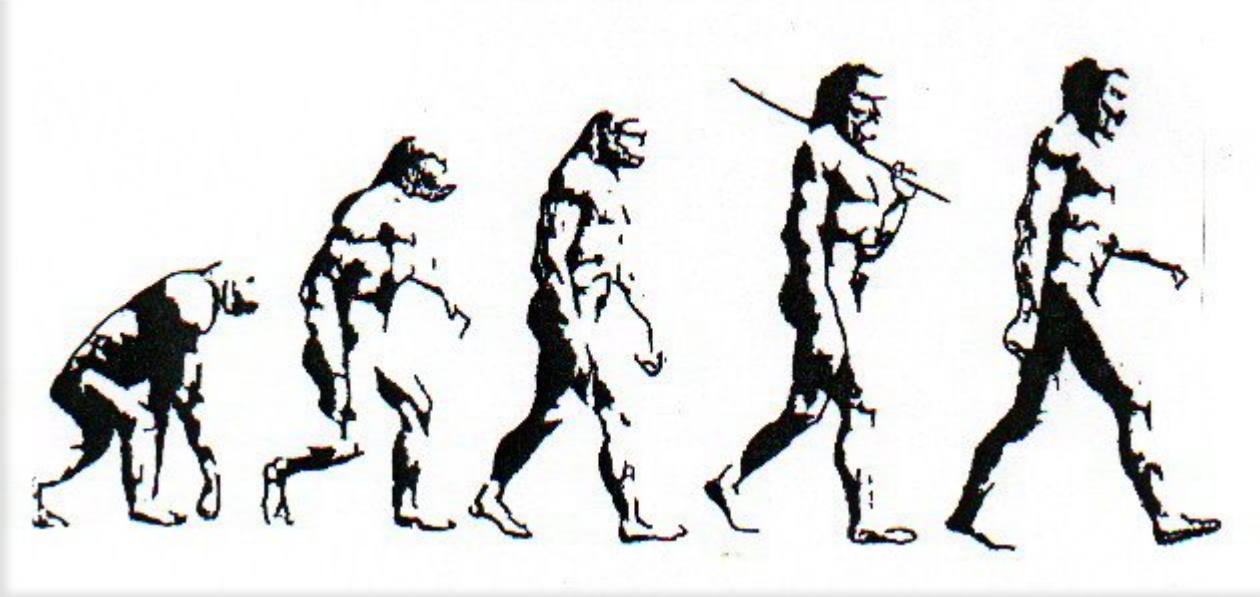
Question: Have you begun to prepare your organization for GPP3?

- Potential answers
  - **Yes**, have begun preparing publications group and the broader organization on upcoming updates to GPP2 14% (9/65)
  - **Somewhat**, have begun preparing publications group, but not the broader organization on upcoming updates to GPP2 11% (7/65)
  - **No**, have not prepared anything. Waiting for GPP3 to be published 75% (49/65)

65 Respondents

EVOLUTION OF THE GOOD PUBLICATION PRACTICES (GPP) GUIDELINES

Progress on core principles



Why the update to GPP2?

- The ISMPP GPP3 Steering Committee has updated the current guidelines for good publication practice (GPP2) to further improve integrity and transparency in industry-sponsored publication planning and development in today's environment.

GPP Evolution

GPP (2003)

Current Medical Research Opinion

- First to describe standards for industry-based manuscripts
- Initiated at a meeting of academics, journal editors, and industry affiliates in 1998
- Five years in the planning and development

GPP2 (2009)

British Medical Journal

- More comprehensive than GPP
- More diverse input (reviewers)
- Additional topics since GPP

GPP3 (2015)

Submitted to Annals of Internal Medicine

- Expand focus of GPP and GPP2 on core values:
  - Integrity
  - Completeness
  - Transparency
  - Accountability
  - Responsibility
- New elements such as:
  - Data sharing
  - Expanded information & evidence base on role of medical writers

What's new in GPP3?

New elements include:
1. Guidance on updated ICMJE 2013 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

New sections

Section	Highlight
Principles of Good Publication Practice For Company-Sponsored Medical Research	• Summary of 'top ten' principles of good publication practice – for quick access and to complement more detailed guidelines included throughout GPP3
Aim and Scope	• To maintain ethical practices in the development and communication of scientific and clinical research
Disclosures	• Previously known as Conflicts of Interest section
Data Sharing	• Sponsors should provide access to patient-level data to 'qualified researchers' upon request • Access to data cannot compromise patient confidentiality

New sections

Section	Highlight
Studies that should be published	• Clinical trials including non-interventional studies involving human participants • Publication regardless of whether finding is positive or negative • Guidance for publication of studies that do not yield medically important results, with multiple journal rejections…
Timing of Publications	• Licensed products: manuscript submissions within 12 months (at latest 18 months) of study completion • Investigational products: within 12 months (at latest 18 months) of product approval or within 18 months of study discontinuation
Plagiarism	• Definition, including self-plagiarism • Copyright permission

Key changes in existing sections

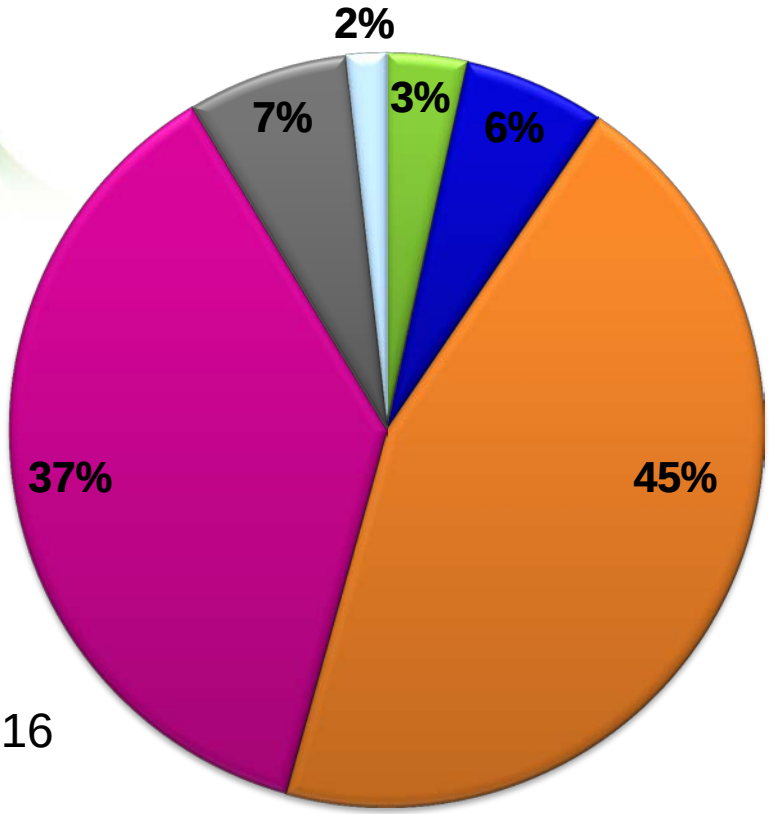
Section	Highlight
Authorship	• Author access to data cannot compromise patient confidentiality • Updated with revised ICMJE criteria • Clarity around ‘guest’ &‘ghost’ authorship • Clarity on authorship payment & reimbursement
Professional Medical Writers	• Included peer reviewed published evidence to support benefits of involving professional writers
Primary and Secondary Publications	• Primary publications should be published before secondary publications
Review articles	• Added reference to PRISMA guidelines for systematic reviews
Publications Steering Committees	• Recommend authorship working group from MPIP authorship framework

GPP3 REVIEWER ANALYSIS

What have we learned?

Reviewer Breakdown

GPP2 vs GPP3



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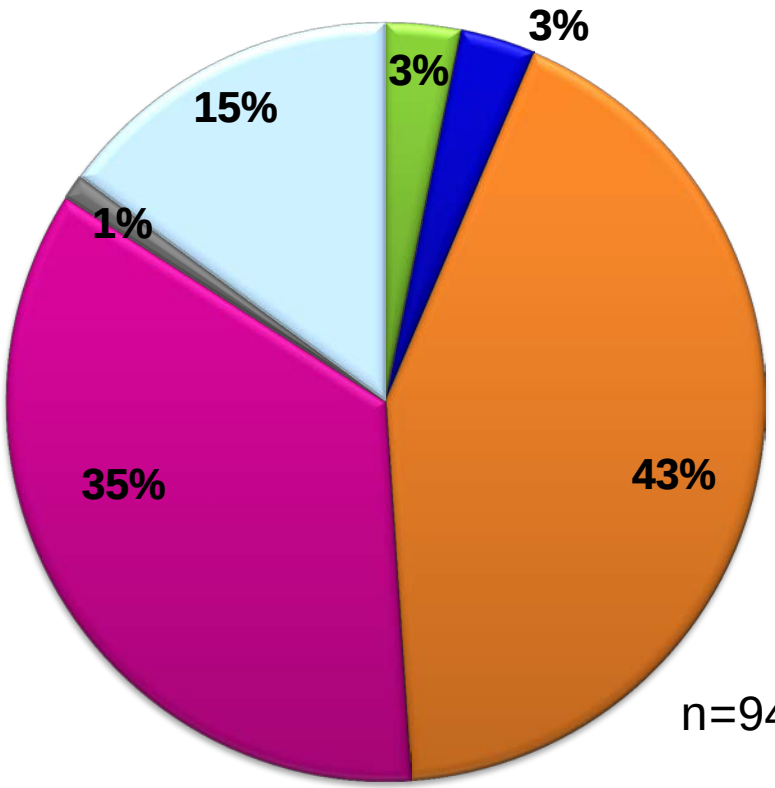
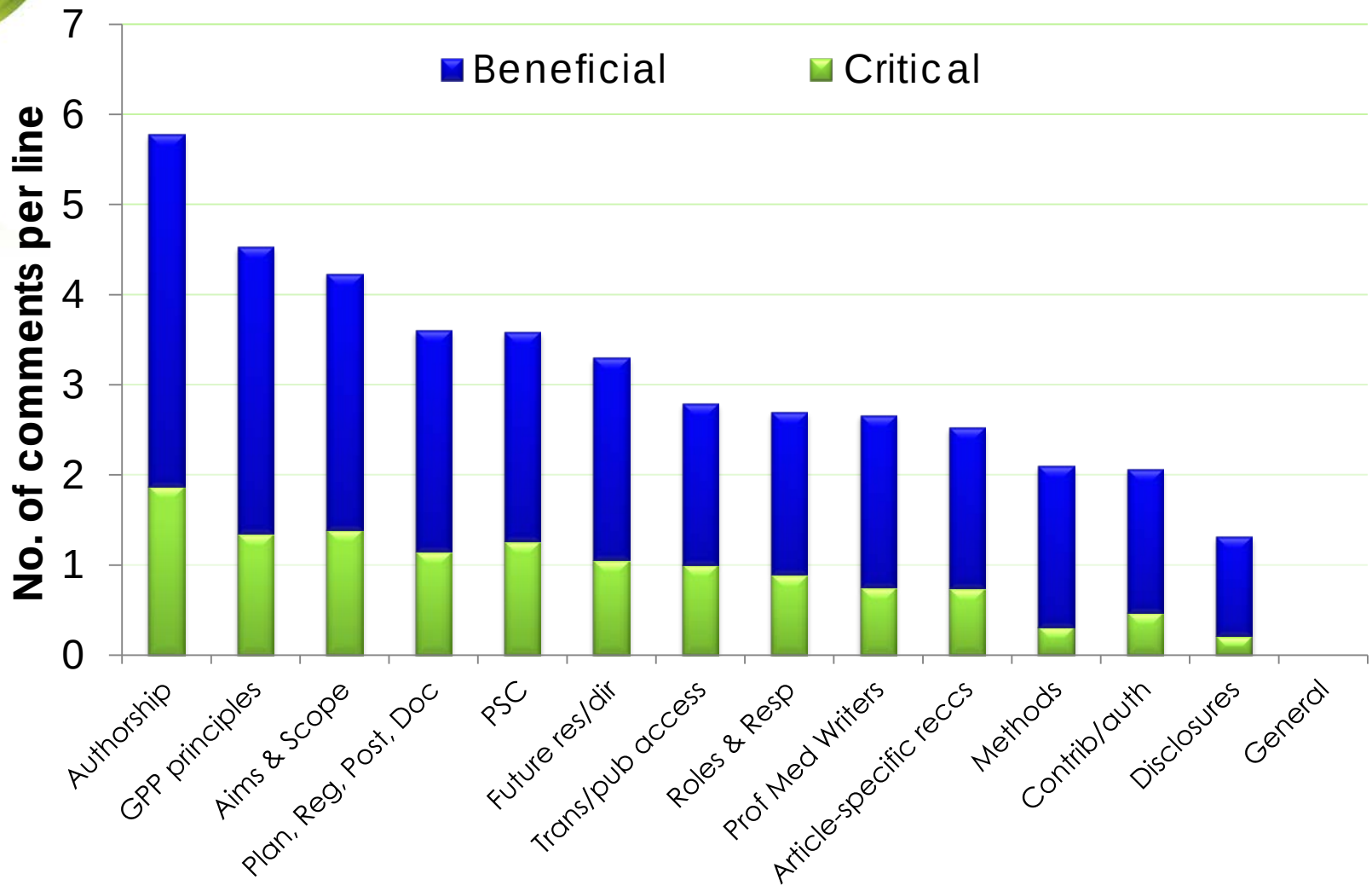


n=94

Academic
Journal editor
Agency/freelance
Industry
Professional organization
Other/unspecified

Density of reviewer comments



Summary from initial data review

- Data show we still have more work to do to engage journal editors in guideline development and review.

- Key areas of interest / debate still boil down to:
  - Authorship
  - GPP Principles
  - Aims and scope of guidelines

Testimonials

- **Clear**, useful guidelines that clarify some ambiguities from GPP2.
- Content very **comprehensive** and relevant.
- I found the draft guidelines to be **comprehensive** and very **useful**. I commend the steering committee for their excellent work. Thank you for the opportunity to review them.
- I have carefully reviewed the draft and am **delighted** to report that I have no substantive recommendations for changes. I think the authorship team has done an **outstanding job** on this draft! Thank you all.
- I thought this was a **great article**! I just had a few comments.
- Overall it is very well done and thought out. I only have a few points of critique. **Good job** to all the authors and thanks for updating GPP2!
- Overall, I think this is an **excellent guidance document**, building upon the GPP2 to where we are today. Kudos to the team, and I look forward to seeing the final document.
- Overall, the GPP3 document is **thorough**, **clear** in its guidance, and a **valuable tool** for beginning and experienced professionals in the publication planning field.
- **Very clearly laid out**, and very **concise**. I like the addition of the list of principles at the beginning of the article so that readers are not required to search through the entire paper to discover them.

GPP3 JOURNAL SUBMISSION

Update

Journal submission update

- January 2015: manuscript **submitted** to *Annals of Internal Medicine*
  - Manuscript is under review

PREDICTING THE IMPACT OF GPP3

How might GPP3 recommendations affect day-to-day publications activities?

What's new in GPP3?

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

Predicting the impact

New elements include:
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PREPARING FOR GPP3

Recommendations for effective communication and roll-out

Where to start?

Step 1

- **Review** current / existing policy and SOPs against new sections & key changes in GPP3
- **Identify** potential areas of 'global' impact that will require communication and training of:
  - Internal & external stakeholders
  - Affiliates in regions
  - Country medical staff
- **Plan** updates to global policy, SOPs & training materials

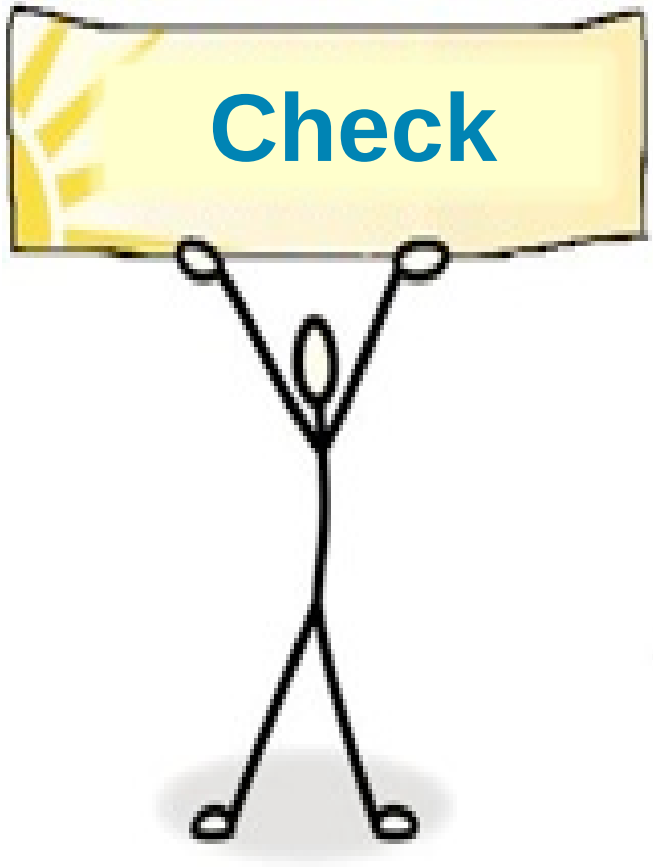
Remember GPP3 is global so think &act globally!

Step 2

- **Develop** customized plans to communicate the right information, at the right level, to the right audience
- **Socialize** potential areas of impact & change with key stakeholders prior to roll-out of communication and training
- **Delay not…** Inform those who need to know in a timely manner

Step 3

- **Identify** GPP3 requirements to monitor in SOPs and training materials
- **Perform** regular baseline assessments of publications against updated guideline
- **Track & Report** on any impact & change related to GPP3 implementation

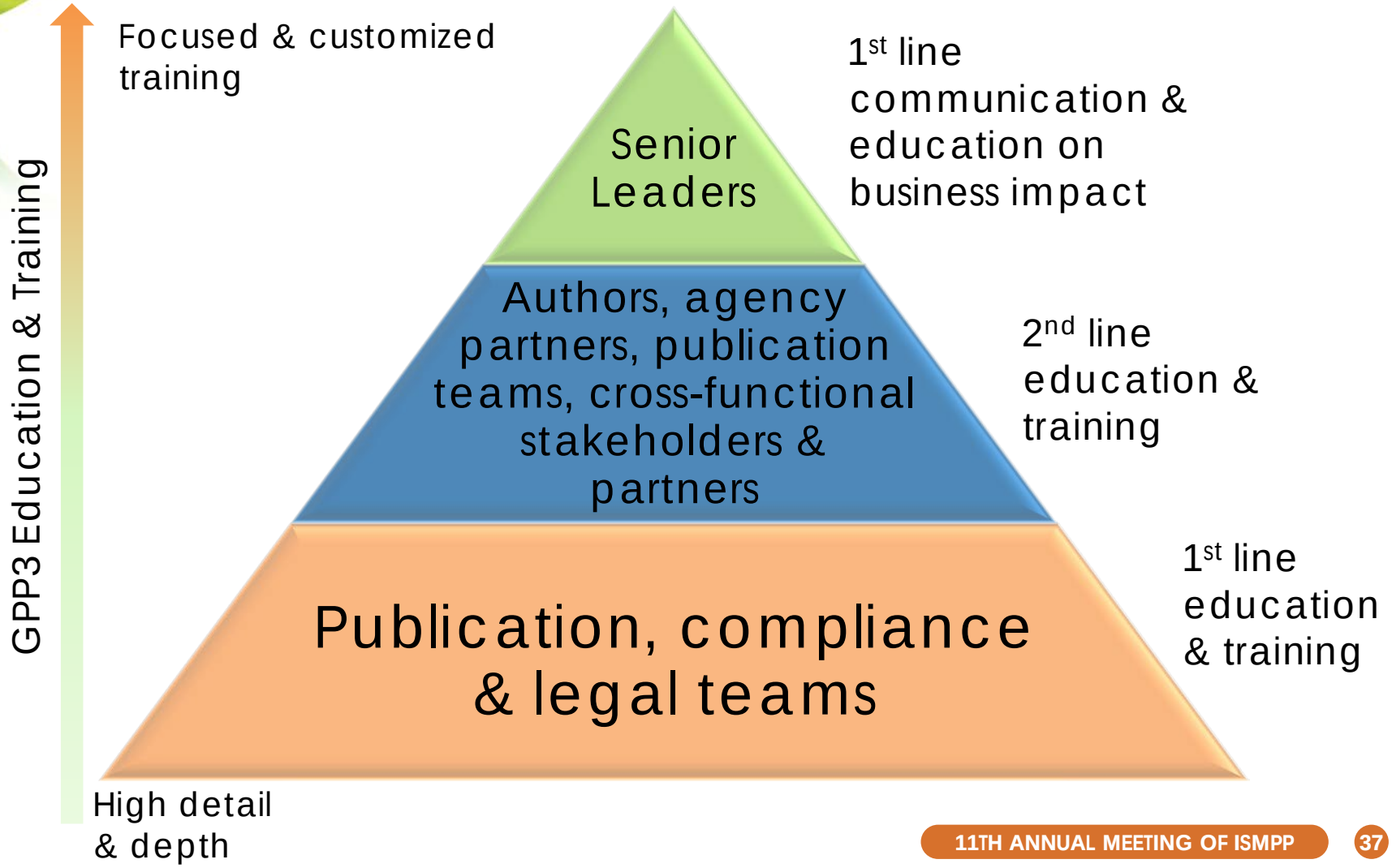


Step 4

- **Evaluate** monitoring data & assess need for additional clarification & training
- **Act** on findings to identify root cause & address potential gaps in GPP3 compliance
- **Publish** research on GPP3 use & value
- **Manage change** go back to Step 1

""The Only Thing That Is Constant Is Change"
Heraclitus

Education & training pyramid



THE JOURNEY HOME

Next steps for GPP3

Key Takeaways

- 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

CLOSING THOUGHTS

In the end, what's it all about?

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BACK-UP SLIDES

GPP3 Steering Committee

Member	Affiliation
Baltzer, Lise	Novo Nordisk A/S, Denmark
Battisti, Wendy*	Janssen Research & Development LLC, USA (Chair)
Bridges, Dan*	Apothecom scopemedical, UK
Cairns, Angela*	Ashfield Healthcare Communications, UK
Carswell, Chris	*PharmacoEconomics*, Springer Int'l Publishing AG., Switzerland
Citrome, Les	*Int'l Journal Clinical Practice*, Wiley-Blackwell, USA
Graf, Chris	Wiley Blackwell, Australia (now UK)
Gurr, James *	MedImmune, USA
Mooney, Laverne	Pfizer Inc., USA
Moore, Jane*	Medtronic, USA
Patel, Mina	Vertex Pharmaceuticals, Inc, USA
Peña, Teresa	Bristol-Myers Squibb, USA
Sanes-Miller, Carol*	Baxter Healthcare, USA
Tokaji, Aya*	McCann Complete Medical, MDS-CMG, Japan
Veitch, Keith	Freelancer, The Netherlands
Wager, Liz	Sideview, UK
Woolley, Karen*	Proscribe Envision Pharma Group, Australia
Yarker, Yvonne*	Medicite LLC, USA

*ISMPP Certified Medical Publication Professional

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