

Good Publication Practice (GPP3)

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Background to GPP

- Council of Biology Editors meeting **(Nov 1998)**
- Three-way meeting: **Journal editors / Academics / Pharmaceutical industry**
- Revealed editors' and academics' uneasiness about industry practices

Concerns

- Selective publication
(non-publication of negative results, over-publication of positive results)
- Failure to disclose conflicts of interest
- Unacknowledged use of medical writers (ghost writers)
- Guest authorship
- Inadequate involvement of named authors

GPP

The first GPP guidelines came out in 2003

GPP2 published in 2010

GPP3 published August 2015

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Good publication practice for pharmaceutical companies

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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

In response to changes in the environment in which authors, presenters, and other contributors work together to communicate medical research the **International Society for Medical Publication Professionals** has updated the good publication practice guidelines

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

Evolution of GPP

Version	Date	Title	Published
GPP	2003	Good Publication Practice for pharmaceutical companies	<i>Current Medical Research & Opinion</i>
GPP2	2010	Good publication practice for communicating company sponsored medical research: the GPP2 guidelines	<i>BMJ</i>
GPP3	2015	Good publication practice for communicating company-sponsored medical research: GPP3	<i>Annals of Internal Medicine</i>

All available at www.ismpps.org

Authors

- **GPP**: Wager, Field & Grossman
- **GPP2**: Graf, **Battisti**, **Bridges**, Bruce-Winkler, Conaty, Ellison, Field, **Gurr**, Marx, Patel, **Sanes-Miller**, Yarker
for ISMPP
- **GPP3**: **Battisti**, Wager, Baltzer, **Bridges**, Cairns, Carswell, Citrome, **Gurr**, Mooney, Moore, Pena, **Sanes-Miller**, Veitch, Woolley, Yarker

International author group



Authors from: US (8), UK (3), Denmark, the Netherlands, Australia, New Zealand & Steering Group member in Japan

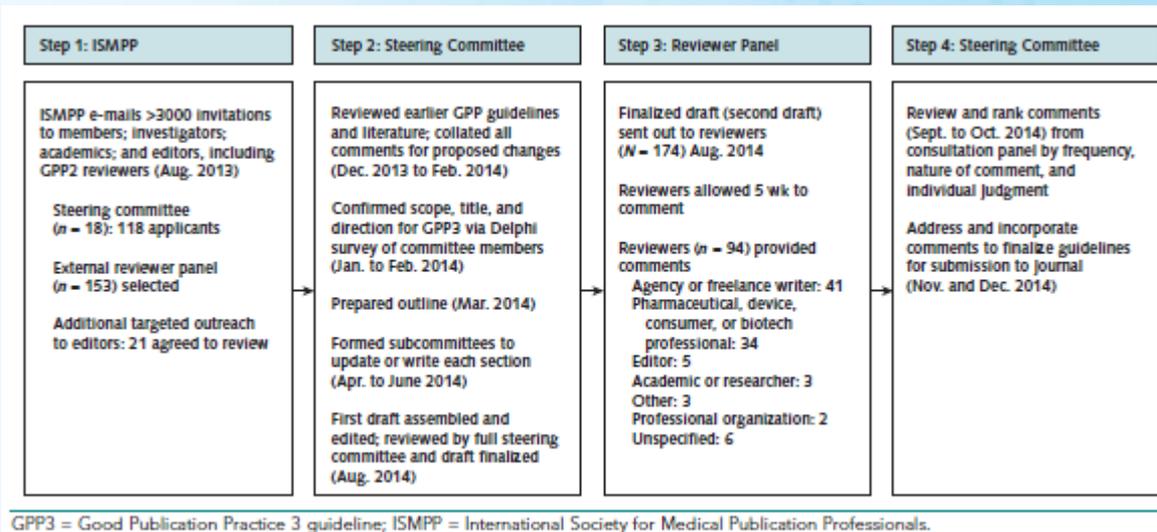
Development

GPP2

- 16 Steering cttee members
- 14 authors
- Draft circulated to 193
- 116 sets of comments

GPP3

- 241 applicants (for author and/or reviewer)
- 18 Steering cttee members
- 15 authors
- Draft circulated to 174
- 94 sets of comments



Key points

- 1st guideline to require drug companies to endeavour to publish results of all trials
- Set out roles and responsibilities of professional medical writers (so they are NOT ghost writers)
- Described relationships between investigators (authors) and companies

Endorsed by journals

thebmj

Research ▾ Education ▾ News & Views ▾ Campaigns

Archive

For authors

Industry sponsored studies

If you are submitting an original article reporting an industry sponsored clinical trial, postmarketing study, or other observational study please follow the guidelines on [Good Publication Practice \(GPP2\)](#) and on properly reporting the [role of professional medical writers](#).



Commercial organizations

Authors from pharmaceutical companies, or other commercial organizations that sponsor clinical trials, should declare these as [competing interests](#) on submission. They should also adhere to the [Good Publication Practice guidelines for pharmaceutical companies](#), which are designed to ensure that publications are produced in a responsible and ethical manner. The guidelines also apply to any companies or individuals that work on industry-sponsored publications, such as freelance writers, contract research organizations and communications companies. BioMed Central will not publish "advertorial" content.

Endorsed by drug companies



Alignment with External Standards—Roche conducts publication activities in alignment with international regulations and industry guidelines, including Good Publications Practice (GPP), Consolidated Standards of Reporting Trials (CONSORT statement), and the ICMJE’s “Uniform Requirements for Manuscripts Submitted to Biomedical Journals” (URM).



USE OF PROFESSIONAL MEDICAL WRITERS

Actelion may offer authors the assistance of professional medical writers to facilitate the development of publications. Such collaborations must follow ethically acceptable practice, as outlined in several internationally recognized guidance documents [GPP; EMWA; AMWA; ISMPP].

Journal Editors (ICMJE), international reporting guidelines (CONSORT, STROBE, etc.), individual journal guideline practice guidelines, such as Good Publication Practice [GPP]; and position statements from the European Medical Writers Association (EMWA), American Medical Writers Association (AMWA) and International Society for Medical Publication Professionals (ISMPP), etc.).

Principles of GPP

1. The design and results of all clinical trials should be reported in a complete, accurate, balanced, transparent, and timely manner.
2. Reporting and publication processes should follow applicable laws (eg, FDAA) and guidelines (eg, ICMJE and reporting guidelines on the EQUATOR Network).
3. Journal and congress requirements should be followed, especially ethical guidelines on originality and avoiding redundancy (that is, duplicate publication).

4. Publication planning and development should be a collaboration among all persons involved (eg, clinicians, statisticians, researchers, and publication professionals, including medical writers) and reflect the collaborative nature of research and the range of skills required to conduct, analyze, interpret, and report research findings.
5. The rights, roles, requirements, and responsibilities of all contributors (ie, authors and any nonauthor contributors) should be confirmed in writing, ideally at the start of the research and, in all cases, before publication preparation begins.
6. All authors should have access to relevant aggregated study data and other information (for example, the study protocol) required to understand and report research findings.

7. The authors should take responsibility for the way in which research findings are presented and published, be fully involved at all stages of publication and presentation development, and be willing to take public responsibility for all aspects of the work.
8. Author lists and contributorship statements should accurately reflect all substantial intellectual contributions to the research, data analyses, and publication or presentation development. Relevant contributions from persons who did not qualify as authors should also be disclosed.

9. The role of the sponsor in the design, execution, analysis, reporting, and funding (if applicable) of the research should be fully disclosed in all publications and presentations of the findings. Any involvement by persons or organizations with an interest (financial or nonfinancial) in the findings should also be disclosed.
10. All authors and contributors should disclose any relationships or potential competing interests relating to the research and its publication or presentation.

The quick version

1. Publish all trials
2. Follow reporting guidelines and laws
3. Follow journal requirements
4. Involve everybody in publication planning
5. Have a publication agreement
6. Give authors access to study data, etc.
7. Authors are responsible for pub's
8. Authorship should be accurate
9. Disclose role of sponsor
10. Disclose Conflicts of Interest

Commitment to publish all trials

- GPP1: Companies should endeavour to publish the results from all of their clinical trials of marketed products
- GPP was the first guideline to call for this

GPP3

- “The design and results of all clinical trials should be reported in a complete, accurate, balanced, transparent, and timely manner” (1st principle)
- Publication plans should ensure “that both positive and negative findings are published” (1.1)
- “Findings from all clinical trials ... should be made public, ideally by publication in a peer-reviewed journal” (1.3)

- “Findings from all clinical trials ... should be made public, ideally by publication in a peer-reviewed journal regardless of whether the findings are positive, negative, or inconclusive or whether the studied intervention is investigational, is licensed, or has been discontinued or withdrawn from the market.” (1.3)

Declaration of Helsinki 2013

- Negative and inconclusive as well as positive results **must** be published or otherwise made publicly available.
- Sources of funding, institutional affiliations and conflicts of interest **must** be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication. (36)

What about trials that are hard to publish?

- “However, not all studies produce publishable data. In such situations (e.g. when the data are of limited scientific or clinical value or in the case of multiple journal rejections), posting results on a public Web site, trial registry site (e.g. ClinicalTrials.gov), or data repository may be an option for disclosure.”

When should trials be published?

- GPP2 “timely”
- **GPP3** New section (1.3.1) on Timing
- “For licensed products, manuscripts should ideally be submitted within 12 months (or 18 months at the latest) of study completion, allowing for congress presentation first (if required). For investigational products, manuscripts should be submitted within 12 months (or 18 months at the latest) of product approval or within 18 months of product discontinuation”.

Authorship

- GPP (1&2) has always endorsed ICMJE criteria
- **GPP3** recommends ICMJE and gives extra guidance and clarification of what this means in practice

Authorship

- “Authorship must not be used as a reward or gift for services rendered... Authorship must represent a **substantial intellectual contribution** to both the research being reported and the development of the publication or presentation, and the willingness and ability to take public responsibility for both” (2.3.2)

ICMJE authorship criteria

www.icmje.com

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
2. Drafting the work or revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any parts of the work are appropriately investigated and resolved.

ICMJE: the essentials

Authors should:

1. take part in the research
2. take part in the publication
3. agree to be listed / the manuscript
4. take accountability

Contributors (ICMJE)

- “Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples include ... writing assistance, technical editing, language editing, and proofreading.”

Are medical writers authors?

- “Medical writers generally do not meet accepted authorship criteria, but there may be exceptions (e.g. if they contribute substantially to a review article). If writers qualify for authorship (i.e. meet ICMJE or journal-specific criteria), they should be listed as authors and their financial relationship with the sponsor should be disclosed.” (2.4.3)

More detail on authorship

ICMJE

1. Substantial contributions ...
2. Drafting or revising
3. Final approval
4. Accountability

GPP3

- intellectual contribution rather than technical (eg drafting protocol, crafting discussion, statistical analysis)
- more than minor corrections for grammar, language, format
- must read the entire manuscript!
- each author is accountable for the work, should have confidence in other authors, should be able to identify who wrote each section

Appendix Table 2

- Number of authors
- Author sequence
- Addition or removal of author
- Death or incapacity of an author
- Change of affiliation
- Company-employed authors
- Professional writers as authors

Payments to authors

GPP2

- OK to reimburse “reasonable out-of-pocket expenses”
- Companies can pay for “specialised services (eg statistical analysis)”

GPP3 (2.3.3)

- Companies may reimburse “reasonable out-of-pocket expenses”
- May “pay for publication activities (eg statistical analysis, medical writing, editing or similar services)”
- “Any such payments should reflect the services provided and be at fair market value”

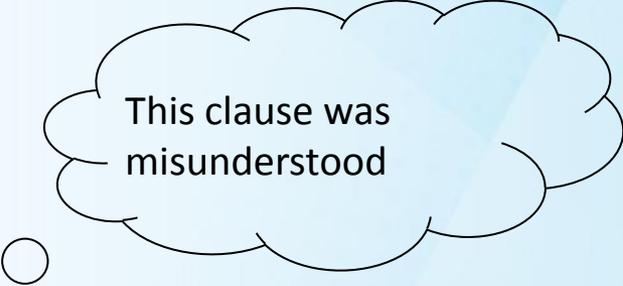
Payments to authors

GPP2

- “No honoraria should be paid for authorship of peer-reviewed articles or presentation”

GPP3 (2.3.3)

- “Payment should never be made (or offered) simply to attract someone to be an author or influence an author’s opinion. As it is difficult to prove specific intent, sponsors may choose to adopt policies that prohibit compensation for time spent authoring a publication or presentation.”



This clause was misunderstood

Acknowledgments

- Follow journal / congress requirements
- Get written permission for acknowledgments
- “Nonauthor contributors listed in the acknowledgments should not be expected to approve the final manuscript or presentation, but a courtesy copy may be provided before submission.” (2.5)

Role of medical writers

- “Properly trained and experienced writers can help authors with the development of publications in a compliant, complete, and timely manner, particularly when authors have limited time or knowledge of publication ethics and current publication and reporting guidelines” (2.4.1)

- “Professional medical writers have a responsibility to ensure that findings are presented clearly and accurately, and without any intent of misleading readers. Emerging evidence suggests that the use of professional medical writers may enhance publication quality and has been associated with a reduced risk of retractions due to misconduct.” (2.4.1)

Role of steering committees (1.2)

The publication steering committee:

- is initiated by the sponsor
- may be a subgroup of the trial steering cttee
- members may become authors if the meet ICMJE criteria
- Recommends an authorship working group

Authorship working group

- “formed by members of the publication steering committee to ensure appropriate and transparent authorship decisions”
- As described in MPIP authorship framework initiative
- Marusic et al *BMC Med* 2014;**12**:197

Data sharing (5.0)

- Journal requirements vary but must be respected
- “We recommend that, in addition ... sponsors grant access to patient-level data to qualified researchers on request” (redacted to protect confidentiality)

Trial registration (1.7)

- Trial registration numbers should be included (even if not required by journal / congress)
- Unregistered clinical trials should be declared as such (and the reason for non-registration provided)

Key points

- Read GPP3
- Discuss the principles
- Update documents / policies that refer to GPP2
- Think about what good publication practice means

and there are other guidelines to be aware of:

- Declaration of Helsinki
- ICMJE Recommendations
- EMWA g/l for medical writers
- EFPIA / PhRMA statements
- WAME, CSE statements
- Individual journal requirements

Reporting guidelines

- CONSORT (RCTs), STROBE (obs/epi), PRISMA, STAR-D, SPIRIT (protocols)
- CHEERS – Consolidated Health Economic Evaluation Reporting Standards
- Check Equator Network
www.equator-network.org



many journals
require these

Reporting guidelines all available on one site:

www.equator-network.org



equator
network

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Research



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The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.



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guidelines



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more resources

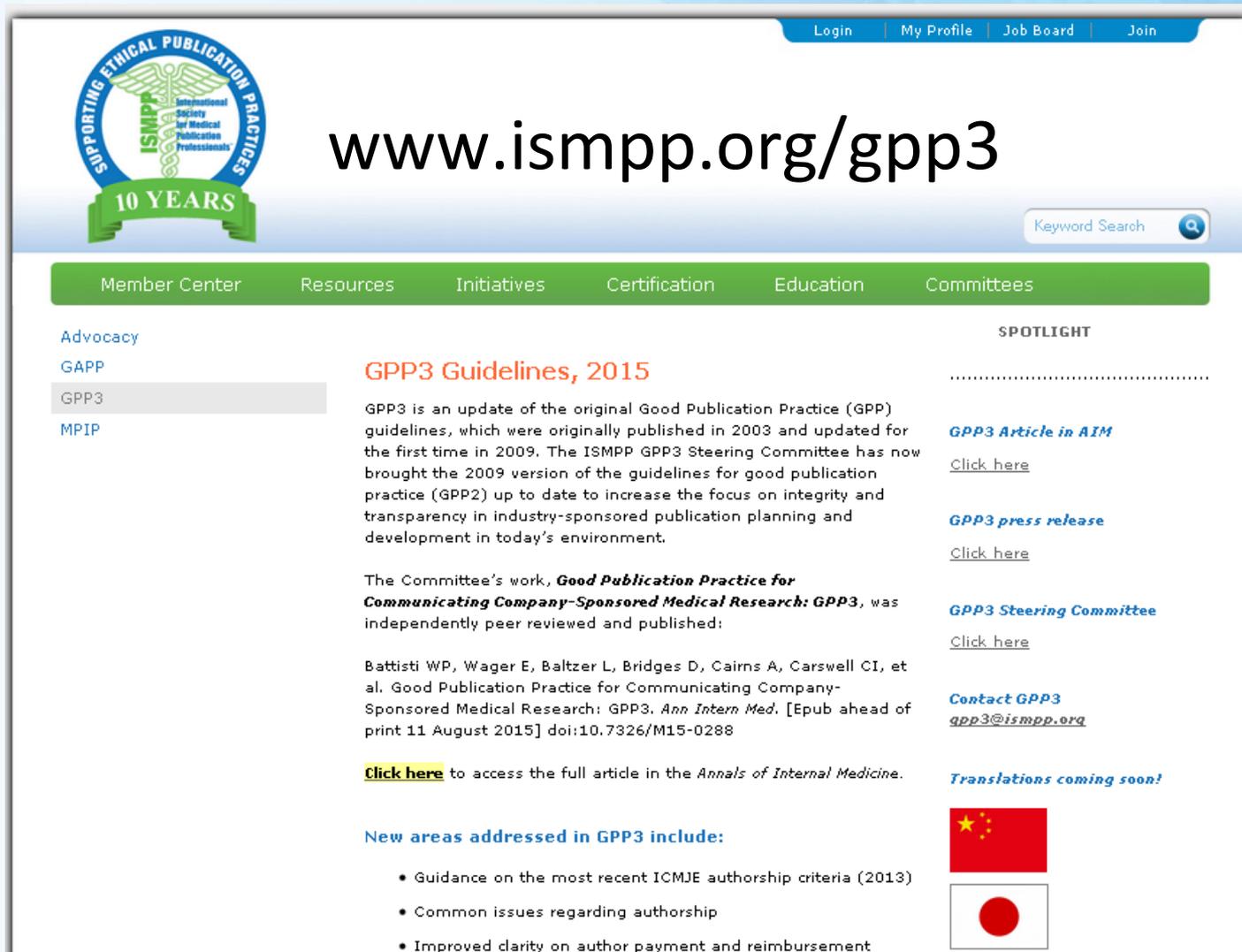


Key reporting
guidelines

CONSORT	Full Record Checklist Flow Diagram
STROBE	Full Record Checklist
PRISMA	Full Record Checklist Flow Diagram
STARD	Full Record Checklist Flow Diagram
COREQ	Full Record
ENTREQ	Full Record
SQUIRE	Full Record Checklist
CHEERS	Full Record Checklist
CARE	Full Record Checklist



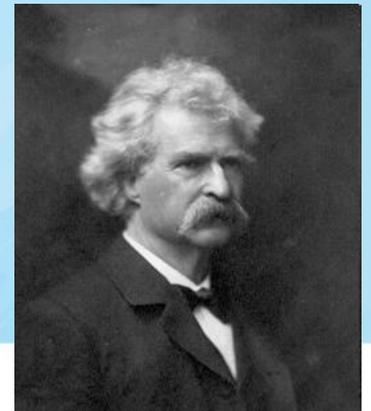
GPP available on ISMPP website



The screenshot shows the ISMPP website homepage. At the top left is the ISMPP logo, which includes a caduceus and the text "SUPPORTING ETHICAL PUBLICATION PRACTICES" and "10 YEARS". To the right of the logo is the URL "www.ismpp.org/gpp3". In the top right corner, there are navigation links: "Login", "My Profile", "Job Board", and "Join". Below the navigation links is a "Keyword Search" box. A green navigation bar contains the following menu items: "Member Center", "Resources", "Initiatives", "Certification", "Education", and "Committees". On the left side, there is a sidebar with a list of categories: "Advocacy", "GAPP", "GPP3" (which is highlighted), and "MPIP". The main content area features the heading "GPP3 Guidelines, 2015" in orange. Below this heading is a paragraph of text explaining that GPP3 is an update of the original Good Publication Practice (GPP) guidelines, which were originally published in 2003 and updated for the first time in 2009. The ISMPP GPP3 Steering Committee has now brought the 2009 version of the guidelines for good publication practice (GPP2) up to date to increase the focus on integrity and transparency in industry-sponsored publication planning and development in today's environment. Below this paragraph is another paragraph stating that the Committee's work, *Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3*, was independently peer reviewed and published. This is followed by a citation: Battisti WP, Wager E, Baltzer L, Bridges D, Cairns A, Carswell CI, et al. Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. *Ann Intern Med*. [Epub ahead of print 11 August 2015] doi:10.7326/M15-0288. A "Click here" link is provided to access the full article in the *Annals of Internal Medicine*. Below this is a section titled "New areas addressed in GPP3 include:" followed by a bulleted list: "Guidance on the most recent ICMJE authorship criteria (2013)", "Common issues regarding authorship", and "Improved clarity on author payment and reimbursement". On the right side of the main content area, there is a "SPOTLIGHT" section with a dotted line separator. It contains four links: "GPP3 Article in AIM" with a "Click here" link, "GPP3 press release" with a "Click here" link, "GPP3 Steering Committee" with a "Click here" link, and "Contact GPP3" with the email address "gpp3@ismpp.org". At the bottom right of the spotlight section, there is a "Translations coming soon!" announcement with two small flag icons: the flag of China and the flag of Japan.

***'Always do right –
this will gratify some
and astonish the rest'***

Mark Twain



Questions



Hmm. All very good questions!

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<http://www.editage.com/insights/tutorials>