

# Medical Publications in the Cross-Hairs of Public Scrutiny



Restoring confidence and credibility in the publication of industry sponsored clinical research.

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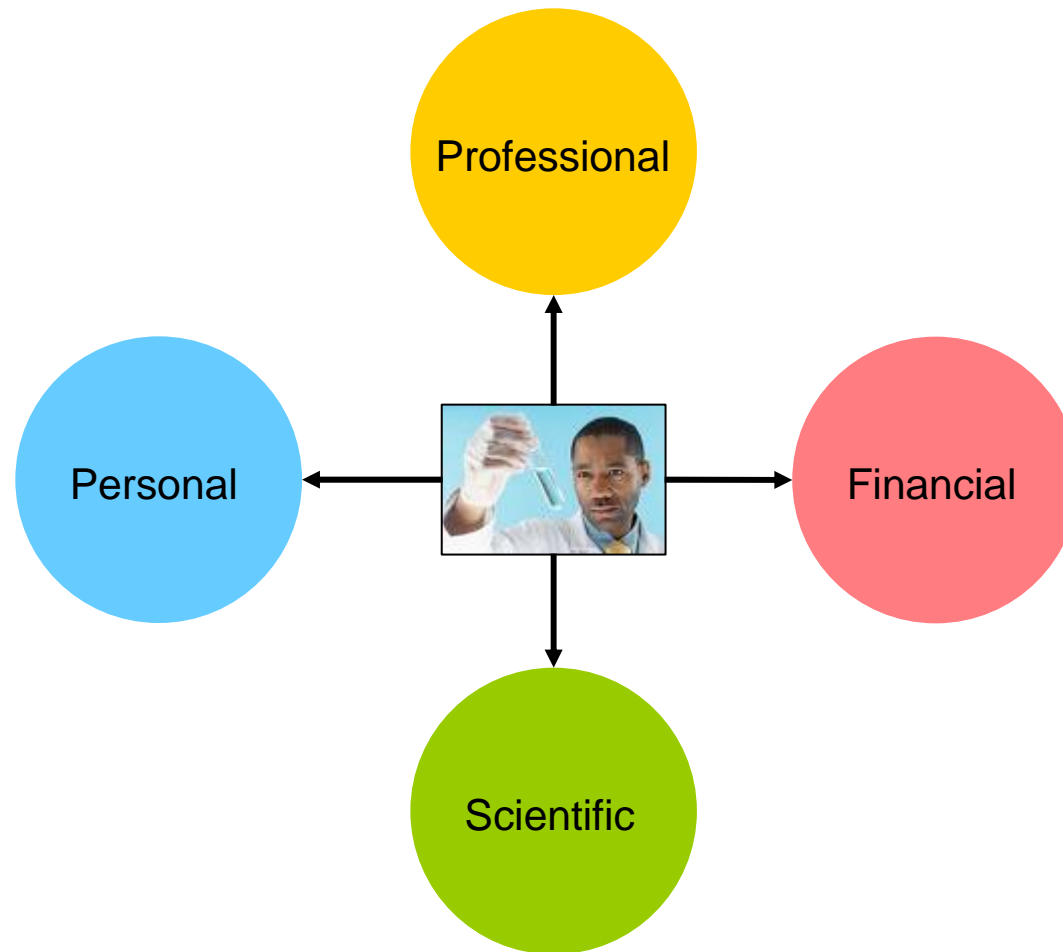
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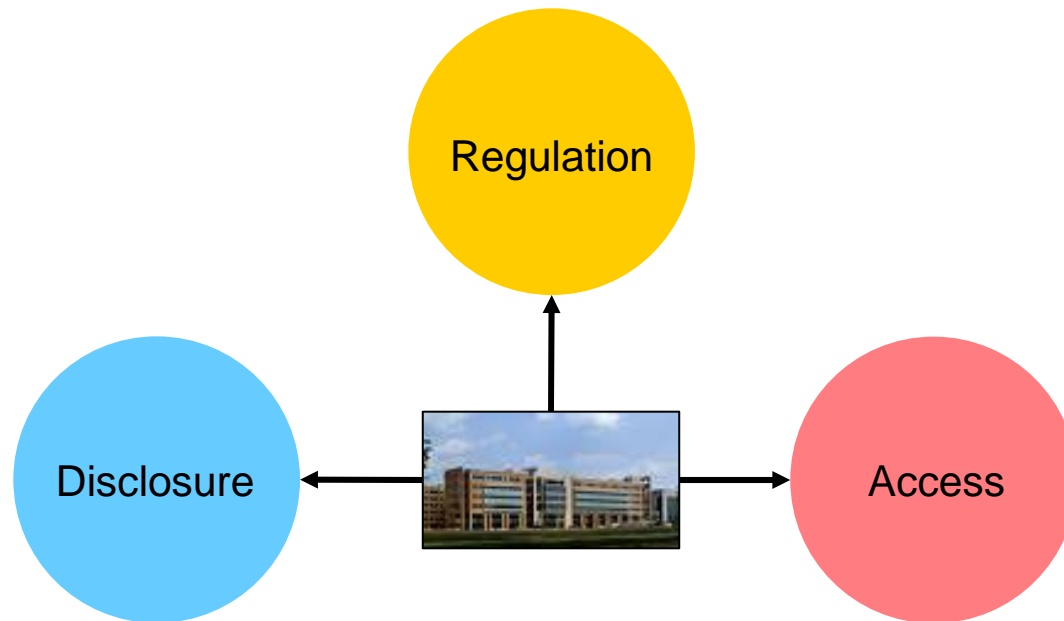
# Agenda

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# Why Publish? (Academic Perspective)



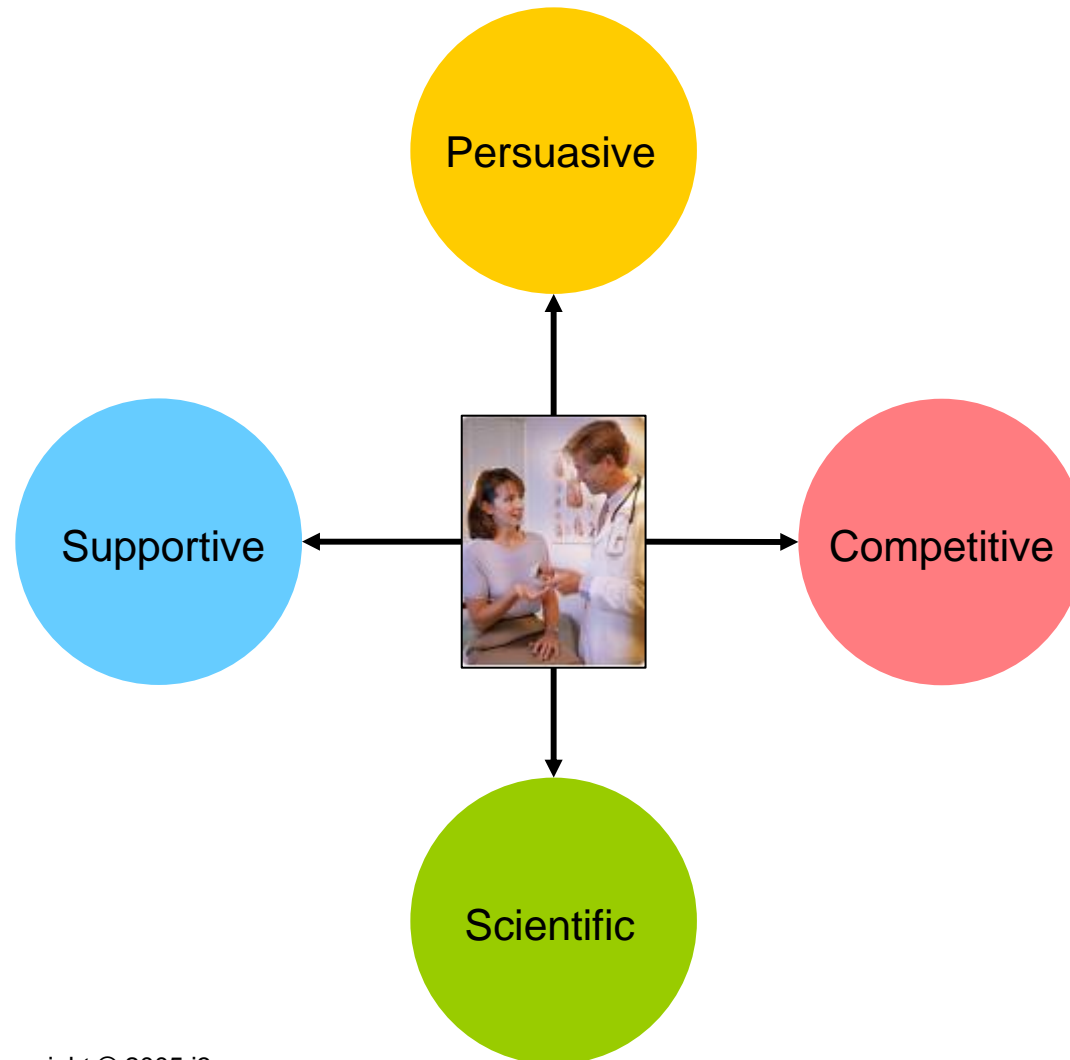
# Why Publish? (US Regulatory Perspective)



- Note: Companies will not be able to publish in ICMJE journals if the clinical trials they conduct have not been registered

[http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_public\\_laws&docid=f:publ085.110](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110)

# Why Publish? (Pharmaceutical Perspective)



# Current Uncertainties

- Authors may be unaware of the need to declare writing assistance.
- Authors may be unwilling to declare writing assistance because of the controversy surrounding authorship practices.
- Approximately 40% of authors may be interested in writing assistance to help them improve manuscript quality and reduce preparation time.
- Demand for medical writing services is growing, with increases in the number of medical writers and the medical writing services market.
- Preliminary evidence suggests that not all medical writers follow ethical publication guidelines.

# Current Headlines

## Pharmaceutical Companies Submit Ghostwritten Articles, Medical Journal Editors Say

Main Category: [Pharma Industry / Biotech](#)  
Article Date: 01 Jun 2005 - 9:00 AM

USA Today on Tuesday examined how some medical journals have

## Merck's Publishing Ethics Are Questioned by Studies

By **RON WINSLOW** and **AVERY JOHNSON**  
April 16, 2008; Page B4

Posted 5/30/2005 10:08 PM

## Medical editors: One-sided drug reviews hard to swallow

## Journal: Drug firm paid MDs for bylines Merck denies studies were ghostwritten

From: [The Boston Globe](#) | Date: **April 16, 2008** | Author: **Alice Dembner**  
Drug maker Merck & Co. manipulated public opinion by paying high-profile doctors to add their names to articles, according to a study.

## Drug industry hires ghostwriters for medical journal articles

Health Imaging News | December 15, 2005 | Industry News

The practice that some pharmaceutical companies are paying ghostwriters to write articles for medical journals as part of marketing campaigns was brought to light on Tuesday on the front page of *The Wall Street Journal*.

## Pharmaceutical Ghostwriting Trend Mars Credibility of Research and Patient Safety

[Business Wire](#), April 17, 2008

[E-MAIL](#) [PRINT](#) [LINK](#)  
pervasiveness of pharmaceutical academic writing

## Drugged Ghostwriters

James Ridgeway  
Tuesday, April 4 2005

WASHINGTON, D.C.—Everyone knows that the big pharmaceutical companies finance the research that is

## Scandal of scientists who take money for papers ghostwritten by drug companies

## Merck Wrote Drug Studies for Doctors

By **STEPHANIE SAUL**  
Published: April 16, 2008

The drug maker [Merck](#) drafted dozens of research studies for a best-selling drug, then lined up prestigious doctors to put their names on the reports before publication, according to an article to be published Wednesday in a leading medical journal.

## Medical Publishing Ethics Need Review

April 15, 2008 - [Insidermedicine](#)) The makers of Vioxx, a painkiller, regularly prepared scientific studies for medical journals, hiring companies and then hired researchers to write them. The amount of ghostwriting was minimal, according to a study by the American Association of Medical Journal Editors.

# Definitions, Cases and Recommendations: Ghost Author

## Ghost Author:

an author who contributed to a piece of work, but is left uncredited.

## Cases

Flanagin et al. Prevalence of Articles With Honorary Authors and Ghost Authors in Peer-Reviewed Medical Journals. *JAMA*. 1998;280:222-224

Ross et al. Guest authorship and ghostwriting in publications related to rofecoxib. *JAMA*. 2008;299:1800-181

Shapiro et al. The contributions of authors to multiauthored biomedical research papers. *JAMA*. 1994;271:438-442

Slone RM. Coauthors' contributions to major papers published in the *AJR*: frequency of undeserved coauthorship. *Am J Roentgenol*. 1996;167:571-579

Goodman NW. Survey of fulfillment of criteria for authorship in published medical research. *BMJ*. 1994;309:1482

# Definitions, Cases and Recommendations: Author

- The Committee on Publication Ethics (COPE)\*
  - The award of authorship should balance intellectual contributions to the conception, design, analysis and the writing of the study against the data collection and other routine work.
- World Association of Medical Editors (WAME)\*\*
  - Authorship implies a significant intellectual contribution to the work, some role in writing the manuscript and reviewing the final draft of the manuscript.
- International Committee of Medical Journal Editors (ICMJE)\*\*\*
  - An “author” is generally considered to be someone who has made substantive intellectual contributions to a published study.

\*<http://www.publicationethics.org.uk/reports/2003/>

\*\*<http://www.wame.org/resources/policies>

\*\*\*<http://www.icmje.org/sponsor.htm>

# Definitions, Cases and Recommendations: Ghostwriter

## Ghostwriter:

a professional writer who was not involved in the research, who helped the named author to develop a publication, and who was not acknowledged as a contributor.

## Cases

Steinman MA et al. Narrative review: The promotion of gabapentin: an analysis of internal industry documents. *Ann Intern Med.* 2006;145:284-293

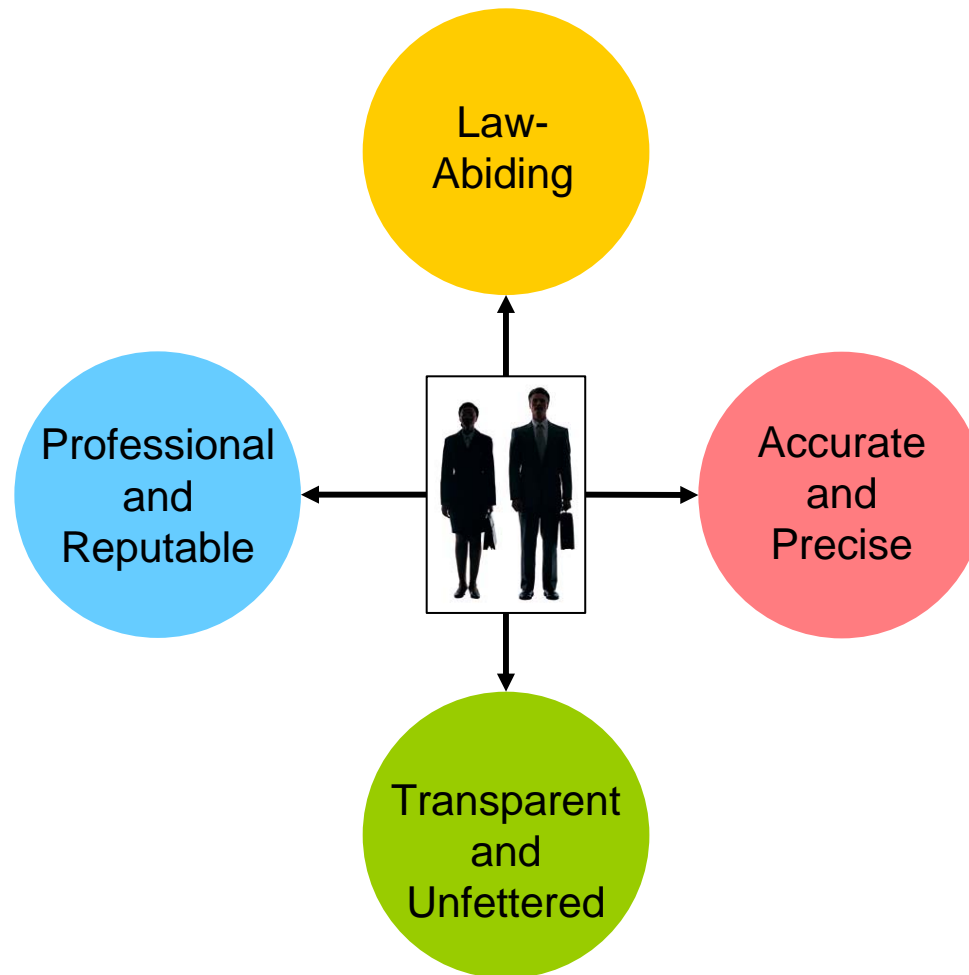
Sismondo S. Ghost management: How much of the medical literature is shaped behind the scenes by the pharmaceutical industry? *PLoSMed.* 2007;4(9):e286

Healy D, Cattell D. Interface between authorship, industry and science in the domain of therapeutics. *Br J Psychiatry.* 2003 Jul;183:22-27

Ross et al. Guest authorship and ghostwriting in publications related to rofecoxib. *JAMA.* 2008;299:1800-1812

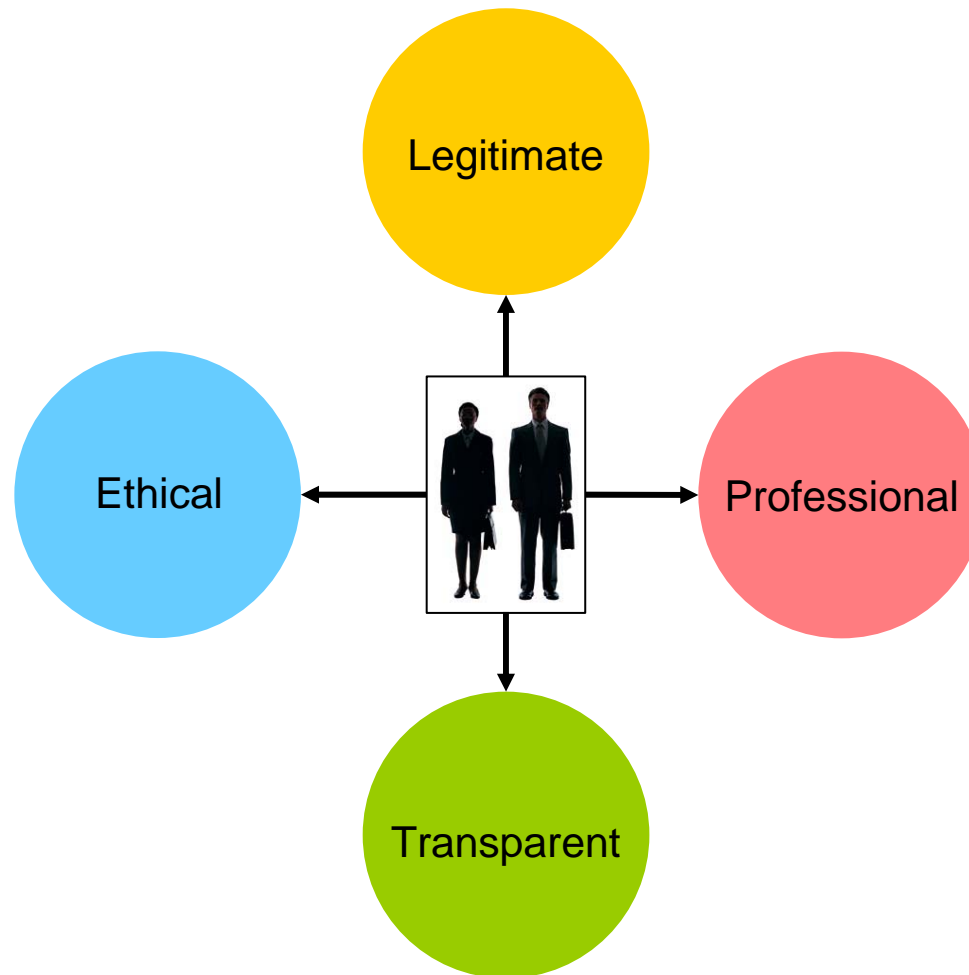
# Definitions, Cases and Recommendations: Profession Writer

- First Four Principles of the American Medical Writers Association's Code of Ethics:



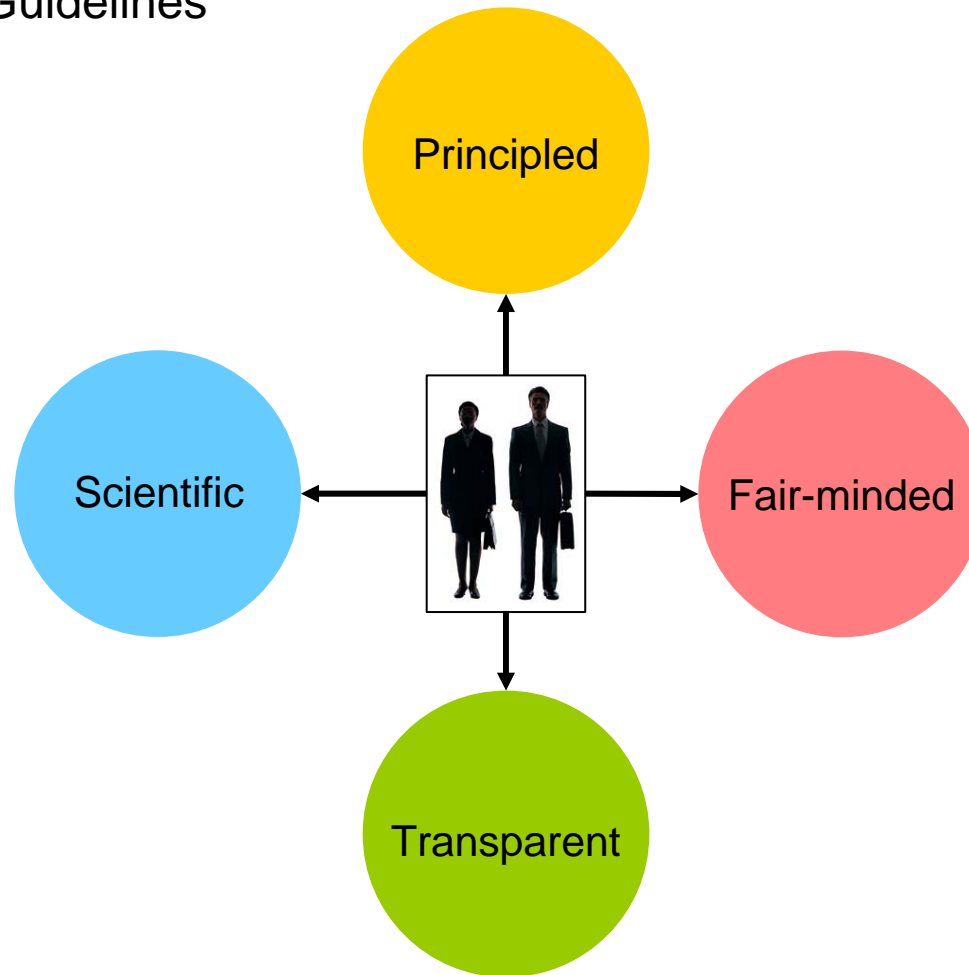
# Definitions, Cases and Recommendations: Profession Writer

- European Medical Writers Association (EMWA) position statement on the role of medical writers in developing peer-reviewed publications:



# Definitions, Cases and Recommendations: Profession Writer

- International Society for Medical Publication Professionals (ISMPP)  
Code of Ethics: III. Specific Professional Conduct Guidelines - A. Publication Preparation Guidelines



# Balancing Competing Interests: Author



- Keep credibility and objectivity intact
- Get own point of view across
- Keep control of content
- Keep biases out
- Keep unsubstantiated claims from being made
- Keep scientific rigor intact
- Work within own available time, taking as much time as needed to get it right



# Balancing Competing Interests: Professional Writer



- Keep the client and the named authors happy
- Keep the journal editor and reviewers happy
- Strive for both clarity and completeness
- Produce readable and reader-centered writing
- Present findings in the most objective way possible
- Keep to budget
- Keep to timeline
- Stay neutral



# Balancing Competing Interests: Clinical Reviewer



- Keep key messages in focus
- Keep fully aware, if not control, of content
- Keep named authors engaged
- Keep to timeline
- Keep on budget



# Balancing Competing Interests: Marketing



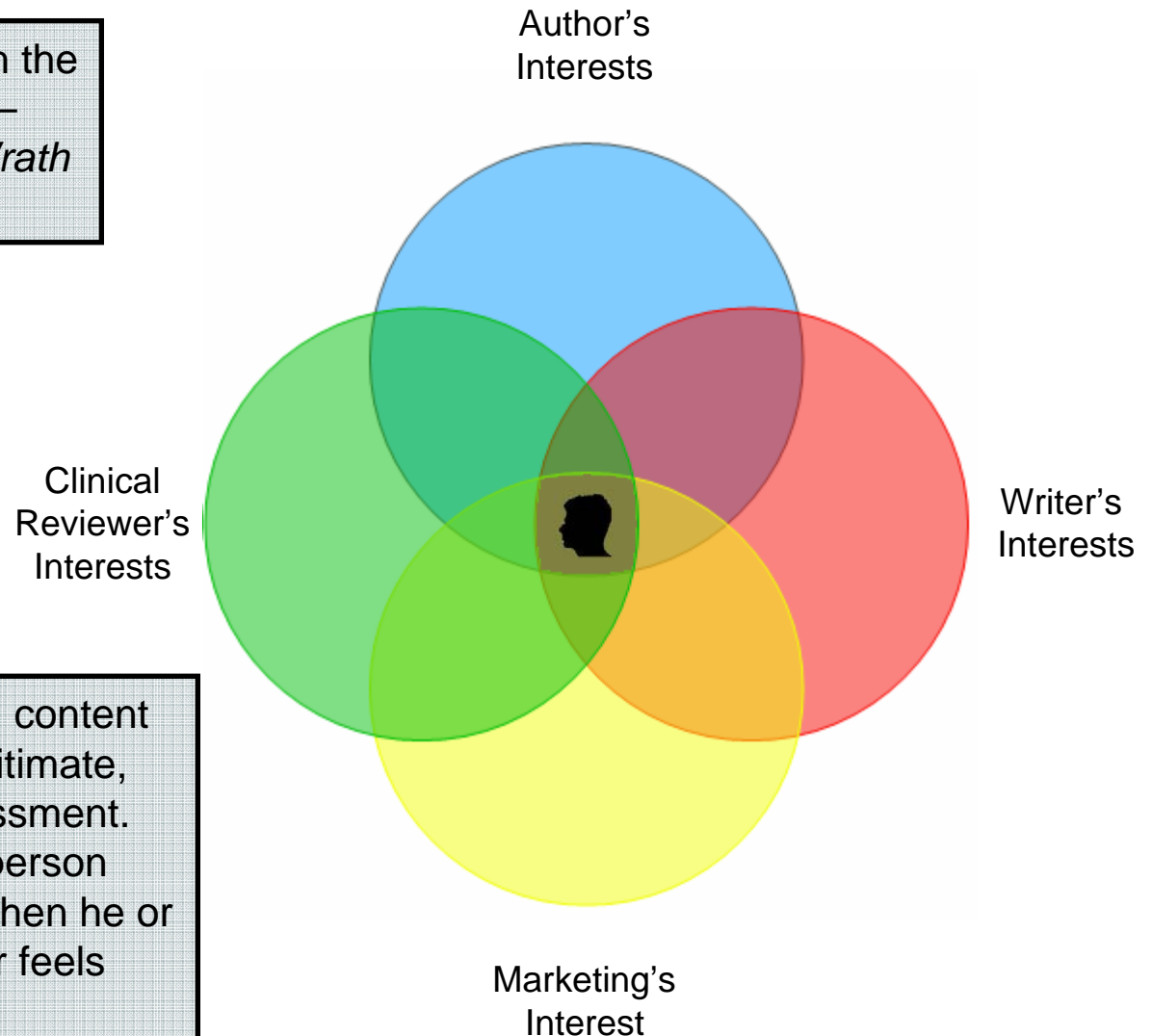
- Show data in best possible light
- Keep key messages in focus
- Keep preferred market terminology and style intact



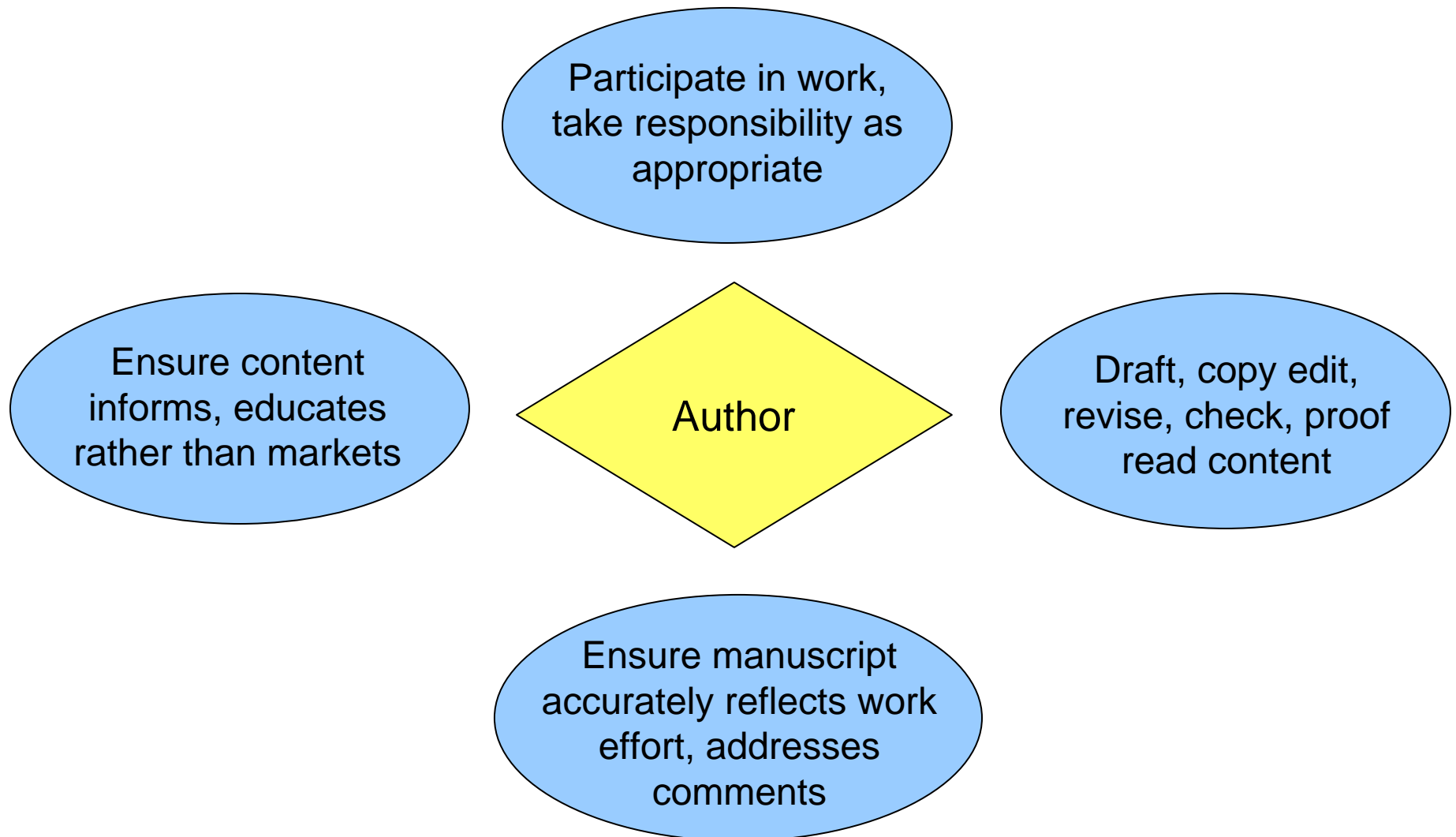
# Balancing Competing Interests with the Public's Interest

“The risks to the many, outweigh the interests of the few or the one.” – *paraphrased, Mr. Spock, The Wrath of Kahn*

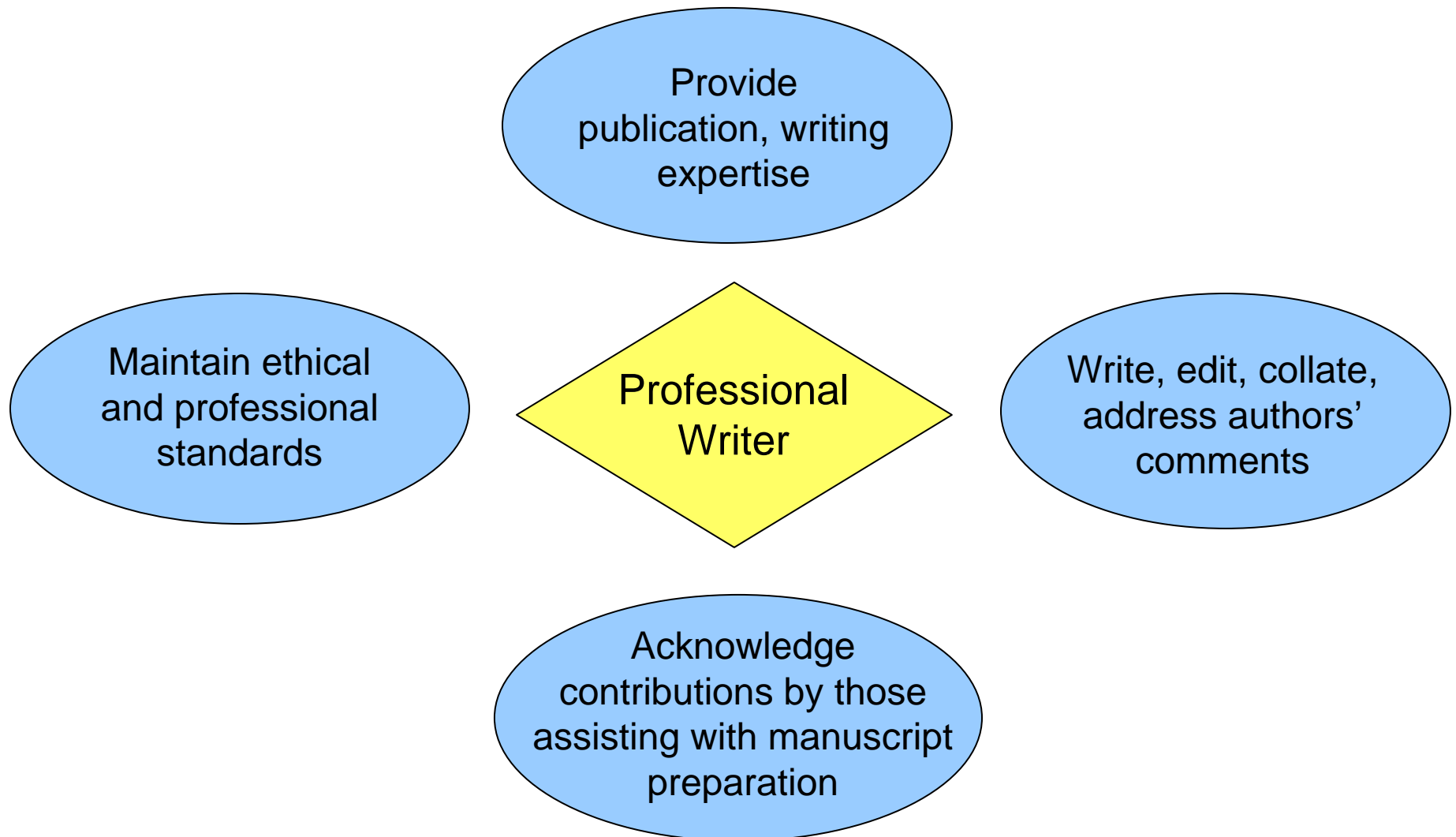
**Red Face Test:** Is the proposed content appropriate, valid, verifiable, legitimate, and not likely to cause embarrassment. The content should not put the person responsible for it in a situation when he or she blushes, is uncomfortable or feels embarrassed.



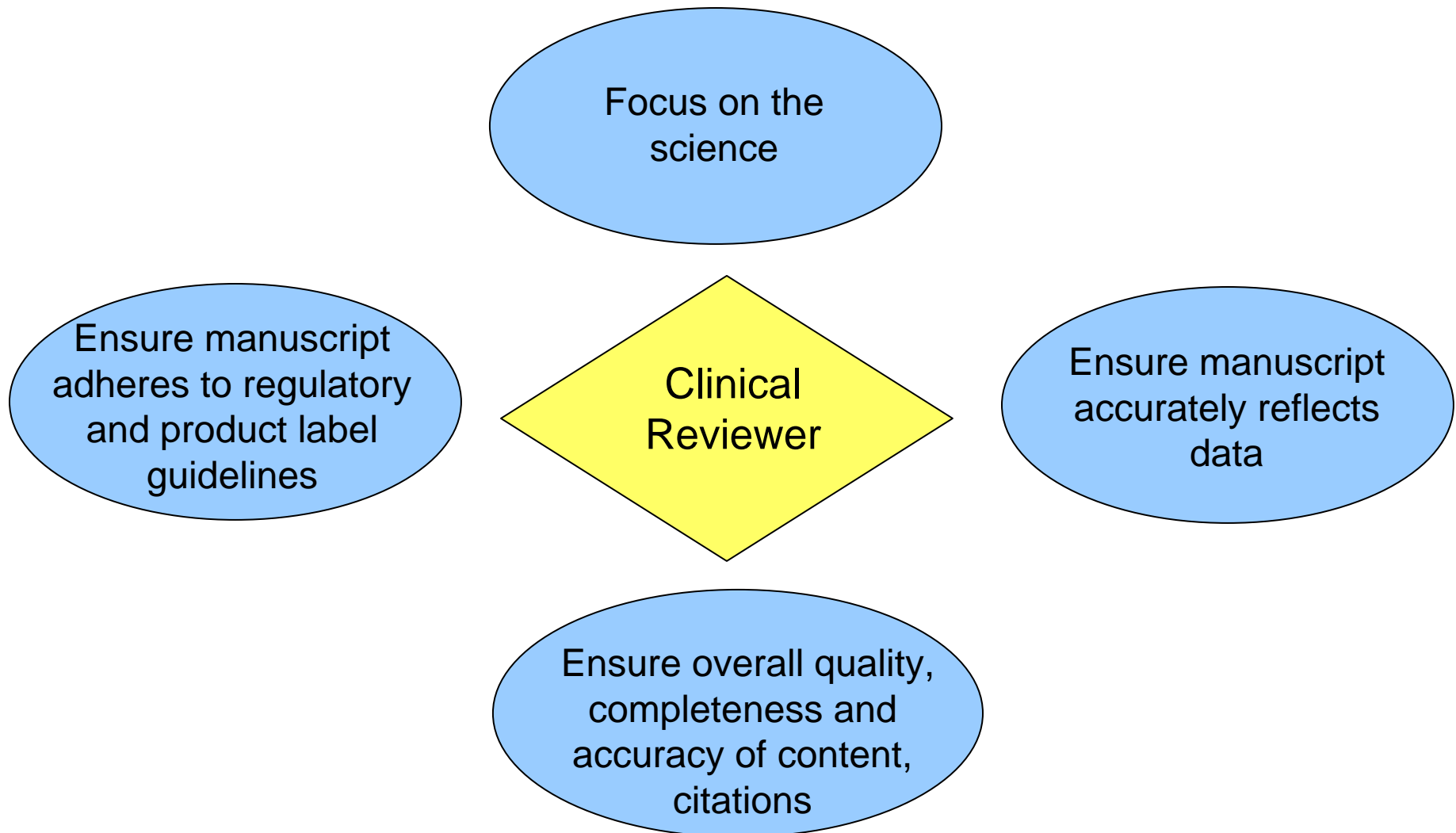
# Sphere of Influence: Author's Role



# Sphere of Influence: Professional Writer's Role



# Sphere of Influence: Clinical Reviewer's Role



# Sphere of Influence: Marketing's Role???

- In 2003, HHS Office of Inspector General issued its compliance guidance to the pharmaceutical industry:
  - Consulting and advisory payments.
    - “....of concern are compensation relationships with physicians for services connected directly or indirectly to a manufacturer’s marketing and sales activities.... While these arrangements are potentially beneficial, they also pose a risk of fraud and abuse. In particular, the use of health care professionals for marketing purposes—including, for example, ghost-written papers.... While full disclosure by physicians of any potential conflicts of interest and of industry sponsorship or affiliation may reduce the risk of abuse, disclosure does not eliminate the risk.” - **Federal Register** / Vol. 68, No. 86 / Monday, May 5, 2003 / Notices
- **Five years after** - Silverman E. Pharma: OIG Compliance Guide Made An Impact. Accessed on 20Aug2008 at <http://www.pharmalot.com/2008/05/pharma-oig-compliance-guide-made-an-impact/>
  - 92% of drugmakers surveyed say the guidelines “significantly impacted” the structure of their medical affairs teams.
  - Many have shifted medical science liaisons and thought-leader development teams away from commercial development.

# Manuscript Prescription

- Develop a Publication Policy
- Extend your Compliance Program to include Publication Practices and Standards
- Plan Early
  - Engage fully with the authors right from the start.
  - Address any issues early and discuss timelines, review processes and journal selection.
  - Discuss manuscript authorship, optimal patent protection and protection of confidential data and information.
  - Discuss the content of the publication.
  - Plan how you might deal with different results/outcomes.

# Manuscript Prescription

- Agree on Workflow
  - Agree exactly how each manuscript will be prepared and reviewed.
- Streamline Review
  - Reach agreement on who really has to see which drafts at each stage and separate ‘required’ reviewers from ‘optional’ reviewers.
  - Keep the number of required reviewers to a minimum.
  - Consider using review meetings rather than endless rounds of electronic document review.
  - Distinguish ‘discretionary’ reviewers’ comments from those that are mandatory.



# Questions and Answers

