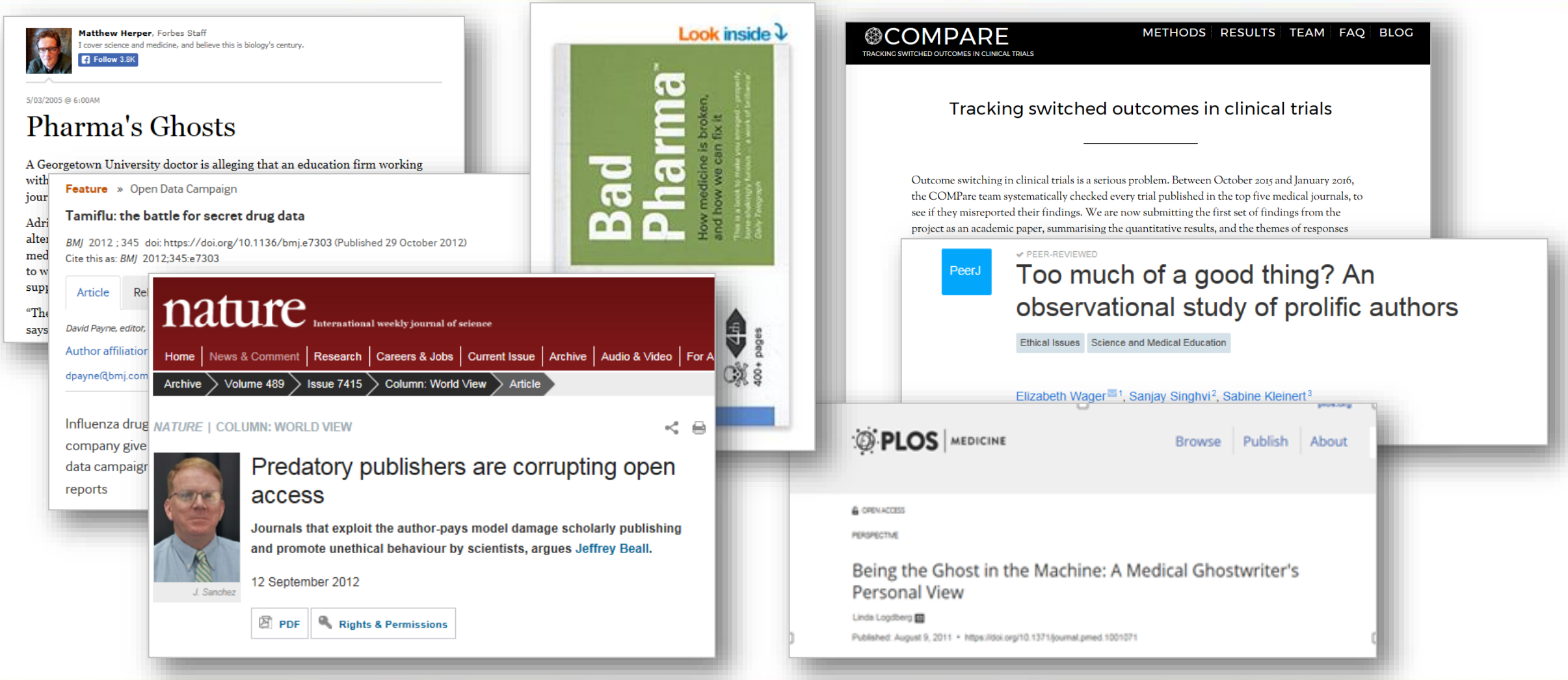
GOOD PUBLICATION PRACTICE

LEARNING OBJECTIVES

By the end of this session, you should:

- Understand the relevance and importance of GPP3 guidelines
- Understand the key elements of the guidelines
- Know how to access key resources related to GPP3

MANY NEGATIVE HEADLINES ABOUT MEDICAL PUBLICATIONS OVER THE YEARS…



MANY NEGATIVE HEADLINES ABOUT MEDICAL PUBLICATIONS OVER THE YEARS…

Authorship

- Ghostwriting
- Guest/honorary authorship
- Prolific authors

Lack of transparency

- Data
- Financial

Retractions

Necessitates the need for education and high standards in the development of medical publications

WHY ARE GPP3 GUIDELINES IMPORTANT?

Provides guidance on responsible and ethical development of medical publications

Demonstrates integrity and commitment to high standards

Broadly applicable to non-industry as well as industry sponsored research

The history

Elizabeth Wager – primary author

2003

Original GPP guidelines published

Wager et al. *Curr Med Res Opin.* 2003;19:149-54.

Chris Graf – primary author

2009

GPP2 guidelines published

Graf et al. *BMJ.* 2009;339:b4330.

2015

GPP3: Good Publication Practice for Communicating Company-Sponsored Medical Research

Battisti et al. *Ann Intern Med.* 2015;163:461-4.

GPP3

Reflects changes in the medical publications environment and aims to clarify and strengthen the principles and practices in earlier versions

Good Publication Practice guidelines

- These guidelines apply to peer-reviewed journal articles and presentations at scientific congresses
- GPP guidelines make recommendations that will help individuals and organisations maintain ethical practices and comply with current requirements when they contribute to the communication of medical research sponsored by companies

Annals of Internal Medicine RESEARCH AND REPORTING METHODS

Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3

Wendy P. Battisti, PhD; Elizabeth Wager, PhD; Lise Baltzer; Dan Bridges, PhD; Angela Cairns; Christopher I. Carswell, MSc; Leslie Citrome, MD, MPH; James A. Gurr, PhD; LaVerne A. Mooney, DrPH; B. Jane Moore, MS; Teresa Peña, PhD; Carol H. Sanes-Miller, MS; Keith Veitch, PhD; Karen L. Woolley, PhD; and Yvonne E. Yarker, PhD

This updated Good Publication Practice (GPP) guideline, known as GPP3, builds on earlier versions and provides recommendations for individuals and organizations that contribute to the publication of research results sponsored or supported by pharmaceutical, medical device, diagnostics, and biotechnology companies. The recommendations are designed to help individuals and organizations maintain ethical and transparent publication practices and comply with legal and regulatory requirements. These recommendations cover publications in peer-reviewed journals and presentations (oral or poster) at scientific congresses. The International Society for Medical Publication Professionals invited more than 3000 professionals worldwide to apply for a position on the steering committee, or as a reviewer, for this guideline. The GPP2 authors reviewed all applications (n = 241) and assembled an 18-member steering committee that represented 7 countries and a diversity of publication professions and institutions. From the 174 selected reviewers, 94 sent comments on the second draft, which steering committee members incorporated after discussion and consensus.

The resulting guideline includes new sections (Principles of Good Publication Practice for Company-Sponsored Medical Research, Data Sharing, Studies That Should Be Published, and Plagiarism), expands guidance on the International Committee of Medical Journal Editors' authorship criteria and common authorship issues, improves clarity on appropriate author payment and reimbursement, and expands information on the role of medical writers. By following good publication practices (including GPP3), individuals and organizations will show integrity; accountability; and responsibility for accurate, complete, and transparent reporting in their publications and presentations.

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For author affiliations, see end of text.
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Incomplete, inaccurate, misleading, or delayed reporting of medical research may result in poorly informed decision making and reduce the efficiency and quality of health care (1). Therefore, scientific and clinical research should be reported in a complete, accurate, balanced, and timely manner. Such research is often initiated by, or involves collaboration with, commercial organizations, such as pharmaceutical, biotechnology, medical device, and diagnostics companies. This updated Good Publication Practice guideline, known as GPP3, is designed primarily to help individuals and organizations maintain ethical practices when they contribute to the communication of this type of research. The principles of GPP3 apply to all research, however, so we expect that this guideline will be applicable to all medical and health care professionals involved in publications.

The GPP guideline, published in 2003 (2) and updated in 2009 (as GPP2) (3), has been widely adopted. In an international survey of almost 500 people involved in publishing industry-sponsored research, more than 90% of respondents said they routinely referred to GPP2, which is a similar proportion to those who reported using International Committee of Medical Journal Editors (ICMJE) guidelines (4). The GPP guidelines have also been endorsed by medical journals (5) and cited in their instructions to authors.

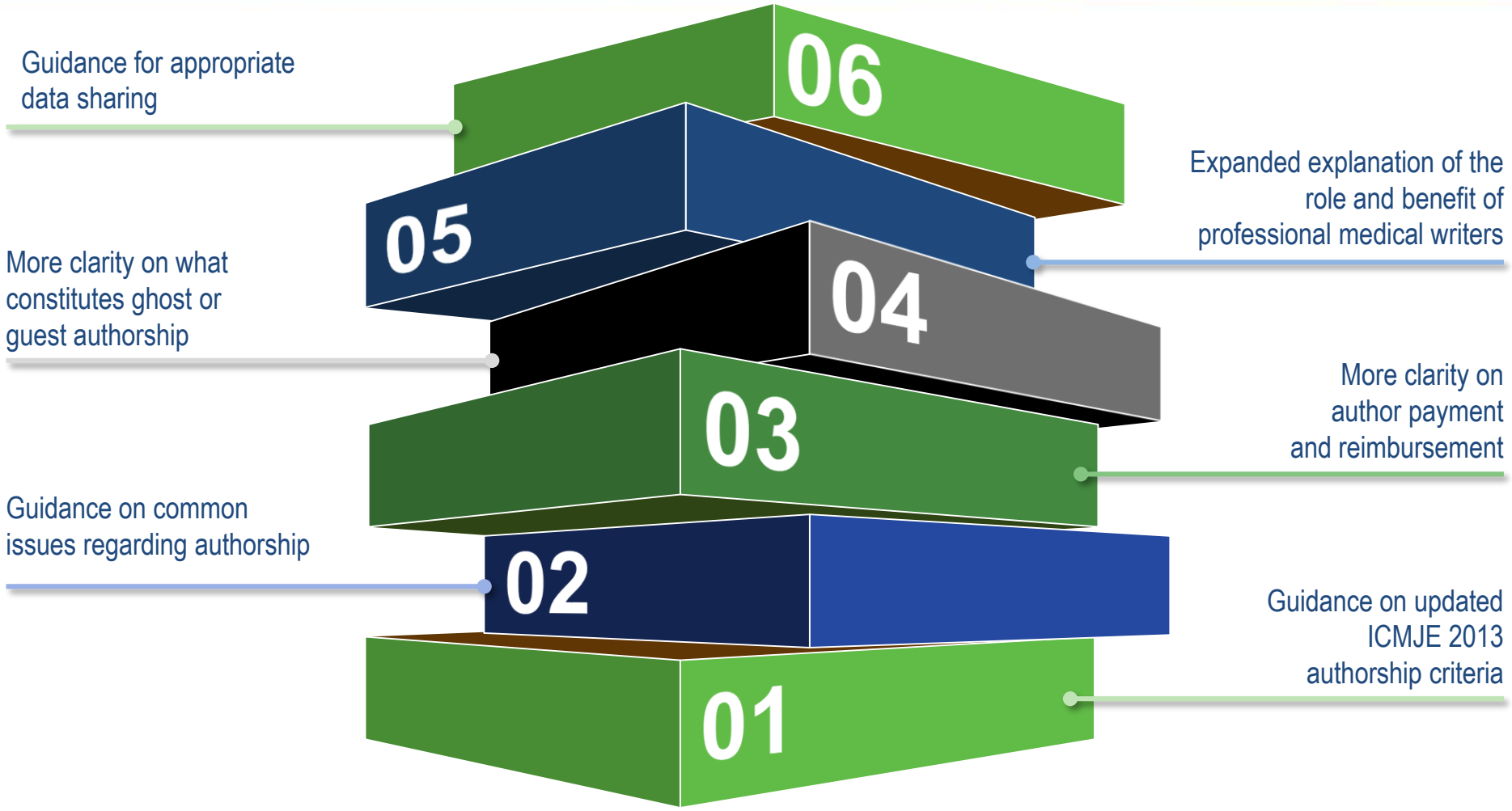
The latest revision, GPP3, reflects changes in the medical publications environment and aims to clarify and strengthen the principles and practices described in earlier versions. This guideline also reflects some important changes from GPP2 (**Table**).

Throughout the guideline, we use the term "publications" to include the full range of formats published in peer-reviewed journals (for example, original research articles, short reports, reviews, or letters to the editor) and "presentations" to include abstracts, posters, and slides for oral presentations at scientific congresses. "Sponsors" are organizations that provide primary support, which may include funding, for a study. "Publication professionals" are professional medical writers, publication planners, and publication managers, usually working either in or for companies. This guideline does not cover regulatory documents, medical education programs, or marketing or advertising materials, all of which are regulated or accredited by specific national or regional authorities.

METHODS

In August 2013, an e-mail invitation was sent to more than 3000 professionals from around the world, including International Society for Medical Publication Professionals (ISMPP) members (n = 1630); persons invited to review GPP2 (n = 288); and a distribution list from the Medical Publishing Insights and Practices initiative that included approximately 1400 investigators, researchers, and journal editors. Candidates were invited to volunteer as members of the GPP3 steering committee or reviewers (or both). Eight GPP2 authors screened the applications (n = 241). Of 118 steering committee applicants, 11 were chosen and joined 7 of the former GPP2 authors to provide a broad range of perspectives (from 7 countries, including employees of pharmaceutical, biotechnology, medical device, and

WHAT'S NEW IN GPP3?



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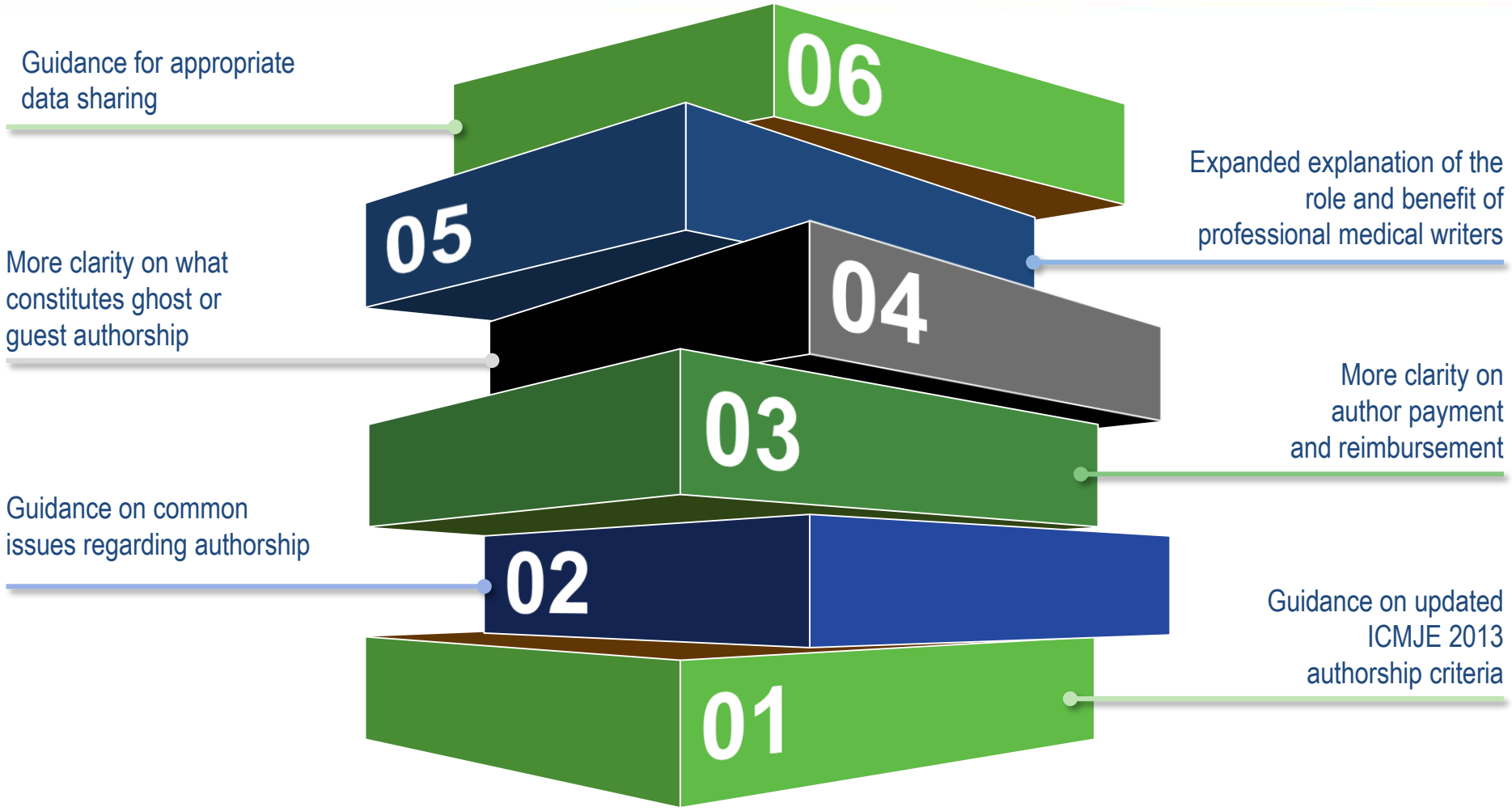


WHAT'S NEW IN GPP3?

GPP3 – NEW AND EXPANDED SECTIONS

Principles
10 steps to guide good publication practice

Data sharing

What should be published?

Plagiarism

Expanded guidance on ICMJE authorship criteria

Common authorship issues

Improved clarity on appropriate author payments and reimbursement

Expanded information on the role of the medical writer

PLUS

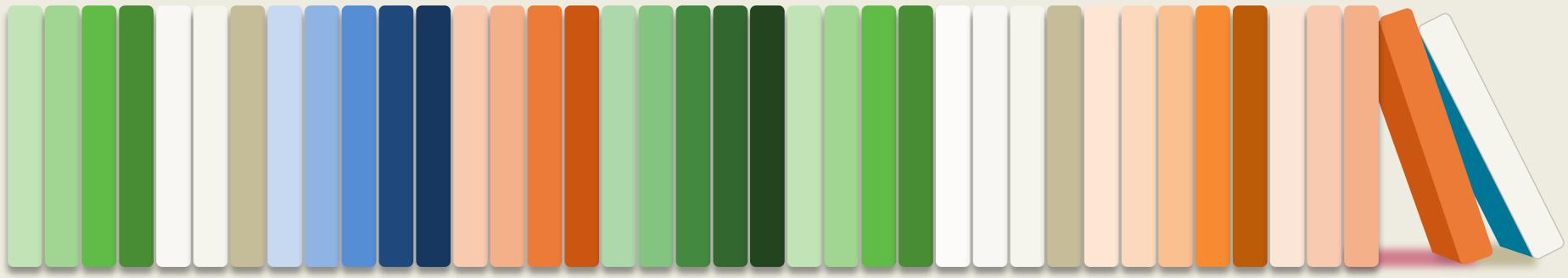
Other key updates

DATA SHARING

- Sharing and public posting of clinical trial data, including full study reports and individual patient-level data, is supported and may enhance trust and transparency
- As of July 2018, ICMJE journals will introduce the need for a data sharing statement to outline the process by which data are shared between investigators and sponsors

WHAT SHOULD BE PUBLISHED?

- Findings from ALL clinical trials (including non-interventional studies involving human participants) should be made public, ideally by publication in a peer-reviewed journal
- Results should be submitted for publication in a peer-reviewed journal regardless of outcome, and irrespective of whether the intervention is investigational, licensed, or has been discontinued or withdrawn from the market
- Not all studies produce publishable data (eg, where the data are of limited scientific or clinical value); in such situations, or in the case of multiple journal rejection, posting of results on a public website, trial registry site or data repository may be an option



PLAGIARISM AND 'SELF-PLAGIARISM'

- Plagiarism is unethical and unacceptable
- Where any material is copied or republished:
  - It should be clearly identified as such
  - Appropriate copyright permission should be obtained
  - The original author(s) and copyright holder should be appropriately acknowledged
- Reuse of authors' previous publications ('self-plagiarism' or 'text recycling') should generally be avoided

INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS (ICMJE) AUTHORSHIP CRITERIA RECOMMENDED

Updated to include a **4th criterion**

ICMJE recommends that authorship be based on:

1

2

3

4

GPP3 PROVIDES GUIDANCE ON COMMON AUTHORSHIP ISSUES

- Optimal number of authors
- How to decide author sequence
- Adding or removing an author
- What to do in the event of the death or incapacity of an author
- Changes to author affiliation
- Pharma company or sponsor-employed authors
- Can professional medical writers be authors?

IMPROVED CLARITY ON APPROPRIATE AUTHOR PAYMENTS AND REIMBURSEMENT

- Pharma companies may reimburse reasonable publication- or presentation-related expenses incurred by authors and other contributors (eg, travel and accommodation)
- Payment should NEVER be made or offered simply to attract someone to be an author or to influence an author's opinion
- As it is difficult to prove intent, pharma sponsors may choose to adopt policies that prohibit compensation for time spent authoring a publication or presentation

EXPANDED INFORMATION ON THE ROLE AND BENEFIT OF PROFESSIONAL MEDICAL WRITERS

- Emerging evidence suggests that the use of medical writers may:
  - Enhance publication quality
  - Reduce the risk of retractions due to misconduct
- Properly acknowledged medical writers are **NOT** ghostwriters
- Medical writers help ensure that all contributors follow good publication practice
- The contribution of medical writers, their funding sources, and any other competing interests MUST be disclosed

OTHER KEY UPDATES

- Timing of publications
- Trial registration and public posting of data
- The written agreement
- Contributorship
- Review articles
- Reporting standards

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Timing of publications

- For licensed products, manuscripts should ideally be submitted within 12 months and no later than 18 months of study completion, allowing for congress presentation first
- For investigational products, manuscripts should be submitted within 12 months and no later than 18 months of product approval or within 18 months of discontinuation
- Public posting of clinical trial summaries on trial registries (eg, ClinicalTrials.gov)
  - Does not constitute ‘prior publication’
  - Does not preclude the ethical obligation to attempt to publish the complete methods and findings
- Presentation of results at congresses is not a substitute for full publication in a peer-reviewed journal

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Trial registration and public posting of data

- Many journals have made trial registration a prerequisite for publication
- Clinical trial registration or identifier numbers should be included in all presentations and publications, including abstracts, even if not required by the journal or congress
- Unregistered trials should be so declared and the reason for non-registration provided

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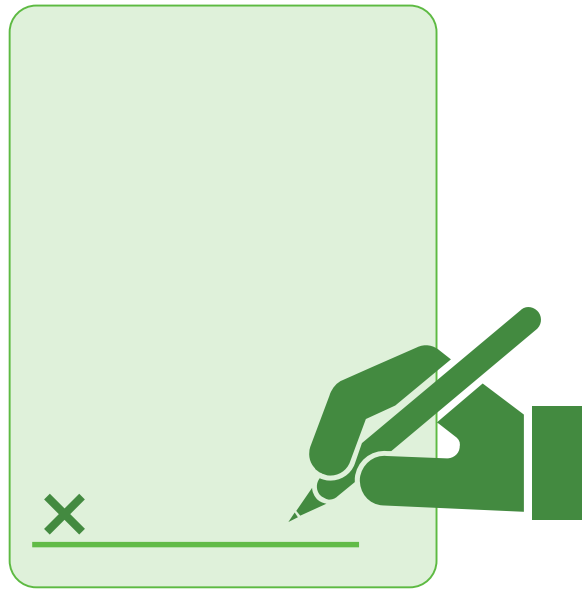
OTHER KEY UPDATES

The written agreement

- Should give authors responsibility for all decisions on publication content and final approval of versions to be submitted / published / presented
- Should give authors and other contributors full access to study data
- Should confirm the authors' freedom to publish without hindrance from the sponsor, while respecting the sponsor's rights to review for accuracy, compliance with any regulatory requirements, and for intellectual property protection
- Should respect the institutional policies of authors, investigators, and other contributors as well as those of the sponsor
- GPP3 recommends that authors should NOT enter into agreements that do not uphold these principles



OTHER KEY UPDATES

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Contributorship

- GPP3 supports the use of a contributorship model to describe each individual's role in a publication
- This should reduce ambiguity about contributions to the work
- Clear, concise descriptions of each author's role and any non-author's contributions (eg, statisticians, medical writers, research personnel) should be included within the presentation or publication

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OTHER KEY UPDATES

Review articles

- Should be comprehensive and the methods for searching, selecting and summarising information documented
- For systematic reviews and meta-analyses, PRISMA guidelines should be followed
- There should be a clear scientific or clinical rationale (educational need, literature gap) for publishing a narrative review
- Discussion or recommendations founded principally on opinion should be clearly identified as such
- The sponsor's role, if any, should be clearly acknowledged

OTHER KEY UPDATES

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Reporting standards

- Authors should follow established reporting standards for specific study types
  - Trials – CONSORT
  - Observational studies – STROBE
  - Systematic reviews – PRISMA
  - These and other guidelines are available on the EQUATOR Network

GPP3 RESOURCES

- Link to GPP3 manuscript
- Chinese and Japanese translations
- Presentation from ISMPP annual meeting
- YouTube presentation
- FAQs
- Historical archives