



A comprehensive single source overview of medical publications.™

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Foreword

Role of the ISMPP

The International Society for Medical Publication Professionals (ISMPP) is a not-for-profit voluntary professional membership society dedicated to advancing medical publication planning and development, supporting medical publication professionals, and ensuring ethical medical publication practices.

ISMPP's **Vision** is *"To become the leading global authority on the ethical and effective publication of medical research to inform treatment decisions."* Its **Mission** statement is to *"Advance the medical publication profession globally through:*

- *enhanced integrity and transparency in medical publications*
- *improved standards and best practices*
- *education, advocacy, and professional collaborations."*

Additional information on the Vision and Mission statements is available on the ISMPP website ([mission-and-vision](#)).

All Information – One Location

The ISMPP Publication Primer (Primer) was developed based upon a core need that has been identified within the greater medical publications industry — there is currently no single location where an interested party can obtain a solid overview of medical publications and publication planning. The Primer is being developed to address this issue / opportunity.

Primary Goal

The Primer has been designed and developed in an effort to provide ISMPP membership with an asset that provides them with an ever-present baseline representation of the current state of medical publications.

Looking Ahead

The ISMPP Publications Primer has been designed as a “living asset”. As such, content within the document will be reviewed and/or updated on a designated schedule (see RED CIRCLE at the beginning of each section). As changes come to the world of Medical Publications, these will be reflected in the ISMPP Publications Primer.

Al Weigel

President & Chief Operating Officer

January 4, 2016

Document Overview

The Primer is being developed as an on-line “document” which will reside on the ISMPP web site, and be available not only to ISMPP members and sponsors, but also to anyone searching the Internet and others outside of ISMPP. The goal is to cultivate the Primer as a “living asset” for ISMPP, one that will be updated periodically on a regular basis to ensure that it will continue to be of value for many years to come.

The Primer is NOT being developed, as a means of conveying everything that one would ever need to know about publications. On the contrary, it is being conceived as a 10000-foot (3000-meter) view of the publications arena, with the primary goal of providing users with a solid overview of this important subject.

ISMPP is in no way attempting to “re-create the wheel” by realizing this effort. The document will contain original content but the majority of the information it contains will be sourced from / linked to existing materials and assets. These include a variety of industry guidelines, a number of ISMPP-generated materials on subjects such as ethics, standards, best practices, etc., and other elements developed by professional organizations, associations and groups.

This endeavor is being undertaken to provide information to a target group of audiences, all of which have one crucial element in common: they are new to and/or unfamiliar with the world of medical publications. This group of audiences would include, but is not limited to:

- 1) Academics
- 2) Industry staff/management
- 3) Agency staff/management
- 4) Medical students and Post Grads
- 5) Medical writers/editors

These are just a few of the groups who could benefit from the Primer. The ISMPP Sponsorship & Benefits Committee extends thanks to all who have already contributed to the development of this document and extends an offer to publication professionals to provide their thoughts, ideas and suggestions for further evolution of the effort.

Key Terms

Key term**What does this mean?**

Abstract

A brief summary of a publication or conference presentation. In a publication, the abstract appears at the beginning of a manuscript (some journals may use other terms, e.g. Summary, Synopsis or Précis). For a conference presentation, the abstract is usually submitted to the organizer ahead of the meeting and there is often a peer review process to select the abstracts that will be presented.

Academician

A member of an institution or association for advancement of sciences, arts or literature. The term is generally used to refer to a scholar or teacher/lecturer/professor at a college/university.

Acknowledgment

An expression of appreciation (by authors) for a person or body that has added value to a publication. For example, a professional medical writer (if used) or a company or institution that has provided financial or other type of support.

Acknowledgments usually appear at the end of a manuscript.

Clinical trial registry

A publicly accessible catalog for registering a clinical trial(s), including posting of summary results, patient recruitment, and trials in progress or completed.

Compliance

Compliance is defined as conformity in fulfilling official requirements. In the area of medical publications these may include external mandates, such as laws and guidelines, as well as internal guidance, in the form of standard operating procedures (SOPs) and policies.

Corporate Integrity Agreement (CIA)	A document outlining the obligations agreed to by a pharmaceutical company as part of a civil settlement. CIAs often mean that guidelines relating to publications become legal requirements. They are enforced by the Office of Inspector General and only apply to companies operating to an extent in the USA.
Disclosure	Declaration of all financial and non-financial relationships amongst author groups which have the potential to bias judgement from a positive or negative perspective.
Ethics	Ethics in medical publications may be summarized as a code of standards and principles for professional conduct and business practice that is appropriate for an individual or a group.
Evidence-based medicine	<i>"...the integration of clinical expertise, patient values, and the best evidence into the decision making process for patient care...The best evidence is usually found in clinically relevant research that has been conducted using sound methodology"</i> (Sackett DL, 1996; USD EBM Model)
Ghost/guest authorship	The practice of receiving credit for work on a publication which was prepared by a ghost writer.
Ghostwriting	The practice of preparing a manuscript and allowing another person (a ghost author) to be credited for it.
Guarantor	Some journals may require one author to be identified as the guarantor, who takes overall responsibility for the integrity of a study and its report. The guarantor must defend the veracity of the paper if it is ever questioned or criticized.
Impact Factor	A metric based on the number of times a publication is cited, impact factor is still the major indicator of the academic prestige of a journal and of its overall influence on medical practice.
Life cycle management	The management of the most appropriate timing for presentation/publication of the data from each phase of the development of a treatment, therapy or device.

Medical writer	Medical writers are professional writers who assist with the preparation of manuscripts in an ethical and transparent manner.
Meta-analysis	A statistical analysis of results from a comprehensive set of studies meeting specific design and quality criteria, in order to produce an estimate of the magnitude of effect of a given treatment; as well as an assessment of the consistency of effect among studies.
Open access journals	Journals that give unrestricted access to their articles based on the payment of publication fees by the submitters of the articles.
Peer review	The critical assessment of manuscripts or other forms of medical communication by professional peers for the purposes of evaluating suitability for publication and improving the quality of the work.
Permission	Before anyone can legally publish or distribute another person's copyrighted work, or even extracts or samples of that work (such as a figure or photograph in a published paper), permission must be requested from, and granted by, the copyright holder. The person reusing the work has an ethical and legal requirement to obtain permission for reuse.
Plagiarism	The practice of taking someone else's work or ideas and passing them off as one's own.
Poster	A type of conference presentation, comprising a large printed piece that is displayed for viewing by delegates. The conference organizer will advise presenters of any specific requirements for format/style, dimensions and content of the poster.
Publication planning	Publication planning is a process, involving many steps, that aims to ensure accuracy and timeliness of the dissemination of clinical or scientific data. The ultimate goal of medical publication planning is to ensure that there is a complete profile of the treatment in the peer-reviewed scientific literature.

Publication steering committee	A committee consisting of investigators, study sponsors, statisticians, and other experts whose responsibility is to plan and oversee the production of publications for a study.
Reporting guidelines	Sets of guidelines created by various key stakeholders (such as editorial groups, publishers, government bodies and medical writing organizations) designed to ensure ethical, transparent, and accurate reporting of health research.
Retractions	If there is clear evidence of misconduct associated with a publication, such as unethical data collection, data fabrication, or errors in experimental design or analysis, plagiarism or duplicate publication, a journal editor may retract a previously published paper. Committee on Publication Ethics (COPE) states that the main purpose of retractions is to correct the literature and ensure its integrity rather than to punish authors who misbehave.
Sunshine Act	A US law requiring all pharmaceutical, medical device, biological, and medical supply manufacturers that participate in US federal health programs to collect, track, and report any payment or other transfer of value greater than \$10 made directly to physicians and teaching hospitals.

Section 1: Publications 101

"The goal of scientific research is publication... A scientific experiment, no matter how spectacular the results, is not completed until the results are published... only thus can new scientific knowledge be authenticated and then added to the existing database that we call scientific knowledge"

From *How to Write and Publish a Scientific Paper*, by Robert A. Day, 1998.

The simplest definition of **publications** is this: the communication of information to the public. Although usually associated with publishing of printed material, publications encompass electronic media, slide presentations, and any other means of providing information to the public.

The original purpose of scientific and medical journals was to permit scientists and physicians to communicate with one another. A newer aim is to permit scientists and physicians to communicate with people who may not be trained as scientists or physicians – i.e., to communicate with the world at large (including students, patients and patient advocates, payors, and others).

1.1 Peer Review

The type of publications produced by authors and medical writers, whether for medical journals, congresses, symposia, or other forums, are invariably subject to a process known as peer review. This is the process that distinguishes these publications from less rigorous forms of medical publications, such as newspaper articles, society newsletters, TV and radio news stories, etc.

What is peer review? It is the critical assessment of manuscripts or other forms of medical communication by professional peers for the purposes of evaluating suitability for publication and improving the quality of the work. Virtually no medical publication is completed without having to make revisions based on reviewers' comments.

However, peer review is not designed to detect fraud, plagiarism, or other forms of publication malpractice. This responsibility rests with the author, and indirectly with a professional medical writer, should one be involved in the writing / editing of a given manuscript.

Key point: Peer review is not designed to detect fraud, plagiarism, or other forms of publication malpractice. This responsibility rests with the author, and indirectly with a professional medical writer, should one be involved in the writing/editing of a given manuscript.

1.2 Why Write And Submit A Manuscript?

Many different reasons exist as to why an author, company or group may wish to develop and submit a manuscript. All of them do so because it is important, and even necessary, for them to communicate information to interested audiences. For example:

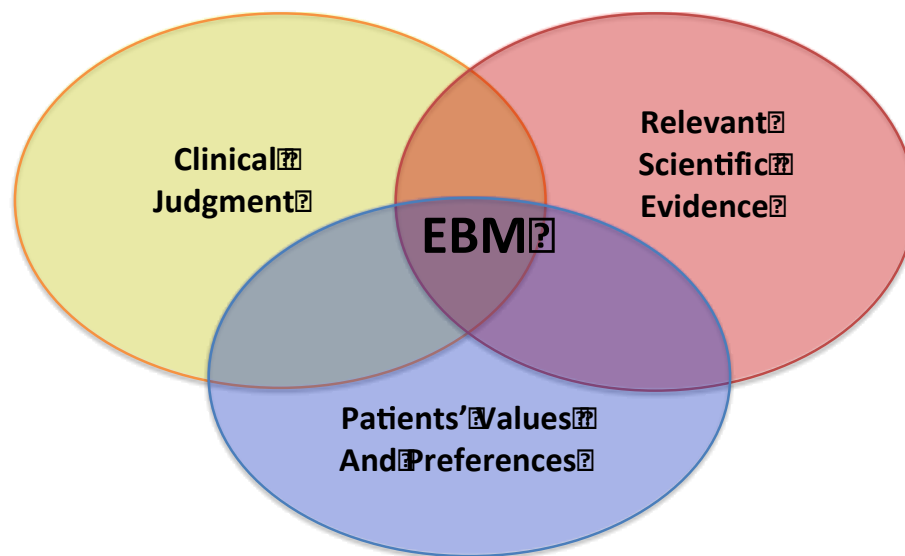
- An academic researcher needs to produce publications in order to obtain and then retain his or her job and to be eligible for promotion, as well as to gain respect and influence ([The Conversation-Publish or Perish](#)).
- Pharmaceutical, medical diagnostic, or medical device companies need to generate publications about the research conducted on the products they develop. There are many reasons for this: ethical, scientific, and commercial.
- Non-academic clinicians can enhance their professional standing by becoming published authors, and can share valuable clinical insights with their peers to advance the quality of patient care.
- Nonprofit organizations, patient advocacy organizations, research foundations, and other groups also have a stake in the medical publications enterprise and wish to have their research or other activities publicized (<http://www.researchamerica.org/>).

Over and above any particular reason why an author or institution would be interested in writing and submitting a medical publication, the overarching reason for medical

publications is that they are the building blocks of evidence-based medicine (Figure 1.2.1). More information about evidence-based medicine is available on the website of the Centre for Evidence-Based Medicine (<http://www.cebm.net>).

Key point: The overarching reason for medical publications is that they are the building blocks of evidence-based medicine.

What is evidence-based medicine?



(Sackett et al, 1996; Citrome & Ketter, 2009)

Figure 1.2.1: Evidence-based medicine.

The content of medical publications covers all 3 of these inter-related domains.

1.3 Basic Publication Structure

Medical writing, undertaken with or without the assistance of a professional medical writer, is a highly disciplined endeavor. Authors and professional writers share a common understanding of how publications are structured. This structure not only facilitates the development of a medical publication but also enables readers to understand the content of the publication by conveying information in an orderly and logical manner. Table 1.3.1 highlights the basic sections of a generic publication.

Table 1.3.1. Elements of a typical publication (journal article)

Structural Element	Description/Purpose
Title and Title Page	<p>The title is the advertisement for the manuscript; it should clearly describe the content of the publication. It should be succinct, yet contain key words that can be used by search engines and indexing databases.</p> <p>Authors, their affiliations and contact information, and keywords are placed below the title.</p>
Abstract	<p>The abstract acts as a preview/summary of the article and allows the reader to decide if he or she is interested in reading further. The abstract is the most visible part of the article because it is freely available on the journal Web site and PubMed (www.ncbi.nlm.nih.gov/); it is often the only part of the article most readers will ever read! It should briefly describe the objective or aim of the study, the methods, pertinent findings, and the conclusion(s) of the study. Journals usually stipulate a word limit (e.g., 200–250 words).</p>
Introduction	<p>The introduction must engage the reader's attention and motivate the reader to keep reading. An introduction should present a balanced overview of major findings in the topic area relevant to that publication, and identify what question(s) this led the authors to investigate. Introductions should generally be no longer than 3 or 4 standard paragraphs.</p>
Methods	<p>Methods are almost always presented with structured subheadings including (but not limited to): study population, study design, outcome measures, sample size, and statistical methods. It is important to provide sufficient details about trial design, patient populations, comparative treatments, use of experimental controls, the source of experimental materials, and statistical tests so that others can duplicate the study. A description of the ethical guidelines followed is mandatory for all trials involving human subjects.</p>

Results	The results section must be an objective presentation of the findings of the study, written using succinct statements that relate the findings to the research question identified in the introduction. The results section should follow a logical progression through the experimental process. Subheadings are usually used, such as demographics, subject disposition, primary and secondary outcomes, safety and tolerability, and others.
Discussion	The discussion allows the authors to highlight the key findings, describe their significance, and put them into context with what is already reported in the published literature. It is here that study results are interpreted and conclusions are drawn. Some speculation is permissible, but findings must not be overstated. There should also be a brief mention of the limitations of the research, how these were addressed, and what implications these may have for the strength of the conclusions.
References	<p>All previously published work used to support claims made or data presented must be cited. More recent citations are generally preferred, and primary sources (i.e. the first publication of a given method, result, or theoretical proposition) are almost always preferable to secondary sources (i.e. subsequent publications, such as review articles). Citing a large number of sources to support a single claim is rarely necessary.</p> <p>Reference software, such as EndNote® or Reference Manager®, should be used, if available. These programs feature styles and formats used by most journals, enable automatic formatting, and allow references to be entered directly from online libraries.</p> <p>(Note: Always check the 'instructions to authors' for the target journal, as some journals specifically request that reference software should not be used in the submitted draft of a manuscript.)</p>
Tables and Figures	Tables are used to present data efficiently and effectively, whereas figures are used to convey results in a graphically persuasive manner. Except for critically important data, there should be no repetition in the text of data shown in a table or figure. The journal guidelines may limit the number of tables and figures, and virtually all journals levy an additional charge for color graphics.
Figure Legends	Figure legends should provide just enough information for the reader to understand what the figure is describing. Here is where the symbols, abbreviations, statistical details, and other elements of the figure are

	defined. Excessively large figure legends should be avoided — they should not be used to compensate for an inelegantly constructed figure.
Supplemental Materials	There may be content that is of interest to motivated readers, or that should be made public for purposes of transparency, that does not fit in the main publication. This could occur because of limits on figures and tables or word count imposed by the journal, or because it would disrupt the flow of the manuscript. Many journals will allow publication of these materials as supplemental data (usually online only). Videos and photographs can also be placed here. As a rule, any table/figure/image that is essential for proper understanding of the manuscript should NOT be presented as supplemental material.

Key point: Manuscripts submitted for publication in peer-reviewed medical journals must conform to a recognized set of structural requirements

1.4 How to Write Medical Publications

From a general perspective, here is a list of the main principles for writing medical publications:

Clarity

- Medical writing should be sufficiently clear that the reader can understand it effortlessly
- Word choice, punctuation, sentence structure, paragraph structure — attention to all of these building blocks of expository writing are the responsibility of the writer

Brevity

- Medical publications are often limited to a defined number of words or characters, making efficient communication critically important.
- Time is precious, attention spans are often short and lives are usually busy; concise writing will be appreciated!

Precision

- Data must be accurate; take the necessary time and pay attention to ensure accuracy.
- Always be sure the data is thoroughly checked, and be vigilant when checking the work of others.

Caution

- Avoid claims that are not clearly demonstrated by the data and the analysis
- Be certain that all source data has been established as the official data.
- Limit speculative discussion; stick to the results at hand.

Developing medical publications is a group effort that requires thoughtful attention to the following elements of successful writing:

Collaboration:

- Invite and welcome ideas, feedback and criticism every step of the way.

Coordination:

- Facilitating cooperation and task completion by a diverse group of participants is a central role of the lead author/medical writer.
- Make the most of the electronic tools available to help with coordination.

Communication:

- Effective written and verbal communication is of utmost importance.
- Developing respectful, considerate, professional relationships is the foundation for successful communication.

Documentation:

- Often work will be passed from one writer to another; if the documentation is poor, it makes the work harder for others.
- Medical publication is a highly regulated activity that depends on documentation to demonstrate compliance with rules and standards.
- If it isn't documented, it didn't happen — always document your work.

Confidentiality

- Respecting confidentiality of proprietary data, ideas, and documents is a MUST.
- When in doubt, confidentiality should be protected.

Finally, established professional standards should be observed, including:

Transparency

- This is a cardinal value of the ISMPP and of regulators (see 2.6: Sunshine Act).
- Financial support for any aspect of publication development must be acknowledged.

- Potential conflicts of interest must be disclosed by all parties connected with a given publication.

Adherence to Recognized Criteria for Authorship, Acknowledgment, and Sponsorship

- There are clear requirements for authorship that must be respected; the International Committee of Medical Journal Editors (ICMJE) recommendations are the most generally accepted (<http://www.icmje.org>).
- Authors have the ultimate authority when it comes to the content of their publications.
- All contributors to a medical publication who do not meet criteria for authorship should be acknowledged, including professional medical writers.
- There should be no guest authors (individuals who are listed as authors but who do not meet criteria for authorship) or ghost authors/ghost writers (individuals who made substantial contributions to writing the publication, but who are not mentioned).
- Financial and material support for production of the medical publication by the sponsor must be acknowledged.

Key point: Medical writing is a collaborative effort; the writer must manage the process of developing the publication as well as ensuring the quality of the content.

The official document of medical publications standards is Good Publications Practice – 3. GPP3 (Battisti et al, 2015) is an update of a document developed and revised in 2009 by the ISMPP Steering Committee to “*address legislative, guidance, and ethical developments since 2003, and to reinforce the aims of the original 2003 publication*” (Graf et al, 2009). GPP3 is discussed further in Section 9.

A related document of medical publications standards is the PhRMA Guidelines “Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results” (www.phrma.org/principles-and-guidelines). PhRMA, the Pharmaceutical Research and Manufacturers of America, represents America's biopharmaceutical researchers and biotechnology companies.

Integrity

- Accurate, complete, balanced, transparent writing; full access to data for authors and contributors before writing begins; absence of redundant publications; honest attribution of authorship

Completeness

- Clear description of research hypotheses; reporting the detail required to ensure unbiased presentation; complete and honest reference to related work; include clinical trial registration or identifier numbers; discussion of limitations of study design and findings; making public or publishing results regardless of outcome

Transparency

- Making clear sources of funding; disclosure of financial and nonfinancial relationships; acknowledging authors and nonauthors who have made significant contributions to the work and by description of the contributions; recognizing the contributions of research sponsor(s)

Accountability

- Being accountable for the work and, in the case of authors and presenters, taking public responsibility for the work; assigning a guarantor

Responsibility

- Making public or publishing results within 12 months of study completion; respecting intellectual property; respecting the responsibilities of contributing individuals and organizations for good publication practice

Figure 1.4.1 Adapted from GPP2 Checklist

Key point: The field of medical publications has evolved substantially since GPP was published in 2003; this evolution continues with the publication of GPP3 in 2015.

1.5 Professional Assistance

Several organizations offer detailed guidance on how to write a medical publication:

- American Medical Writers' Association (amwa.org): This organization is the oldest and largest organizations devoted to providing education, training, support, and accreditation for writers, editors, and other communicators of medical information. Sister organizations include the European Medical Writers' Association (emwa.org) and the Australasian Medical Writers Association (medicalwriters.org).
- International Society of Medical Publication Professionals (ISMPP): The organization responsible for developing this Publication Primer; established in

2004 to provide a voice for the profession and to facilitate establishment of professional standards. ISMPP also provides educational opportunities for medical writers as well as publication planners, including a certification program in publication planning (<http://www.ismpp.org/certification>).

- Medical Communications Companies: Many of these companies provide extensive internal training programs for medical writers on staff, as well as direct supervision and mentoring of new writers.
- University Programs: There are university-based certificate programs in medical writing, which may be especially useful for writers with little medical or scientific training who wish to enter the field. These programs may require a limited amount of time on site, but the bulk of the course work is done online. Links to more information about some of these programs are provided below.
 - University of the Sciences at:
<http://www.gradschool.usciences.edu/biomedical-writing/biomedical-writing-program-overview>
 - Johns Hopkins University at:
<http://advanced.jhu.edu/academics/graduate-degree-programs/writing/the-experience/science-writing-at-hopkins/>
 - University of Chicago at:
<https://grahamschool.uchicago.edu/noncredit/certificates/medical-writing-editing/index>

1.6 Different Types of Publications

Table 1.6.1. Examples of different types of medical publications

Journal articles

Primary manuscript
Secondary manuscript
Systematic review, with or without a meta-analysis
Narrative review
Short communication
Case study
Supplement

Other types of medical publications

Abstract
Poster
Slide presentation

Different types of manuscripts

Primary Manuscript. A “primary” or “original research” manuscript reporting the results of a clinical study will include the purpose of the study, the methods used, the results, and a discussion of the findings in the context of previously published findings and current practice. The primary manuscript can communicate results of a variety of study endpoints, including clinical pharmacology, pharmacodynamics, pharmacokinetics, safety, efficacy, and quality of life (QoL).

Secondary Manuscript. A number of secondary articles may be developed to further highlight significant aspects of the study that were not reported in detail in the primary manuscript. Some of the most familiar types of secondary publications are articles based on subset data analyses or pooled data analyses. Alternatively, they may report on tertiary, exploratory, QoL or other data not included in the primary manuscript. It is important to cite the primary publication(s) in a secondary manuscript.

Subset analyses. After a clinical trial is completed, investigators may perform a comprehensive analysis of the entire data set. Once that is completed, they will evaluate the data as it pertains to specific patient characteristics, such as age, race, and sex, or concomitant conditions or drug regimens. These subset analyses provide the basis for additional publications to expand understanding of the study and the compound.

Post-hoc analysis. In a post-hoc analysis, a given data set is re-examined or examined in more detail following completion of a trial. The analysis may focus on results that were not anticipated when the trial was designed. Results of a post-hoc analysis should be explicitly labeled as such in reports and publications.

Health Economics and Outcomes Research (HEOR). This refers not to a type of publication but a thematically related area of medical publications that is often organized as a distinct branch of medical publications within sponsoring organizations. HEOR deals with the cost of diseases; the cost, treatment effectiveness, and cost effectiveness of therapies; patient-centered outcomes, and other topics related to the course and consequences of disease and its treatment in the real-world setting. (See Figure 1.6.1)

Narrative review: A typical review article provides a summary of current research and consensus on a clinical topic through a critical assessment of existing literature and data. When done well, a review article can provide perspective on a disease state and its treatment and any unmet needs in terms of diagnosis and treatment. Some journals commission all review articles and will not accept unsolicited manuscripts or consider review manuscripts sponsored by pharmaceutical companies or written by pharmaceutical company employees. Therefore, it is prudent to carefully read the journal's "Instructions for Authors" to ascertain their policies, or call the editor of the journal to inquire if a particular article would be of interest.

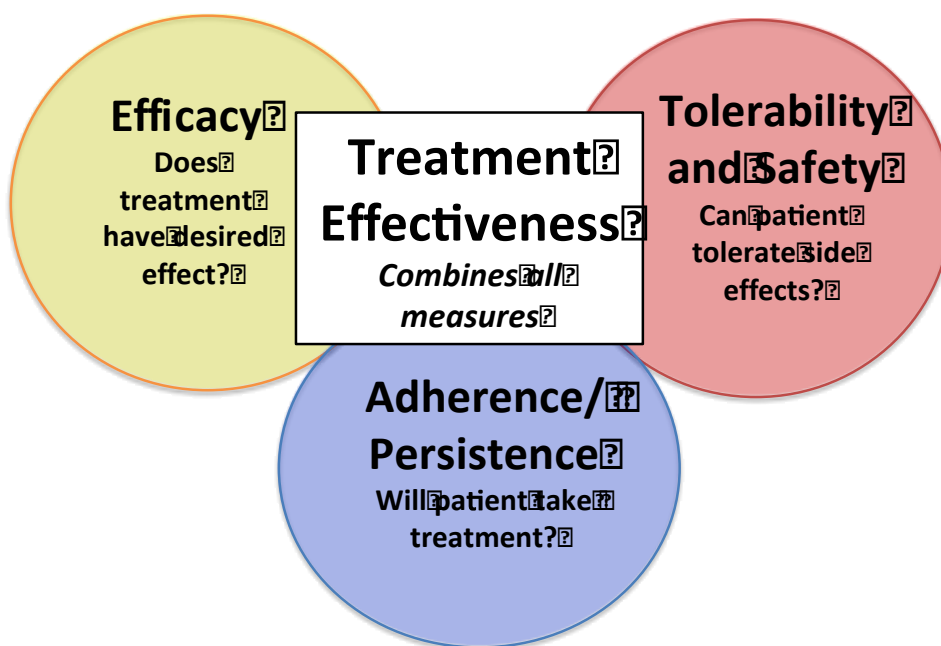
Systematic reviews: These reviews, such as those done by the Cochrane Collaboration, (<http://www.cochrane.org/cochrane-reviews>) seek to collate all evidence that fits prespecified eligibility criteria to address a specific research question. They are highly structured works that must conform to standardized guidelines, to ensure completeness of coverage of the published literature and to minimize bias. Many, if not most, systematic reviews include a meta-analysis.

Meta-analysis. A meta-analysis statistically combines the results of a comprehensive set of studies meeting specific design and quality criteria and

that address a shared research hypothesis. Just as individual studies summarize data collected from many participants in order to answer a specific research question (i.e., each participant is a separate data-point in the analysis), a meta-analysis summarizes data from individual studies that concern a specific research question (i.e., each study is a separate data-point in the analysis). A meta-analysis is conducted to produce an estimate of the magnitude of effect of a given treatment and assess the consistency of effect among studies.

Well-conducted meta-analyses that use data from well-designed and well-conducted clinical trials provide the highest level of evidence.

What is treatment effectiveness?



(Lehman et al, 2004; Swartz et al, 2003; Lieberman et al, 2005)

Figure 1.6.1. Treatment effectiveness.

Other formats for journal publications

Short Communication: Many journals provide space for short communications of important research findings. The objective is to communicate key findings from a smaller data set segment in a rapid fashion.

Case study: Many journals publish case studies or case reports, which comprise a review of a patient case, commentary from the practitioner-author, and a short review of relevant literature. Cases are usually unique or provide an example of a key point.

Supplement: Some journals publish supplements, which are separate from the regularly published journal issue. Some pharmaceutical, biotech or device companies can sponsor a supplement, however, many companies now have policies in place to not sponsor supplement publications. This practice is evolving, and individual journal guidelines will provide specific details.

Key point: There are many different types of manuscripts, each of which has its own particular set of requirements.

Other types of medical publications

Abstract: Most presentations at congresses begin with development and submission of an abstract for review by the congress program committee. The abstract is a brief summary of a study (clinical research, trial, survey, case report) presenting the objectives, methods, results, and main conclusions. If accepted, the abstract will be published in conference proceedings and may be published in a journal as well. Although very similar to an abstract of a manuscript, there are some important differences:

- Often the word or character limit for congress abstracts is longer (e.g. up to 350 words or 3,500 characters)
- Usually a table can be included, with a corresponding reduction in word count

Poster: A scientific poster expands on data presented in the abstract and usually comprises an introduction to the topic, methods, results, and conclusions. Posters are

large printed pieces (dimensions must conform to those specified by the conference or congress) and are hung in a poster hall for presentation during specified times. Some congresses now maintain a repository of posters in electronic format and make them available for download from specific web sites. Posters should include tables, charts, illustrations, and figures to present data and to complement the text.

- Same structure as abstract
- Bulleted text
- Graphics are the central element of any poster

Slides: Slides, usually created in PowerPoint™, are the foundation of all medical communications delivered in a lecture format.

Platform/Oral Presentation A platform or oral presentation is a brief (5- to 15-minute) slide presentation of the study referenced in the abstract. The speaker will present the slides to an audience in a meeting room. Following the presentation, the speaker will take questions from the audience.

Promotional Symposium: A promotional symposium is an industry-supported educational event held in conjunction with an organization's meeting or congress. Recently, a number of associations have begun to offer opportunities for "promotional" symposia (as opposed to accredited or continuing education symposia). A promotional symposium is fully funded by its sponsor, typically a pharmaceutical company, and all content must be "on label" (i.e., consistent with the information contained in the official Prescribing Information document for that product) and be in compliance with the company's medical/legal guidelines and those of US FDA or other governing regulatory authority. The content can comprise information on a specific brand or a disease state (disease awareness), or both, depending on the company guidelines.

Promotional Speakers' Bureau: These are educational venues, often packaged as dinner events, which provide health care practitioners (HCPs) in the community with an opportunity to learn about a new therapy or a new indication for an existing therapy.

The regulations regarding the content of these programs are quite stringent and are similar to those described in the paragraph above.

Key point: These other forms of medical communication are just as much a part of medical publications work as manuscripts.

1.7 Different Types of Journals

The universe of medical journals is large and still growing, and must be navigated skillfully by the author/medical writer to find the best possible home for each publication. Although the responsibility for journal choice is ultimately that of the author(s), the medical writer plays a major role in assisting with this decision (e.g., by drawing up a list of potential journals and displaying all of the relevant metrics for each journal).

Journals differ on a number of dimensions:

- **Journal Aims & Scope:** The stated purpose of the journal and a description of topics covered.
- **Impact Factor:** A metric based on the number of times a publication is cited, impact factor is still the major indicator of the academic prestige of a journal and of its overall influence on medical practice
- **Acceptance rate:** Tends to correlate strongly and inversely with impact factor; it provides a clear estimate of the likelihood of a submitted article being accepted (often it is presented as a Rejection Rate, which is the inverse of the acceptance rate)
- **Publication lead times:** There is significant variability in the time it takes for a submitted manuscript to be published; most companies and authors prefer journals with relatively shorter publication times, though there is often a trade-off with respect to the prestige of the journal.
- **Open Access:** Open access is a major development in medical publications, largely in the 21st century. It allows for publications in their entirety to be freely available to the public, rather than limited to journal subscribers. The funding for this access is a fee charged to the author of the article, which is typically

covered by the sponsor of the publication. Some journals are exclusively open access (see BioMed Central journals – <http://www.biomedcentral.com/journals>), others are primarily closed access but provide an option for open access (for a fee – as noted above).

- **Print vs Online:** Given the expense of print publication, and the widespread use of electronic media, many journals are now published only electronically. Most journals, however, still provide print publication to their subscribers, and many authors prefer to publish in these journals.
- **Circulation:** This varies widely, from just a few hundred subscribers to several hundred thousand. It is somewhat less important today when published material is available on line for free or for a fee. In general, a journal with larger circulation will have more influence on practice.
- **Society Affiliation:** Specialty journals, in particular, are often published by a medical society dedicated to research of a particular disease or group of related diseases and/or to the care of such patients. These same societies are also the hosts/sponsors of major national and international congresses and often publish abstracts from congresses in the journal.
- **Country-based vs. International:** The majority of primary medical publications is aimed at an international audience and published in English. National and local medical journals in the language of the country, however, play a prominent role in second-tier communications to assure that important medical information is shared more broadly.
- **Other factors that differentiate journals include:** availability of pre-submission inquiries, author services, ethics policies, extent of online usage and other electronic offerings, and attitudes and policies regarding professional medical writers.

These and other factors to keep in mind when choosing a target journal are discussed in Section 7.6.

Key point: Being able to work with authors to facilitate the selection of a suitable journal for each manuscript is a core function of the medical publications professional.

1.8 Reporting Guidelines

Many biomedical journals require authors to comply with the recommendations prepared by the ICMJE (ICMJE 2014; <http://www.icmje.org>). However, some journals do not, instead providing their own specific guidance, or leaving it up to the author to determine what data must be reported and how it should be presented.

A number of useful Web sites outline how to report research methods and findings. A good starting point is the EQUATOR (Enhancing the QUAlity and Transparency of health Research) Network (www.equator-network.org), which “...seeks to improve the quality of scientific publications by promoting transparent and accurate reporting of health research.”

In addition to the ICMJE recommendations (ICMJE, 2014), a number of reporting guidelines have been developed by groups of experts to facilitate reporting of research studies, and a number of medical journals require compliance to all or some of them. More information on reporting guidelines can be found Section 8 (Table 8.1.1)

All of these guidelines have produced checklists to assist the writer in writing a manuscript that is compliant with the requirements of the guideline. These checklists are extremely helpful and, in many cases, must be followed in order for the manuscript to be accepted by a particular journal. They are also excellent training tools to help a writer establish internal mental checklists that will greatly improve the quality and efficiency of her/his work.

Key point: Guidelines are extremely useful documents that help to ensure the quality and consistency of the medical literature.

1.9 Submission Requirements

Although the specifics of submission requirements will vary slightly by the journal chosen for submission, the requirements are fairly well standardized across journals.

These details can be readily accessed for any journal at the journal's web site, usually under the heading "Instructions for Authors (IFA)". See below for links to some examples of author resources provided by a journal/publisher:

- *The BMJ* (formerly the *British Medical Journal*) – <http://www.bmj.com/about-bmj/resources-authors>
- *The New England Journal of Medicine* (NEJM) – <https://cdf.nejm.org/misc/authors/>
- *Atherosclerosis* – <http://www.elsevier.com/journals/atherosclerosis/0021-9150/guide-for-authors>
- *Diabetes* – <http://diabetes.diabetesjournals.org/site/misc/ifora.xhtml>

The major elements required for most journal submissions are:

1. Cover letter: ideally this should briefly describe the significance of the work, highlight the main findings of the study, its uniqueness, and its relevance or contribution to the scientific research area or medical community. For full transparency, it is advisable to state the roles of each of the authors in the study and their contributions to the article, details of any medical writing support received, and the congresses where any of the data have already been presented. The cover letter should be written by the lead or corresponding author (usually the same person), however assistance may be provided by a professional medical writer, if requested.
2. Author information: contact information and institutional affiliation must be provided for all authors, not just the corresponding author.
3. Publication type: the submission needs to be identified as a particular type of publication accepted by the journal and must conform to its requirements.
4. Keywords: these are used to search for publications online; sometimes the author is free to choose his/her own keywords, other journals use a drop down menu from which keywords must be chosen. There is usually a limit of between 5-7 words.
5. Manuscript content: in most cases the abstract is electronically submitted and uploaded separately, as well as the figures. The manuscript itself with tables and references included is generally uploaded together.

6. Financial conflict of interest forms: these are almost always required for any medical publication; the form developed by the ICMJE is often used (<http://www.icmje.org>).
7. Copyright Assignment: this document assigns the copyright to the journal and is always required prior to publication, though it is sometimes requested at the time of submission.
8. Peer Reviewer Requests: some journals provide authors with the opportunity to suggest peer reviewers who they feel would be well suited to review their work, or to request that certain individuals not be asked to review their work. No reasons need be given.

1.10 Reviewer's Comments and Resubmission

Keep in mind that reviewer's comments are meant to be helpful (Chipperfield et al, 2010). When addressing the reviewer's comments, follow the journal's guidelines for revising the manuscript, and make sure to address all comments (Chipperfield et al, 2010).

Since most journals are "peer-review," most publications require this step. Reviewers are typically very knowledgeable about the subject of the publication and add value by pointing out ways to strengthen the publication. Editors may also add their critiques.

More than one resubmission may be needed. Please be mindful of the journal requirements for responses to reviewer comments. For example, some journals may require any added statements to be highlighted in a tracked copy version of the revised draft. Most journals will want a call out of revised statements by page and line number in a separate document along with the revised draft of the publication.

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Section 2: Compliance

2.1 Comply With What?

Compliance is defined as conformity in fulfilling official requirements (Merriam Webster's 10th edition). In the area of medical publications, compliance requirements exist on different layers and scales. These include external mandates in the form of laws and guidelines from government agencies, industry groups, journals and publishers, and professional societies, as well as internal guidance in the form of SOPs and policies from individual companies, organizations, and departments.

Compliance regulations/topics affecting medical publication professionals extend beyond those that dictate authorship principles and good publication practice and include clinical trial data transparency, timeliness of publication, payments to health care providers, and principles of scientific exchange (vs product promotion) among others.

2.2 Why Comply?

Within any industry, compliance measures are established for specific reasons. In the field of medical publications, external laws and guidelines were developed primarily to ensure that companies that develop, manufacture, and sell drugs, biological products, or devices are not inappropriately influencing physicians to prescribe or use their products. Internal policies and SOPs were developed to ensure companies are following the principles put forth by external guidance so as to avoid penalties as well as to show their own commitment to doing the right thing.

Penalties for noncompliance are as diverse as the number of guidelines that exist. They may include monetary fines in the billions of dollars against a company if a government law is determined to be broken; rejection of a manuscript when journal policies are not followed; or individual disciplinary action for failure to follow an SOP.

2.3 Compliance Guidelines

International Committee of Medical Journal Editors

The ICMJE is a group of medical journal editors and representatives of selected related organizations that focuses on the quality of medical science and reporting. ICMJE developed “*Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals*” and updates these guidelines periodically. The guidelines review best practices and ethical standards for authors, editors, and others involved in the creation and distribution of accurate and unbiased medical journal articles. Under the ICMJE guidelines, “authors” must take responsibility for at least one component of the work, should be able to identify who is responsible for other components, and must make substantive intellectual contributions. The criteria for authorship include: 1) substantial contribution to conception, design, execution, and/or data acquisition/interpretation; 2) participation in drafting, reviewing, and/or revising intellectual content; 3) providing final approval and; 4) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. In an effort to establish true transparency, the final publication must include: 1) anyone who qualifies as an “author” listed in the byline in the final publication and 2) anyone who provided technical help, writing services, or general support identified as a “contributor” in the final publication’s acknowledgments, along with the funding source for these services; and 3) a description of the role of the study sponsor. Finally, all participants in the development of medical publications must disclose all potential conflicts of interest relationships. Many company publication policies and SOPs are based on principles included in the ICMJE guidelines.

Pharmaceutical Research and Manufacturers of America

The Pharmaceutical Research and Manufacturers of America (PhRMA) was established in the late 1950's, as a US trade group representing pharmaceutical and biopharmaceutical companies, with a mission to advocate public policies that encourage the discovery of new medicines. Recently, PhRMA issued "*Principles on Conduct of Clinical Trials & Communication of Clinical Trial Results*," which includes authorship guidelines and disclosure requirements adapted from the ICMJE guidelines that all member companies are expected to follow.

The European Federation of Pharmaceutical Industries and Associations

EFPIA/PhRMA Joint Principles for Responsible Clinical Trial Data Sharing to Benefit Patients, which were issued in 2013 state that "*all company-sponsored clinical trials should be considered for publication in the scientific literature irrespective of whether the results of the sponsors' clinical trials are positive or negative. At a minimum, results from all phase 3 clinical trials and any clinical trial results of significant medical importance should be submitted for publication*"

(<http://transparency.efpia.eu/uploads/Modules/Documents/data-sharing-prin-final.pdf>).

The recently published Global Publication Survey reported that many companies had policies that provided specific timing for submission of clinical trial manuscripts to peer-reviewed journals, typically within 12-18 months from end of study (Wager et al, 2014).

International Society for Medical Publication Professionals

In 2009, the International Society for Medical Publication Professionals (ISMPP) issued revised publication guidelines, "*Good Publication Practice for Communicating Company-Sponsored Medical Research*" (GPP2) that detailed: 1) the role of authors and other contributors, 2) publication steering committees, 3) reimbursement and honoraria, 4) publication planning documents, and 5) the role of professional medical writers. The current GPP guidelines (GPP3) were published in August 2015.

Medical Device Manufacturers Association

The Medical Device Manufacturers Association (MDMA) has developed a “compliance toolkit” that includes sample governance documents, training documents and auditing documents. The toolkit is available to its members at the organization’s website (www.medicaldevices.org).

2.4 Special Compliance Issues

Established in 1976, the US Office of Inspector General (OIG) was created to protect the integrity of the Department of Health & Human Services (HHS) programs and the health and welfare of program beneficiaries. The OIG is at the forefront of US efforts to fight waste, fraud, and abuse in Medicare, Medicaid and more than 300 other HHS programs. The OIG negotiates corporate integrity agreements (CIA) with health care providers (in this case, pharmaceutical and biopharmaceutical companies) that outline the obligations the company agrees to as part of the finding of wrongdoing from federal investigations. OIG had developed a series of voluntary compliance program documents directed at various segments of the health care industry, including “Compliance Program Guidance for Pharmaceutical Manufacturers” in 2003. In 2010, a false claims act lawsuit was filed against a major pharmaceutical company, accusing the company of paying doctors to serve as authors on publications the company had written itself to promote off-label use of one of its products, also violating federal Anti-Kickback Statute (AKS). This began a new initiative in which the OIG became involved with the issues around ghostwriting and began to incorporate authorship disclosure requirements into its CIAs. In 2007, as then Chief Counsel to the Inspector General, Lewis Morris, testified before a House of Representatives committee, sharply condemning the practice of ghostwriting. In 2011, the OIG continued its efforts to shed light on issues concerning ghostwriting and transparency, highlighting them in a presentation at the Third Annual Summit on Disclosure, Transparency and Aggregate Spend.

2.5 Corporate Integrity Agreements

As previously discussed, a CIA is an enforcement tool used by the OIG to improve the quality of health care and to promote compliance to health care regulations. The CIA is an agreement entered into as part of civil settlement between the Government and a pharmaceutical company or a health care provider that has been the subject of investigations arising under the False Claims Act or who has been found guilty of defrauding Medicare, Medicaid or any other Federal health care programs. Pharmaceutical Companies consent to the obligations detailed in the CIA in exchange for the OIG's agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid and other Federal health care programs. Once a company is under a CIA, aspects of good publication practice become legally enforced (Wager et al, 2014). CIAs share common elements but also include some elements tailored to address specific violations. A CIA usually lasts for 5 years and requires pharmaceutical companies to:

- Hire a compliance officer/appoint a compliance committee
- Develop written standards and policies
- Implement a comprehensive employee training program
- Retain an independent review organization to conduct annual review
- Establish a screening process to prevent employment of ineligible persons (people who have been barred from participating in US federal health care programs)
- Report overpayments, reportable events and ongoing investigations/legal proceedings; and
- Provide an implementation report and annual reports to OIG on the status of compliance activities

2.6 Sunshine Act

The US Patient Protection and Affordable Health Care Act was signed into law in March 2010 and includes the Physician Payment Sunshine Act (Sunshine Act). As of August 1, 2013, pharmaceutical, medical device, biological, and medical supply manufacturers that participate in US federal health programs must collect, track and report any

payment or other transfer of value greater than \$10 made directly to physicians and teaching hospitals. They are also required to describe how the recipient received the payment such as cash or cash equivalent, in-kind items or services, or stock, stock option(s), or any other ownership interest, dividend, profit, or other return on investment. In addition to direct payments, manufacturers must also report certain payments and transfers of value that are made indirectly to a physician or that are made to a third party as requested by a physician or designated as being made on behalf of a physician. The information is reported annually to the [Centers for Medicare and Medicaid Services](#) (CMS) and then posted to a searchable publically available website. The goal of the law is to enhance patient safety by increasing the transparency of financial relationships between health care providers and manufacturers.

CMS has not offered specific guidance to companies regarding the reporting of payments and transfers of value related to publication support. Instead companies are to determine their own method for reporting along with the related assumptions. This had led to different reporting approaches being taken by different companies ranging from reporting all transfers of value related to publication support to no TOV reporting.

Regions outside the US have also introduced laws and regulations similar to the US Sunshine Act. In June 2013, EFPIA adopted the Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations and required that member associations adopt the provisions into their country codes by December 2013. Data collection will begin in 2015 and be reported in 2016. The EFPIA code states that member associations must adopt sanctions to ensure compliance with the Code. These may include warnings, fines, or expulsion. Unlike the US rules, the EFPIA guidelines require HCP consent for reporting.

2.7 Anti-Bribery and Corruption Laws

Anti-Bribery and Corruption (ABAC) laws exist in many countries and the CMS has provided a useful international guide with summaries for several countries (<http://www.cmslegal.com/CMS-Guide-to-Anti-Bribery-and-Corruption-Laws1>). The

implications for publications are in the interactions between the parties involved (e.g., authors, investigators, medical writers, sponsors, journals etc.). The UK Bribery Act defines the offence of bribing another person as where a person “*offers, promises or gives a financial or other advantage*” to another person with the intention of inducing, or rewarding for, improper performance of a relevant function or activity. Bribery is also considered to occur where a person offers, promises, or gives financial or other advantage to another person, while knowing or believing “*that the acceptance of the advantage would itself constitute the improper performance of a relevant function or activity*” (<http://www.legislation.gov.uk/ukpga/2010/23/section/1>). Corruption is defined by Transparency International as “*abuse of entrusted power for private gain*” (<http://transparency.org/>).

POSSIBLE SCENARIOS FOR PUBLICATIONS

- Many (if not all) HCPs are “government officials” under FCPA/UKBA
 - Any payment could come under scrutiny
- Your posters are stuck in customs
 - Avoid facilitation payments to get them out
- Agencies and agents suggesting payments as “usual business practice”
 - Don’t do it. Ensure contracts and records exist for bone fide payments
 - Be aware of the “knowing” standard
- Requests for “honorary authorship”
 - Could be considered an item of value under FCPA

From ISMPP U Presentation given by Christopher Rains, Head of Global Publications
Senior Director – Global Medical Affairs, Shire:
ANTI-BRIBERY & CORRUPTION LAWS
WHAT MEDICAL PUBLICATION PROFESSIONALS NEED TO KNOW
October 3, 2012

Note: The Sunshine Act and Anti-bribery and Corruption laws are also discussed in Sections 3 and 5.

2.8 Compliance Examples

In the US in the 2000s, the practices of ghostwriting and guest authorship were spotlighted during high-profile litigation brought against pharmaceutical companies. This increased both media and government focus and heightened the importance of the need for total transparency in the development of medical publications. In 2010, United States Senator Charles Grassley released a Minority Staff Report, *Ghost Writing in Medical Literature*, and multiple letters to the US National Institute of Health (NIH) that provided details of investigations into pharmaceutical companies' publication practices. The report cited ghostwriting as "prevalent" and urged government to prohibit such practices. The increased media and government pressure resulted in the development and/or revision of industry guidelines detailing best practices for the development of medical publications. The first systematic review on the reporting of the prevalence of ghostwriting in the medical literature concluded, "*Evidence for the prevalence of ghostwriting in the medical literature is limited*" (Stretton, 2014). The findings of this review appear to suggest that, contrary to common perception, ghostwriting may not be a major issue in medical writing.

2.9 International Compliance Guidance

As highlighted at the start of this section, compliance regulations/topics affecting medical publications are not limited only to principles of authorship and good publication practice but also include clinical trial data transparency and ethics. Listed here are some sources of guidance for medical publications professionals.

- American Medical Writers Association (AMWA) position statement on the contribution of medical writers to scientific publications. (Hamilton CW et al. AMWA Journal. 2003;18:13-16.

- http://www.amwa.org/files/About%20Us/AMWA_PositionStatement_Contributions.pdf
- Committee of Publication Ethics (COPE) has issued a number of guidelines
 - <http://publicationethics.org/resources/guidelines>
 - Including "COPE Ethical guidelines for peer reviewers" (March 2013)
 - <http://publicationethics.org/files/Peer%20review%20guidelines.pdf>
- Council of Science Editors (CSE) White Paper on Promoting Integrity in Scientific Journal Publications (2012 update)
 - <http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3331>
- EQUATOR Network (Enhancing the QUALity and Transparency Of health Research)
 - <http://www.equator-network.org>
- European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer reviewed publications. (Jacobs & Wager, 2005)
 - <http://www.emwa.org/Mum/EMWAguidelines.pdf>
- Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. (Graf C, et al, 2009)
 - <http://www.bmj.com/content/bmj/339/bmj.b4330.full.pdf>
- GRP Getting Research Published: A to Z of Publication Strategy (2nd edition, 2010)
- IFPMA/EFPIA/JPMA/PhRMA Joint Position on the Publication of Clinical Trial Results in the Scientific Literature. Announced June 10, 2010.
 - http://www.efpia.eu/uploads/Modules/Documents/20100610_joint_position_publication_10jun2010.pdf
- International Committee of Medical Journal Editors (ICMJE) recommendations. Recommendations for the conduct, reporting, editing and publication of scholarly work in medical journals. Updated December 2014.
 - <http://www.icmje.org>
- Medical Publishing Insights and Practices (MPIP) Author's Submission Toolkit. (Chipperfield L et al. 2010).
- Office of Inspector General, US Department of Health and Human Services.
 - <http://oig.hhs.gov>
- World Association of Medical Editors (WAME).

- Principles of transparency and best practice in scholarly publishing. Posted December 2013. Developed in collaboration with the Committee on Publication Ethics (COPE), the Directory of Open Access Journals, and the Open Access Scholarly Publishers Association.
<http://www.wame.org/about/principles-of-transparency-and-best-practice>
- Conflict of Interest in Peer-Reviewed Medical Journals. Updated July 2009.
<http://www.wame.org/about/conflict-of-interest-in-peer-reviewed-medical>
- World Medical Association (WMA) Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Amended by 64th WMA General Assembly, Fortaleza, Brazil, October 2013
 - <http://www.wma.net/en/30publications/10policies/b3/>

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research among publication professionals: the Global Publication Survey. *BMJ Open* 2014;4:e004780. doi:10.1136/bmjopen-2013-004780.

ISMPP U webinars

Anti-Bribery & Corruption Laws: What Medical Publication Professionals Need to Know Christopher Rains, Head of Global Publications, Sr Director - Global Medical Affairs, Shire Pharmaceuticals Moderator: Michael Platt, President, MedVal Scientific Information Services, LLC; Chair, ISMPP U Committee
Wednesday, October 3, 2012

Section 3: Ethics

3.1 Background

The pharmaceutical industry has come under increasing scrutiny and public interest in the last few years. The real and perceived role in shaping the medical literature has come under criticism. The increasing involvement of ethical considerations in every step of medical publishing has therefore shaped the current publication environment.

Key point: The increasing involvement of ethical considerations in every step of medical publishing has shaped the current publication environment.

Past practices have included publishing of falsified data, data being collected or analyzed unethically, publication bias in terms of missing trial data or duplicate or unnecessary publications, lack of balance within a publication, and plagiarism. Authorships were sometimes paid for, gifted or wrongly attributed, and conflicts of interest (including funding and medical writing support) not disclosed. It should be highlighted that these problems are not limited to the pharmaceutical industry, and have also been prevalent in academic publications. Historically, across the research community, positive results were considered the only interesting results. However, given the role of pharmaceutical companies in developing and selling drugs, the outcome of these practices has potentially more negative consequences in terms of healthcare, and therefore changing practice has been largely directed at the industry.

Over the last few years new laws have been implemented (Food and Drug Administration Amendments Act (FDAAA) of 2007, Anti-Bribery and Corruption (ABAC) laws, Sunshine Act), and sound, ethical principles and guidelines have been developed by the industry, medical editorial societies and medical writing agencies/medical writers (eg IFPMA/EFPIA/JPMA/PhRMA Joint Position on the Publication of Clinical Trial Results in the Scientific Literature, GPP3, ICMJE guidelines, and World Association of Medical Editors [WAME] policies and recommendations) which are now being universally adopted as medical publishing industry standard. Links to these resources are provided below:

IFPMA/EFPIA/JPMA/PhRMA Joint Position on the Publication of Clinical Trial Results in the Scientific Literature. Announced June 10, 2010.

http://www.efpia.eu/uploads/Modules/Documents/20100610_joint_position_publication_10jun2010.pdf

GPP3 guidelines: Battisti W, et al. Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3. *Ann Int Med* 2015; 163(6):461-464. doi:10.7326/M15-0288

GPP2 guidelines: Graf C, et al. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ* 2009; 339-b4330

<http://www.bmj.com/content/bmj/339/bmj.b4330.full.pdf>

ICMJE recommendations: International Committee of Medical Journal Editors.

Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals. Updated December 2014. <http://www.icmje.org>

WAME policies and recommendations: <http://www.wame.org/policies-and-resources>

The role of ethics in medical publishing now ensures that authors are qualified to publically stand behind the data, and the interpretation of the data in the publication with their name on the byline. Compliance with publication ethics also ensures that the data reported have been ethically collected, reference sources are adequately acknowledged, and permission to reuse intelligence is sought.

Key point: Laws and guidelines exist to ensure ethical publications.

3.2 Publication Planning

In order to effectively communicate about any treatment/therapy/device in development, there should be a plan for what data will be generated and discussed, which audience will find the data important, and when this data will be available for publication/presentation. The ultimate goal of medical publication planning is to ensure that there is a complete profile of the treatment in the peer-reviewed scientific literature. Publications describing the characteristics, efficacy, and safety of a treatment/therapy/device provide the evidence that physicians, patients, regulatory

agencies, payors, and others in the healthcare industry assess to decide how to use the product and whether it provides a benefit compared with other treatments for the same condition. Publications also serve as a forum for public disclosure of data from clinical trials where the results are put into context and vetted by other scientists/clinicians during the process of peer review at scientific/medical journals, unlike when the basic data from the trial is posted to clinical trial registry databases. More information on the purpose and processes of Publication Planning is included in Section 7.

Publication steering committee

When planning the publication of clinical trials you should ensure that authors are involved as early as possible in the planning process. GPP3 guidelines recommend the formation of a publication steering committee (PSC) for a clinical study (Battisti et al, 2015). More information about the composition and responsibilities of the PSC can be found in Section 7.4.

Trial disclosure and publication timing

The FDAAA requires the reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials. However, NIH encourages results reporting for all NIH supported clinical trials registered in ClinicalTrials.gov, regardless of whether or not they are required to do so under FDAAA.

Trials considered to be "applicable clinical trials" under the statute are subject to FDAAA. Applicable clinical trials generally include:

- Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation; and

- Trials of Devices: Controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance.

Thus, applicable clinical trials generally include interventional studies (with one or more arms) of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the U.S, involves a drug, biologic, or device that is manufactured in the US (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE) (<https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered>). At this time, FDAAA requires that all interventional clinical trials be registered before enrollment on their clinical trial registry site (ClinicalTrials.gov), and the primary results of the trial are required to be posted in this same database within 12 months after the last patient's last visit for a product already approved for marketing or within 12 months of when the product is approved (<https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered>). The Trial and Experimental Studies Transparency (TEST) Act (currently proposed) aims to expand on the data reporting required to ClinicalTrials.gov, to include studies conducted in other countries, Phase I studies, and providing additional documentation such as protocols (<https://beta.congress.gov/bill/113th-congress/house-bill/2031>).

The European Medicines Agency (EMA) has also created the European Clinical Trials Database (EudraCT), a clinical trials registry and results database for trials conducted in the European Union (<https://eudract.ema.europa.eu>), and other countries have or are considering their own trial registry and results databases. In addition to the requirements to register clinical trials and post results, biopharmaceutical companies have committed to post summaries of their clinical study reports, briefly describing the results of the study, on their publically accessible company websites at around the same time as the basic results are posted to regulatory clinical trial databases.

When results are posted to these sites, there is no discussion of the data, no conclusions, and no context of how this data fits into what is already known about the

product or therapeutic area as would be found in a publication. Therefore, it is considered important that trial results are also submitted for peer-review publication.

The IFPMA/EFPIA/JPMA/PhRMA Joint Position on the Publication of Clinical Trial Results in the Scientific Literature was developed by regional pharmaceutical associations with the responsibility of self-governance of the industry, including the European Federation of Pharmaceutical Industries and Associations (EFPIA), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA). The statement recommends “*all industry-sponsored clinical trials should be considered for publication in the scientific literature irrespective of whether the results of the sponsors' medicine(s) are positive or negative*”. They also state that “*at a minimum, results from all phase 3 clinical trials and any clinical trial results of significant medical importance should be submitted for publication. This includes investigational clinical products whose development programs are discontinued.*” Studies should be submitted within 12 months, if possible, and no later than 18 months of the completion of the clinical trial (if the product is marketed), or regulatory approval or a decision to discontinue development (in the case of investigational products). The full statement can be accessed via the following link http://www.efpia.eu/uploads/Modules/Documents/20100610_joint_position_publication_10jun2010.pdf.

The Medical Publishing Insights and Practices (MPIP) group, which includes representatives of the pharmaceutical industry and ISMPP, also recommends publishing “*all results, including negative or unfavourable ones, in a timely fashion, while avoiding redundancy*” (Mansi et al, 2012).

The Biotechnology Industry Organisation (BIO) agrees to the FDAAA regulations and also states “*BIO member companies already routinely publish their clinical trials in peer-reviewed scientific journals and present their results at scientific meetings and workshops. A growing number of BIO member companies also voluntarily share patient-level clinical trial data through their own company-specific initiatives, as well as*

innovative public-private partnerships and consortia.” Their minimum commitment in terms of publishing clinical trials is that “BIO member companies will submit for publication in the scientific literature, or otherwise make available to the scientific community (i.e., on a company-sponsored website, at an appropriate scientific conference, etc.), the results of all company-sponsored Phase 3 clinical trials and clinical studies of significant medical importance regardless of whether their outcomes are positive or negative” (<http://www.bio.org/articles/bio-principles-clinical-trial-data-sharing>).

Key point: Applicable clinical trials must be reported on all relevant clinical trial registries, and should be submitted for peer-review publication in a timely fashion.

3.3 Publication Development

Authorship responsibilities

Ghostwriting along with ghost authorship, is the practice of using the services of a writer (the ghost writer) to prepare a manuscript and then crediting this work to another person (the ghost or guest author). Historically, sometimes the guest author was also paid. Examples of this practise have been displayed and condemned publically, but nevertheless had a long lasting and damaging effect on the medical publishing industry and its sponsors as a whole. The prevalence of ghostwriting in the medical literature, according to common perception and evidence-based review, is discussed in Section 2.8.

Ethical concerns raised have seen the introduction of strict standards for authorship qualification, for disclosures of medical writing assistance and the funding for all assistance provided in the course of manuscript development. In addition, a requirement of most journals now is that all contributions to the manuscript from participants who may not have qualified as authors, must be acknowledged in a separate acknowledgments section.

The International Committee of Medical Journal Editors (ICMJE) is a group of medical journal editors and representatives of selected related organizations that focuses on the quality of medical science and reporting. ICMJE developed “*Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals*” and updates these guidelines periodically. The guidelines review best practices and ethical standards for authors, editors, and others involved in the creation and distribution of accurate and unbiased medical journal articles. Under the ICMJE guidelines, “authors” must take responsibility for at least one component of the work, should be able to identify who is responsible for other components, and must make substantive intellectual contributions. The ICMJE criteria for authorship and authors' roles and responsibilities are discussed in Section 4. Many company publication policies and SOPs are based on principles included in the ICMJE guidelines.

Some journals do not require all ICMJE criteria to be met for authorship, and some require medical writers be included as authors. When identifying authors and journals for publication, journal requirements must be considered and met.

Authors should always have full access to study data in order to ensure that the publication of data is accurate and transparent and that the interpretation is balanced. They should ensure patient confidentiality, prevent premature release of data and avoid duplicate or redundant publication. A secondary publication must clearly refer to the primary publication (Section 1). Authors should also agree to meet the sponsor's commitment to follow guidelines (including research reporting guidelines, discussed in Section 8 (see Table 8.11.1 and accompanying text.)

Key point: Always ensure that all authors fulfill ICMJE authorship criteria and/or journal requirements.

Use of a medical writer

Professional medical writers are not ghost writers, as their involvement in a publication is always disclosed. The assistance provided by a medical writer can be valuable to authors and can raise the overall quality of publications (Chipperfield et al, 2010).

Medical writers are expected to exercise sound judgment and adhere to best practices in professional publication and the tasks and activities they undertake to support authors with manuscript development should be ethical and transparent. To adhere to ethical medical writing, the authors provide direction to the medical writer at every stage of manuscript development (outline, each draft, etc.), have final approval, and acknowledge medical writing assistance. Following these guidelines provides transparency and should preclude misconceptions about acceptable medical writing. Sources of guidance on best practices for medical writers are listed in Section 8, along with additional details on ways in which they may assist and support authors. The roles and responsibilities of authors are discussed further in Section 4.

Key point: Engagement of a professional medical writer is not the same as ghostwriting. Always ensure medical writing assistance is acknowledged, that authors provide direction to the medical writer and that all authors provide final approval.

Referencing

When another work is used to support statements made within a separate or new manuscript it adds credibility to that document, but only if the source of that material is credited with a citation. Any previously published work must be cited.

The key points to good referencing are: adequate, and accurate.

- Any specific statement should be referenced, but referencing a general statement may not be necessary
- If you are going to cite something, it is important to read it first! Although you may think that the bibliography of a well-balanced review will provide comprehensive and accurate referencing, this is not always true, and journals and authors do sometimes make mistakes.
- The practice of secondary referencing can detract from the credibility of the work you are presenting, as well as showing an inattention to detail. Wherever possible, it is usually preferable to go back to the original source.

- Sometimes self-referencing may be appropriate (i.e., your own work may be the best reference to use), but it is important not to gratuitously self-cite.
- The journal guidelines for reference style and acceptability will provide examples of reference styles for numbering, positing in text, the bibliography, and whether terms such as “data on file”, “manuscript submitted for publication”, or “unpublished results” are acceptable.

Acknowledgments

All contributors to a medical publication who do not meet criteria for authorship should be acknowledged. GPP3 guidelines recommend that each manuscript include statements to acknowledge the contribution of authors, writing support, editors, researchers, sponsors (Battisti et al, 2015). Other study personnel, patients/study participants and their families (usually as a group) may also be thanked, as well as people involved in study design or critical review or analysis of the data or paper. Authors should include their full contact information and role, and each person acknowledged should have the opportunity to review and provide written agreement of their inclusion. Acknowledgment of funding sources should specify the type and amount, and if funding was for research, presentation of data, manuscript development, or publication. Often disclosures appear in the acknowledgments section. Appropriate journal guidelines should be followed.

Disclosure

In order for proper peer review to be accomplished, the reviewer must be reassured that all potential sources for bias or conflict of interest are disclosed.

But what is a conflict of interest? The ICMJE website provides this information: “A conflict of interest exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain). Perceptions of conflict of interest are as important as actual conflicts of interest.”

The term 'conflict of interest' is often interpreted as 'actual' rather than 'perceived' conflict, despite the definition above, so it is often preferred to use the term 'disclosures' to ensure that all relationships, financial or non-financial are declared, whether they have the potential to bias judgment from a positive or negative perspective.

Key point: The term 'conflict of interest' is often interpreted as 'actual' rather than 'perceived' conflict, so the term 'disclosures' may be preferred, to ensure that all relationships, financial or non-financial are declared.

Of course, everyone involved in the medical publishing process will have a conflict of interest of some kind, be it financial, professional, competitive, religious, political – the list is endless. What is important in order for a piece of work to be fairly reviewed (and seen to be fairly reviewed), is that these potential conflicts of interest are disclosed, according to industry guidelines and also the journal guidelines. However, just as an author has conflicts of interest to be disclosed, so too does the reviewer have an ethical obligation to acknowledge and report their own conflicts of interest and, if necessary, exclude themselves from the peer review of a manuscript.

Most journals now make it simple to declare a conflict of interest and provide the ICMJE conflict of interest form on their website. The authors should note that disclosing a conflict or potential conflict of interest does not necessarily mean it will be published, or that it will prevent acceptance of the publication.

GPP2 guidelines recommend transparency and full disclosure as noted above as well as "contractual relationships or consultancy fees for scientific, government, or legal services, or equity in the company" (Graf et al, 2009). The newly published GPP3 guidelines (Battisti et al, 2015) support these earlier recommendations.

More information about what is required for "full disclosure" is included in Section 8.

Key point: It is important that authors disclose all 'actual' and 'perceived' conflicts of interest.

Plagiarism

Plagiarism is the practice of taking someone else's work or ideas and passing them off as one's own (<http://www.oxforddictionaries.com/definition/english/plagiarism>).

Although direct use of text from elsewhere is the easiest form to detect, plagiarism can also refer to the use of ideas, images and data

(<http://publicationethics.org/resources/guidelines>). All reference to previously published material should be appropriately cited (see **Referencing** above). Authors and writers should also bear in mind that re-using their own previous work may be considered self-plagiarism, and copyright may be owned by the journal in which it was published. It is often possible to reproduce some previously published work if the appropriate copyright is obtained (see **Permissions** section below).

Journal editors now employ special software (e.g. iThenticate) to help detect plagiarism in submitted papers. Plagiarism, suspect or non-scientific methodology, and outright fraudulent research has led to increasing numbers of retractions (see **Retractions** section below) in the medical and scientific literature.

Permissions

In many cases, charts, tables and/or images created or utilized in previously published material might be suitable to illustrate the data or point being made in a new paper that you are currently developing. While it may seem that there is no reason to create or recreate something that exists already, it should be remembered that the piece you would like to use belongs to someone else – this is copyright. In the same way that an object such as a car, a t-shirt or a book can be owned by a person, published material is owned by the copyright holder; and permission needs to be requested, and granted, before it can be reused.

Before anyone can legally sell, publish or distribute another person's copyrighted work, or even extracts or samples of that work, it is their responsibility to seek permission from

the copyright holder. The person reusing the work has an ethical and legal requirement to obtain permission for reuse.

Failure to obtain permission may result in prosecution and a fine, damaging your own reputation and, if you are an employee, that of your employer also.

While not always a straightforward process, obtaining permission from copyright holders such as journals and publishing companies through the STM (International Association of Science Technical and Medical Publishers) agreement, or directly from a journal is possible. Nearly all major STM publishers, have signed the STM agreement, providing rights to use limited portions of text or figures, for example up to three visual elements, or up to 400 words, free of charge. It should be noted, the while this permission may be provided freely, permission must still be requested, and granted. It is also important to note that copyright permissions may be extremely expensive, so it is wise to check in advance. For open access journals the copyright is not transferred to the journal and is usually owned by the author or institution/organisation and permission may still need to be sought – if you are unsure, always check the journal guidelines.

Retraction

If there is clear evidence of misconduct associated with a publication, such as unethical data collection, data fabrication, or errors in experimental design or analysis, plagiarism or duplicate publication, a journal editor may retract a previously published paper. They may also issue a correction if a small change is required, or an 'expression of concern' if there isn't enough evidence to determine misconduct or errors.

Committee on Publication Ethics (COPE) states that the main purpose of retractions is to correct the literature and ensure its integrity rather than to punish authors who misbehave. (<http://publicationethics.org/files/retraction%20guidelines.pdf>)

3.4 Other Legal Requirements For Sponsors And Authors

Sunshine Act

The US Patient Protection and Affordable Health Care Act was signed into law in March 2010 and includes the Physician Payment Sunshine Act (Sunshine Act). As of August 1, 2013, pharmaceutical, medical device, biological, and medical supply manufacturers that participate in US federal health programs must collect, track and report any payment or other transfer of value greater than \$10 made directly to physicians and teaching hospitals. The information is reported annually to the [Centers for Medicare and Medicaid Services](#) (CMS) and then posted to a searchable publically available website. The goal of the law is to enhance patient safety by increasing the transparency of financial relationships between health care providers and manufacturers.

CMS has not offered specific guidance to companies regarding the reporting of payments and transfers of value related to publication support. Instead companies are to determine their own method for reporting along with the related assumptions. This had led to different reporting approaches being taken by different companies ranging from reporting all transfers of value related to publication support to no TOV reporting. The Sunshine Act is discussed in more detail in Section 2.

Regions outside the US have also introduced laws and regulations similar to the US Sunshine Act. In June 2013, EFPIA adopted the Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations and required that member associations adopt the provisions into their country codes by December 2013. Data collection will begin in 2015 and be reported in 2016. The EFPIA code states that member associations must adopt sanctions to ensure compliance with the Code. These may include warnings, fines, or expulsion. Unlike the US rules, the EFPIA guidelines require HCP consent for reporting.

Key point: Any payment or other transfer of value greater than \$10 made directly to physicians and teaching hospitals by pharmaceutical, medical device, biological, and medical supply manufacturers that participate in US federal health programs must be tracked and reported under the Sunshine Act. Other regions also have reporting requirements which must be followed.

Anti-Bribery and Corruption laws

Anti-Bribery and Corruption (ABAC) laws exist in many countries and the CMS has provided a useful international guide with summaries for several countries (<http://www.cmslegal.com/CMS-Guide-to-Anti-Bribery-and-Corruption-Laws1>). The implications for publications are in the interactions between the parties involved (e.g., authors, investigators, medical writers, sponsors, journals etc.). The UK Bribery Act and other sources of guidance are explored further in Section 2.7.

POSSIBLE SCENARIOS FOR PUBLICATIONS

- Many (if not all) HCPs are “government officials” under FCPA/UKBA
 - Any payment could come under scrutiny
- Your posters are stuck in customs
 - Avoid facilitation payments to get them out
- Agencies and agents suggesting payments as “usual business practice”
 - Don’t do it. Ensure contracts and records exist for bone fide payments
 - Be aware of the “knowing” standard
- Requests for “honorary authorship”
 - Could be considered an item of value under FCPA

Corporate Integrity

From ISMPP U Presentation given by Christopher Rains, Head of Global Publications
 Senior Director – Global Medical Affairs, Shire:
 ANTI-BRIBERY & CORRUPTION LAWS
 WHAT MEDICAL PUBLICATION PROFESSIONALS NEED TO KNOW
 October 3, 2012

Agreements

In addition to other legal requirements, many pharmaceutical companies are subject to what is known as a Corporate Integrity Agreement (CIA). These often mean that guidelines related to publications become a legal requirement for them. The Office of Inspector General (OIG) negotiates CIAs with health care providers (in this case, Pharmaceutical Companies) that outline the obligations the company agrees to as part of the finding of wrongdoing from federal investigations. In 2010, a false claim act law suit was filed against a major pharmaceutical company, accusing the company of paying doctors to serve as authors on publications the company had written itself to promote off-label use of one of its products, also violating federal Anti-kickback Statute (AKS). This began a new initiative in which the OIG became involved with the issues around ghostwriting and began to include authorship disclosure requirements into its CIAs. In 2011, the OIG continued its efforts to shed light on issues concerning ghostwriting and transparency by presenting a program on “*Disclosure, Transparency and Aggregate Spend*” at the Third Annual Summit, and later issued “*Compliance Program Guidance for Pharmaceutical Manufacturers*”, which identified multiple common or problematic relationships between pharmaceutical companies and physicians. CIAs are discussed in more detail in Section 2.5.

It should be noted that while CIAs are enforced by the OIG, and therefore only apply to companies operating to an extent in the USA, most pharmaceutical companies have enough activities in the region to make them subject to a CIA should the OIG deem it necessary. While many of the requirements are aimed at US healthcare professionals and specific to individual countries, they are generally regarded as the minimum standard of practice and should be applied universally.

References for Section 3

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ISMPP U webinars

Anti-Bribery & Corruption Laws: What Medical Publication Professionals Need to Know Christopher Rains, Head of Global Publications, Sr Director - Global Medical Affairs, Shire Pharmaceuticals Moderator: Michael Platt, President, MedVal Scientific Information Services, LLC; Chair, ISMPP U Committee.
 Wednesday, October 3, 2012

Section 4: Authorship

4.1 Which Rules Apply?

ICMJE authorship criteria

Because authorship gives credit, and can be beneficial academically, socially and/or financially, rules have been devised as guidelines for who qualifies to be an author. Authorship requires responsibility and accountability for the publication. Many journals and company and/or institutional publication policies follow the criteria recommended by the International Committee of Medical Journal. At the time of preparing the Primer, the most recent version of the ICMJE recommendations was the version updated in December 2014 (ICMJE 2014; <http://www.icmje.org/recommendations/>).

The ICMJE criteria (listed below) were developed to uphold the best practice and ethical standards for the conduct and reporting of published research that is accurate, clear and unbiased:

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

Authorship requires fulfillment of all four criteria, including study design or a publication outline; significant contribution to writing/revising the publication; approval of the final version; ethical obligation to account for all data analyzed and all written statements in the publication. One way to potentially engage authors who have not provided critique of the publication is to target questions to a specific author during draft revisions (using comment boxes), and asking for the author's input via email.

Different interpretations of ICMJE criteria

Some journals do not require all four ICMJE criteria to be met for authorship, and some require medical writers be included as authors. For example, *Neurology* defines authorship as requiring a substantive contribution for at least one ICMJE criteria (but an author does not have to meet all four ICMJE criteria) and medical writers must be included as authors (www.neurology.org/site/misc/auth2.xhtml). On *Neurology's* website, authorship is defined as all persons who have “made a substantive intellectual contribution”, which includes professional writers. The journal considers any undisclosed authorship to be unethical. *The Journal of General Internal Medicine* also requires anyone who contributed to writing any draft of a manuscript to be listed as an author or in the acknowledgments, and all must disclose any conflict of interest. In the instructions to authors, honorary authorship for someone who was not “actively and significantly involved” in the research or manuscript is cited as an example of “inappropriate authorship”, and it is stated that “author inflation.... cheapens the work of the other authors, and is misleading” (<http://www.springer.com/medicine/internal/journal/11606>). Some journals, e.g., *The Lancet* require a description of the individual contributions to the manuscript for authors and contributors, and these are published at the end of the article (<http://www.thelancet.com/lancet/information-for-authors/statements-permissions-signatures#authors-and-contributors>). In this manner, the contributions that qualify each individual as an author can be described (ICMJE 2014; Graf et al 2009).

Key point: Always adhere to the specific journal guidelines for authorship criteria. If the journal criteria have not yet been defined, follow ICMJE criteria.

Acknowledgments

Those individuals who should be acknowledged but do not meet all four criteria identified by ICMJE may be considered contributors, and should be properly identified in the acknowledgment section of the publication (ICMJE, 2014). Contributorship may be conferred for individuals who supervise the research in the publication, study design, data collection and/or interpretation, clinical investigators, statistical analysis, analysis

of published literature, and/or those who assisted in writing or editing the publication (ICMJE, 2014; Graf et al, 2009). Many journals require written permission for acknowledgment (Graf et al, 2009), as acknowledgment may imply endorsement (ICMJE, 2014).

In the acknowledgment section, any person who added value to the manuscript may be acknowledged. However, to be acknowledged as a contributor, one must have a more involved, specific role, which should be described. For example, when the publication was being written, an author may have a lengthy discussion with a colleague about a certain part of the publication. This discussion may result in a significant retooling of the section and the author may want to acknowledge the colleague as a scientific advisor; however, this colleague would not be considered a contributor (ICMJE, 2014). On the other hand, examples of a contributor include a person who provided patient data (e.g., a principal investigator at a clinical site) or statistical analysis, but did not fulfill the authorship criteria.

Guarantorship

The ICMJE criteria require each author *"In addition to being accountable for the parts of the work he or she has done ... should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors."* However, some journals may require one author to be identified as the guarantor, who takes overall responsibility for the integrity of the study and its report (Graf et al, 2009). For example, *Military Medicine* requires one author to be identified as the Guarantor by signing a document taking responsibility for the integrity, veracity, and legitimacy of the publication (<http://publications.amsus.org/page/milmed/author-guidelines>). The Guarantor must defend the veracity of the paper if it is ever questioned or criticized.

Transparency

To provide readers with an accurate assessment of the published work, and because professional judgment may be influenced by financial relationships or academic competition, authors must disclose all potential conflicts of interest, including sources of support for the research and/or any writing assistance (ICMJE, 2014). Many journals require authors to fill out a form for disclosure of conflicts of interest (ICMJE, 2014). As many clinical trials are sponsored by pharmaceutical and medical device companies, the need for accurate disclosures is imperative, and allows the reader to understand the relationships between the authors and companies. (Drazen et al, 2009). Identifying medical writing support diminishes the misperception of “ghostwriting” (Stern & Lemmens, 2011).

The Open Access Scholarly Publishers Association (OASPA) has posted guidance on transparency, entitled the “*Principles of Transparency and Best Practice in Scholarly Publishing*” (<http://oaspa.org/principles-of-transparency-and-best-practice-in-scholarly-publishing/>). The 16 principles of transparency and best practice are a collaboration of World Association of Medical Editors (WAME), the Committee on Publication Ethics (COPE), the Directory of Open Access Journals (DOAJ), and OASPA. They include guidance on peer review, governing bodies, the editorial team, author fees, copyright, misconduct, ownership, web site, journal name, conflicts of interest, access, revenue sources, advertising, publishing, archiving, and direct marketing.

Good publication practices espoused by ISMPP, WAME, and COPE, among others, do not condone “ghostwriting,” and require accurate disclosures to ensure transparency and the integrity of all published works.

Key point: Always adhere to good publication practices by ensuring all authors disclose any potential conflicts of interest.

Certified Medical Publication Professional (CMPP) ethics

The International Society of Medical Publication Professionals (ISMPP) strives to advance the medical publication profession globally. Many members of ISMPP elect to take an exam to become credentialed as a CMPP. The CMPP designation requires individuals to embrace all ethical considerations and be advocates for good publication practices. Each CMPP is an expert in publication planning and demonstrates leadership among publication professionals. A Certification Code of Conduct has been developed to establish the core ethical standards for the professional behavior of CMPPs (<http://www.ismpp-pubs.com/ismpp-cmpp-coc-july14/index.html>). CMPPs promote ethical standards, integrity, and transparency, and accept responsibility for their actions. They must also avoid situations in which conflicts of interest could arise and disclose any circumstance that might be construed as a potential conflict of interest.

4.2 Addressing Potential Conflicts

By following ICMJE criteria, most potential conflicts can be avoided. Many companies/institutions have adopted authorship agreement letters that outline the expectations of authorship; authors are required to sign before the writing (and ideally, the research) occurs. If the authors request writing assistance, the medical writer should be qualified based on the “GATE principles” (Daskalopoulou & Mikhailidis, 2005). These are:

- Guarantee: Are the authors guarantors of the article
- Advice: Was the professional writer ‘advised’ by the author(s) before, as well as after, starting the assignment?
- Transparency: The contribution of professional writers should be acknowledged
- Expertise: Does the professional writer have sufficient knowledge in the relevant specific field?

To avoid potential conflicts, the medical writer should not hesitate to reach out to editors or to ask questions, e.g., for information about the publication plan, and any information needed to clarify the authors' institutional policies (Chipperfield et al, 2010). Pharmaceutical, medical device, and biotechnology companies may require evidence of substantive author feedback on all drafts sent for review (Clemens, ISMPP Annual Meeting, 2012). An activity scoring system may be used to evaluate appropriate authorship (Clemens, ISMPP Annual Meeting 2012), and can determine if an individual should be an author or a contributor.

Authorship conflicts may arise; various examples are included in the table below.

Examples of Authorship Conflicts (the source for the first 4 bullet points is an ISMPP U webinar, in which challenging authorship cases were considered*; the last bullet point is a personal communication, based on the author's experience)
<ul style="list-style-type: none"> • An author who may become unengaged in a project mid-stream* • Addition of a new author in the final draft* • An author who is deceased before the final draft is submitted* • An author asked to withdraw his/her name from authorship after the manuscript was accepted for publication* • An author does not understand the language in which the manuscript is written

*ISMPP U, 7th November 2012. Challenging Cases in Publication Planning. Focus on Authorship.

If an authorship agreement that details the criteria for authorship has been signed, resolution of the conflict should occur after pointing out the relevant sentence(s) of the agreement. If not, an appropriate, ethical, and acceptable solution may be found during a discussion with the author, sponsor's publication team, medical writer, and/or journal editor(s).

Key point: By identifying authorship criteria at the beginning of the project, many potential conflicts can be avoided.

4.3 How to Begin

Authorship agreement letter

Often, an authorship agreement letter will be sent to potential authors that details authorship criteria, such as the four ICMJE criteria. The sponsor acknowledges the company/institution will grant full access to study data to the authors, and the authors have the freedom to publish or publicize the study results (Graf et al, 2009). Other content of the letter generally includes acknowledgment of medical writing assistance, disclosures of conflicts of interest and funding, and any sponsor/client requirements (Graf et al, 2009). Also many authorship agreements make note that premature or duplicate publications are not allowed, and outline a plan for publication targets (journals/congresses) in a timely and accurate manner (Graf et al, 2009). Finally, authorship agreements note the sponsor's publication policy (Graf et al, 2009). The authorship agreement letter should be signed before a kick off call commences. Some study site contracts with investigators may already have authorship agreements as part of the contract (source: ISMPP U webinar "Authors: Setting Expectations and Successful Collaboration").

Authorship letters identify the expectations of the sponsor (pharmaceutical, device, or biotechnology company), and the responsibility of the sponsor to provide the study data to the authors. The authorship letter also provides the author with recommended guidelines for his/her involvement in the publication. Any potential conflicts of interest between the authors' institutions and the sponsor's publication policy can be ironed out at this early time point in the publication process.

Publication steering committee (PSC)

PSCs can be developed at the beginning of a study to help direct publications throughout the study. PSCs can be invaluable for a multicenter clinical trial to make sure the study results are disseminated appropriately and in a timely manner. Direction from the PSC can target specific congresses and journals where the data should be published. After a primary manuscript has been published, the PSC is able to direct secondary publication(s) and congresses for publishing the data.

Members of the PSC may or may not be authors on any resulting publications (Graf et al, 2009); authorship will be determined by the authorship criteria. However, each publication should try to include a member of the PSC as an author (ISMPP U, November 20, 2013). More information about PSCs can be found in Section 7.4.

Kick off call

Authorship requirements should be discussed and reiterated during the kick off call before writing begins. The extent to which a medical writer will be assisting the authors (e.g., at the level of outline, drafts, journal submission, or drafts only as the authors will provide an outline) should be agreed upon at this time. Also at this time, author order (Graf et al, 2009) and the corresponding author (Chipperfield et al, 2010) should be agreed upon by all authors. The discussion for a target journal(s)/congress should begin during the kick-off call. The Authors' Submission Toolkit can help the publication team ask the questions needed to identify the most effective target journals/congresses to reach the intended audience (Chipperfield et al, 2010).

Medical writing assistance can be valuable to authors, if the medical writers assist the authors and do not “ghostwrite.” Medical writing “can raise the overall quality of publications” (Chipperfield et al, 2010)

To adhere to ethical medical writing, the authors should provide direction to the medical writer at every stage of manuscript development (outline, each draft, etc.), have final approval, and acknowledge medical writing assistance. Following these simple guidelines provides transparency and should clear up any misconceptions about acceptable medical writing support.

Drafts

Often, multiple drafts are needed before the manuscript is ready for submission. Following the journal's instructions for authors for formatting and length can streamline manuscript preparation (Chipperfield et al, 2010). For best practices in manuscript

preparation with detailed guidance for each section, please see Table 1 in the Author's Submission Toolkit (Chipperfield et al, 2010).

Maintaining version control, especially with multiple authors, is a critical task for the publication professional. At a minimum, the date and to whom the draft was sent should be identified. First, second, third, etc. draft should also be part of the naming of the draft document. When each author returns his/her comments, the medical writer or publication professional should note this when archiving the document. Software programs are available to help the publication professional with this task (e.g., PubsHub™, Datavision™, PubSTRAT). Sometimes it can be helpful to combine all authors' critiques into one document to be able to respond to all comments.

Keypoint: Using a source of guidance such as the Authors' Submission Toolkit (Chipperfield et al, 2010) can help with manuscript preparation.

Reviewer's comments and resubmission

Keep in mind that reviewer's comments are meant to be helpful (Chipperfield et al, 2010). When addressing the reviewer's comments, follow the journal's guidelines for revising the manuscript, and make sure to address all comments (Chipperfield et al, 2010).

Since most journals are "peer-review," most publications require this step. Reviewers are typically very knowledgeable about the subject of the publication and add value by pointing out ways to strengthen the publication. Editors may also add their critiques.

More than one resubmission may be needed. Please be mindful of the journal requirements for responses to reviewer comments. For example, some journals may want added statements highlighted in a tracked copy version of the revised draft. Most journals will want a call out of revised statements by page and line number in a separate document along with the revised draft of the publication.

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ISMPP U webinars

Authors: Setting Expectations and Successful Collaboration.

Catherine Datto, MD, Research Physician, AstraZeneca

Art Lazarus, MD, MBA, Senior Research Physician, AstraZeneca

Moderator: Elizabeth Crane, Senior Manager, Medical Publications, Astellas Pharma Global Development Inc.

Wednesday, May 18, 2011

Anti-Bribery & Corruption Laws: What Medical Publication Professionals Need to Know.

Christopher Rains, Head of Global Publications, Sr Director - Global Medical Affairs, Shire Pharmaceuticals

Moderator: Michael Platt, President, MedVal Scientific Information Services, LLC; Chair, ISMPP U Committee

Wednesday, October 3, 2012

Challenging Cases in Publication Planning. Focus on Authorship.

Brian Scheckner, PharmD, BCPP, ISMPP CMPP™, Director, Scientific Publications, Global Medical Affairs, Shire

Mukund Nori, PhD, ISMPP CMPP™, Senior Medical Writer, UBC-Envision Group

Robert Lersch, PhD, Deputy Director of Publications, Sanofi Pasteur

Speaker and Moderator: Michael Platt, ISMPP CMPP™, President, MedVal Scientific Information Services, LLC

Wednesday, November 7, 2012

Publication Steering Committees: What Should Publication Professionals Consider.

Kenneth Pomerantz, PhD, Director, Medical Publication Group, Clinical Development and Medical Affairs, Boehringer-Ingelheim Pharmaceuticals, Inc.

Brian Scheckner, PharmD, BCPP, ISMPP CMPP™; Director, Scientific Publications, Global Medical Affairs, Shire

Moderator: Gary Burd, PhD, ISMPP CMPP™; Director of Scientific Services, Caudex Medical

Wednesday, November 20, 2013

Other ISMPP assets

Authorship and algorithms: assessing contributions at Lilly.

Jeffrey Clemens, PhD, Consultant and Medical Lead for Communications, Eli Lilly.

8th Annual Meeting (April, 2012). General session Day 1.

Section 5: Industry Governance

5.1 Introduction

As described in the Ethics section, the pharmaceutical industry has come under increasing scrutiny and public interest in the last few years. The result is increasing governance which can largely be divided into four main categories; legal requirements, industry self-governance, journal requirements and accepted publication recommendations or guidelines. Some of these categories overlap, for example legal requirements or journal requirements may require some guidelines to be adhered to. Many pharmaceutical company SOPs are based on a combination of these.

5.2 Legal Requirements

Trial disclosure and publication timing

The Food and Drug Administration Amendment Act (FDAAA) requires the reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials. However, NIH encourages results reporting for all NIH supported clinical trials registered on their clinical trial registry site, ClinicalTrials.gov (<https://www.clinicaltrials.gov>), regardless of whether or not they are required to do so under FDAAA. Details of trials that are considered to be "applicable clinical trials" under the statute are included in Section 3.2.

At this time, FDAAA requires that all interventional clinical trials be registered before enrollment on ClinicalTrials.gov, and the primary results of the trial are required to be posted in this same database within 12 months after the last patient's last visit for a product already approved for marketing or within 12 months of when the product is approved (<https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered>).

The Trial and Experimental Studies Transparency (TEST) Act (currently proposed) aims to expand on the data reporting required to ClinicalTrials.gov, to include studies

conducted in other countries, Phase I studies, and providing additional documentation such as protocols (<https://beta.congress.gov/bill/113th-congress/house-bill/2031>).

The European Medicines Agency (EMA) has also created the European Clinical Trials Database (EudraCT), a clinical trials registry and results database for trials conducted in the European Union (<https://eudract.ema.europa.eu>), and other countries have or are considering their own trial registry and results databases. In addition to the requirements to register clinical trials and post results, biopharmaceutical companies have committed to post summaries of their clinical study reports, briefly describing the results of the study, on their publically accessible company websites at around the same time as the basic results are posted to regulatory clinical trial databases.

When results are posted to these sites, there is no discussion of the data, no conclusions, and no context of how this data fits into what is already known about the product or therapeutic area as would be found in a publication. Therefore, it is considered important that trial results are also submitted for peer-review publication.

Key point: Applicable clinical trials must be reported on all relevant clinical trial registries, and should be submitted for peer-review publication in a timely fashion.

Sunshine Act

The US Patient Protection and Affordable Health Care Act was signed into law in March 2010 and includes the Physician Payment Sunshine Act (Sunshine Act). As of August 1, 2013, pharmaceutical, medical device, biological, and medical supply manufacturers that participate in US federal health programs must collect, track and report any payment or other transfer of value greater than \$10 made directly to physicians and teaching hospitals. The information is reported annually to the [Centers for Medicare and Medicaid Services](#) (CMS) and then posted to a searchable publically available website. The goal of the law is to enhance patient safety by increasing the transparency of financial relationships between health care providers and manufacturers. More information about the Sunshine Act can be found in Section 2.6.

Regions outside the US have also introduced laws and regulations similar to the US Sunshine Act. In June 2013, EFPIA adopted the Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organizations and required that member associations adopt the provisions into their country codes by December 2013. Data collection will begin in 2015 and be reported in 2016. The EFPIA code states that member associations must adopt sanctions to ensure compliance with the Code. These may include warnings, fines, or expulsion. Unlike the US rules, the EFPIA guidelines require HCP consent for reporting.

Key point: Any payment or other transfer of value greater than \$10 made directly to physicians and teaching hospitals by pharmaceutical, medical device, biological, and medical supply manufacturers that participate in US federal health programs must be tracked and reported under the Sunshine Act. Other regions also have reporting requirements which must be followed.

Anti-Bribery and Corruption laws

Anti-Bribery and Corruption (ABAC) laws exist in many countries and the CMS has provided a useful international guide with summaries for several countries (<http://www.cmslegal.com/CMS-Guide-to-Anti-Bribery-and-Corruption-Laws1>). The implications for publications are in the interactions between the parties involved (e.g., authors, investigators, medical writers, sponsors, journals etc.). The UK Bribery Act defines the offence of bribing another person as where a person “*offers, promises or gives a financial or other advantage*” to another person with the intention of inducing, or rewarding for, improper performance of a relevant function or activity. Bribery is also considered to occur where a person offers, promises, or gives financial or other advantage to another person, while knowing or believing “*that the acceptance of the advantage would itself constitute the improper performance of a relevant function or activity*” (<http://www.legislation.gov.uk/ukpga/2010/23/section/1>). Corruption is defined by Transparency International as “*abuse of entrusted power for private gain*” (<http://transparency.org/>). More information about ABAC laws can be found in Section 2.7. and possible scenarios for publications are discussed in Section 3.

Corporate Integrity Agreements

In addition to other legal requirements, many pharmaceutical companies are subject to what is known as a Corporate Integrity Agreement or CIA. These often mean that guidelines related to publications become a legal requirement for them. The Office of Inspector General (OIG) negotiates CIAs with health care providers (in this case, Pharmaceutical Companies) that outline the obligations the company agrees to as part of the finding of wrongdoing from federal investigations. More information about CIAs, and the role and activities of the OIG, can be found in Section 2.5.

It should be noted that while CIAs are enforced by the OIG, and therefore only apply to companies operating to an extent in the USA, most pharmaceutical companies have enough activities in the region, which would make them subject to a CIA should the OIG deem it necessary. While many of the requirements are aimed at US healthcare professionals and specific to individual countries, they are generally regarded as the minimum standard of practice and should be applied universally.

5.3 Industry Self-Governance

The majority of pharmaceutical, biotech and device companies are represented by their regional industry associations, which develop policies in relation to a broad range of activities, agreed to by member companies. These include:

- IFPMA – International Federation of Pharmaceutical Manufacturers & Associations (<http://www.ifpma.org>)
- PhRMA – Pharmaceutical Research and Manufacturers of America (<http://www.phrma.org>)
- EFPIA – European Federation of Pharmaceutical Manufacturers & Associations (<http://www.efpia.eu>)
- CDSCO – Central Drug Standards Control Organization (India) (<http://www.cdsc0.nic.in>)

- CMDE – Center for Medical Device Evaluation (China)
<http://cmde@cmde.org.cn>
- JPMA – Japan Pharmaceutical Manufacturers Association
(<http://www.jpma.or.jp/english/>)
- PMDA – Pharmaceutical and Medical Devices Agency (Japan)
(<http://www.pmda.go.jp/english>)
- ABPI – Association of the British Pharmaceutical Industry
(<http://www.abpi.org.uk/Pages/default.aspx>)
- Advamed – Advanced Medical Technology Association
(<http://advamed.org>)
- Eucomed – “represents the medical technology industry in Europe”
(<http://www.eucomed.com>)
- EuropaBio – European Association for Bioindustries (<http://www.europabio.org>),
- BIO – Biotechnology Industry Organization (<https://www.bio.org>)
- BIA – UK BioIndustry Association (<http://www.bioindustry.org/home/>)

In relation to publications specifically, a Joint Position statement has been developed by regional pharmaceutical associations, including EFPIA, IFPMA, JPMA and PhRMA (http://www.efpia.eu/uploads/Modules/Documents/20100610_joint_position_publication_10jun2010.pdf). It recommends “all industry-sponsored clinical trials should be considered for publication in the scientific literature irrespective of whether the results of the sponsors’ medicine(s) are positive or negative”. It also states “at a minimum, results from all phase 3 clinical trials and any clinical trial results of significant medical importance should be submitted for publication. This includes investigational clinical products whose development programs are discontinued.” Studies should be submitted within 12 months, if possible, and no later than 18 months of the completion of the clinical trial (if the product is marketed), or regulatory approval or a decision to discontinue development (in the case of investigational products).

The Medical Publishing Insights and Practices (MPIP) group, which includes representatives of the pharmaceutical industry and ISMPP, also recommend publishing

“all results, including negative or unfavorable ones, in a timely fashion, while avoiding redundancy” (Mansi et al, 2012).

The Biotechnology Industry Organization (BIO) agrees to the FDAAA regulations and also states *“BIO member companies already routinely publish their clinical trials in peer-reviewed scientific journals and present their results at scientific meetings and workshops. A growing number of BIO member companies also voluntarily share patient-level clinical trial data through their own company-specific initiatives, as well as innovative public-private partnerships and consortia.”* Their minimum commitment in terms of publishing clinical trials is *“BIO member companies will submit for publication in the scientific literature, or otherwise make available to the scientific community (i.e., on a company-sponsored website, at an appropriate scientific conference, etc.), the results of all company-sponsored Phase 3 clinical trials and clinical studies of significant medical importance regardless of whether their outcomes are positive or negative”* (<http://www.bio.org/articles/bio-principles-clinical-trial-data-sharing>).

5.4 Journal Requirements

The International Committee of Medical Journal Editors (ICMJE) have developed *“Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals”* and updates these guidelines periodically. The recommendations include best practices and ethical standards for authors, editors, and others involved in the creation and distribution of accurate and unbiased medical journal articles.

Some journals do not require all of the ICMJE criteria for authorship to be met, and some require medical writers be included as authors. When identifying authors and journals for publication, specific journal requirements must be considered and met.

As well as authorship and disclosure requirements, journals also publish their ‘Instructions to authors’ which include the style and format of the publication to be adhered too (length, referencing etc.), additional documentation for submission, such as cover

letter, copyright agreement or protocol. Often manuscripts are rejected because the content is either not novel or of interest to the readership of the journal. A phone call or email to the journal's editorial office (information found on the journal website) to ask if they would be interested in the subject matter with a brief overview of the work is all that is required. Instructions differ from journal to journal so must be reviewed and implemented before submission, and ideally before development of a publication. More information on journal requirements can be found in Sections 4 and 8.

5.5 Publication Recommendations and Guidelines

Good publication practice

In 2015, the ISMPP GPP3 Steering Committee released updated publication guidelines, “*Good Publication Practice for Communicating Company-Sponsored Medical Research: GPP3*” (Battisti et al, 2015). GPP3 expands on the earlier GPP2 guidelines to further improve integrity and transparency in industry-sponsored publication planning and development in today's rapidly changing environment and includes several key resources, such as: 1) a summary of ‘top ten’ principles of good publication; 2) detailed appendices on GPP3 guideline and recommendations, and contributorship; and 3) quick reference tables illustrating guidance on authorship criteria and common issues about authorship.

GPP3 reflects recent industry developments and clarifies and strengthens the principles and practices described in earlier versions. More information about the GPP3 guidelines can be found in Section 1 (Figure 1.4.1 and accompanying text) and Section 8. An overview of GPP3 can be viewed here ([GPP3 Overview](#)).

Reporting guidelines

The EQUATOR (Enhancing the QUAlity and Transparency of health Research) Network (www.equator-network.org) is an online tool designed to educate the scientific and medical community on the reporting of medical research and “... seeks to improve the quality of scientific publications by promoting transparent and accurate reporting of health research.” Furthermore, the EQUATOR Network provides a library of resources on ethics in research and publications, in addition to a comprehensive collection of

good practice guidelines for reporting research. The website includes guidelines developed by various stakeholders: editorial groups, government bodies, publishers, medical writing and publication professional organizations ([EQUATOR library](#)).

The EQUATOR Network also offers resources and guidelines for writing research results for publication: experimental studies (including randomized controlled trials), observational studies, diagnostic accuracy studies, systematic reviews and meta-analysis, qualitative research, economic evaluations, and quality improvement studies. Examples of some key guidelines, including their scope and website addresses, are listed in Section 8.11.1; additional guidelines have been developed for specific research and study groups, eg [EQUATOR](#) (updated May 2014).

Further guidance on publication development can be found in Sections 1, 3, 4, 7, and 8.

Key point: Guidelines and resources for writing research results for publication are available on the EQUATOR Network website.

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Section 6: Role of Publications

6.1 Introduction

Reporting the results of biomedical and healthcare research in print and digital publications allows investigators to disseminate the analyses of data, and provide context in the form of discussions and conclusions. Scientific and medical publications contribute to the collective knowledge base in the life sciences and act as a communications vehicle between and amongst researchers and scholars. Medical publications are the most widely used method today for the scientific community to announce and interpret the outcomes of research into new drugs, medical treatments, and biomedical devices.

Publications are usually the end result and “deliverable” of research funded by institutions, government funding agencies (e.g. the National Institutes of Health in the US), and the biopharmaceutical and device industry (company-sponsored and investigator initiated studies). Publications for lay audiences via print (newspaper and magazines), TV, radio, and electronic media serve to communicate and translate scientific and experimental results to patients, payors, the general public, and legislators.

The global audience for publications is diverse, including the scientific community, physicians, physician assistants, patients, caregivers, payors, regulatory agencies, peers, pharmacists, nurses, nurse practitioners, and pharmaceutical and device manufacturers. These groups depend on publications to provide information that has a great impact on healthcare decisions.

Because publications, such as primary study manuscripts and review manuscripts, have the potential to change behaviors and attitudes, they therefore carry a heavy burden of responsibility (Wager, 2007). Ultimately, publications add to and expand the wealth of knowledge that clinicians and patients possess to make more appropriate healthcare decisions. The faithful representation and analysis of trial data is crucial to protect the integrity of scientific discourse.

Key point: Because publications have the potential to change behaviors and attitudes, they carry a heavy burden of responsibility.

Most scientific journals that publish healthcare research are peer-reviewed, which means that a submitted publication is reviewed by qualified professionals to determine its credibility and suitability prior to publication. Publications with flaws or questions are rejected and sent back to their authors, often with comments from the independent reviewers. The authors may consider the comments, edit their article, and resubmit it to the same journal for reconsideration, or submit it to a new journal. This process is designed to maintain standards of quality, provide credibility, and filter out potential bias in the reporting of trial data.

In addition to their impact on healthcare decisions, it is through publications that medical research can be validated. Other investigators can attempt to replicate and authenticate published findings to build on past work. Or they can avoid expending time and resources on repeating failed research.

Key point: Scientific and medical publications contribute to the collective knowledge base in the life sciences and act as a communications vehicle between and amongst researchers and scholars.

6.2 The Publication “Ecosystem”

The publication ecosystem is a diverse and multi-stakeholder community that is influenced and shaped by a number of guidelines, standards, and practices as well as compliance mandates. Stakeholders include authors and researchers, editors, editorial boards, manuscript reviewers, and publishers, as well as organizations such as the International Society of Medical Publication Professionals (ISMPP) that develop guidelines for good publication practice (<http://www.ismpp.org/>).

The International Committee of Journal Medical Editors (ICMJE) is widely regarded as the gold standard of recommendations for the “conduct, reporting, editing and publication of scholarly work in medical journals” (<http://www.icmje.org/>).

ISMPP GPP3 provides comprehensive guidance on roles of authors and contributors as well as on reimbursement and honoraria and use of professional medical writers, and offers recommendations regarding publication planning and documentation (Battisti et al, 2015).

A number of statements, guidelines and recommendations that may be of value to medical publications professionals are listed (with weblinks and/or reference details) in Section 2.9.

Authors

Authors plan and conduct academic research (funded and non-funded) across the spectrum of basic science and clinical and translational medicine. Publications serve to report scientific findings and clinical trials and can be original research, reviews, meta-analyses and systematic reviews, books, editorials, and theses. A strong publication record for authors can be very useful for academic advancement and serve as a global measure of academic success and scholarship.

There are a number of Research Reporting Guidelines that offer authors guidance and checklists for various types of research. More information on these guidelines can be found in Section 8.11.

Research is increasingly a team effort both within and outside institutions where collaboration is the norm. Sponsored clinical trials are multi-center and are usually done in many countries and across geographic areas. As a result, publications usually have multiple authors. Authorship is guided by recommendations and guidelines, such as those developed by ICMJE, but how to rank and list authors is highly variable from institution to institution and sponsor company to sponsor company. Practices include

alphabetical listing, listing by highest number of patient enrollers in clinical trials, senior authors listed either first or last, and a limited number of authors (as per journal practice) with the remaining listed in an appendix. It is important for company-sponsored multi-center trials that authorship guidelines and qualifications are determined at the start of the study and governed by sponsor guidelines and Standard Operating Procedures (SOPs).

Current issues facing the multi-stakeholder publications ecosystem include plagiarism, study reproducibility, retractions, and publication bias.

The use of previously published work in a manuscript without appropriate attribution has increased to the point where journal editors now must employ special software (e.g. iThenticate) in an attempt to uncover plagiarism in papers submitted to Journals. Plagiarism, suspect or non-scientific methodology, and outright fraudulent research has led to increasing numbers of retractions in the medical and scientific literature.

Study reproducibility is also an area of concern wherein experiment and clinical study results cannot be replicated by other institutions or researchers. Irreproducibility may be due to overestimating statistical significance, small sample size, poor statistical analysis and study design and mixing of statistical vs. clinical significance. Publication bias is due to the publication of only positive studies showing the beneficial safety and efficacy of a product, which may give a skewed view if any negative studies that showed safety concerns or little or no benefit are not published.

Journals

There is a multiplicity of journals worldwide and the number of journals has rapidly increased outside the US and Europe, particularly in the Asia Pacific, Latin American, and African regions of the world. Currently, there are over 2,000 journal publishers worldwide with the “big three” being Reed Elsevier, Springer, and Wiley.

Journal publishers, like authors, are governed by the same guidelines and compliance mandates that have been discussed throughout the Primer. New software programs such as iThenticate and Cross Check are increasingly being utilized in an attempt to identify plagiarism.

Upon submission to a journal, initial peer-review is followed by the editorial decision and if accepted, the manuscript undergoes sub-editor review, copy-editing, typesetting and subsequent publication.

Journals are evolving in the modern milieu of the digital age. Print-only publication has morphed into combination print and electronic publication and the move to open access journals (scholarly journals that are available online) continues unabated. Some journals are a hybrid of traditional and open access format. Types of journals include general medical journals, such as the *Journal of the American Medical Association*, the *New England Journal of Medicine*, and the *Lancet*, those that represent a specialty or sub-specialty and those that are therapy-based or practice-focused. Many of the newer journals fall into the latter non-general categories.

Industry professionals

Scientific and clinical publications play an important role for the 'medical' industry as publications provide support for a continuous competitive edge and future product development. The medical industry includes pharmaceutical, biotechnological, and medical device companies, which sponsor the research that involves newly developed company products and produces the clinical results to be published demonstrating the safety and effectiveness of novel pharmaceuticals and medical products. The medical publication professionals employed by medical companies, medical publications and communications agencies are responsible for processing clinical research data in the form of publications so that the data can be reviewed and utilized by other stakeholders who are not involved in the research itself; primarily the clinicians but also payors.

Academicians

The individuals who teach and conduct scientific research at academic institutions depend heavily on scientific and medical peer-reviewed journal publications to support student teaching and training with the most up-to-date scientific findings and to advance their research. Academicians also utilize the findings from publications to develop research plans and to secure competitive funding for their research. Scientific publications are also a means of disseminating the academician's own research results, and a strong bank of publications is still one of the most important requirements for career advancement in academia.

Students

Scientific publications play an important role for medical students, graduate-level students in life sciences, and postdoctoral fellows. Most often, postdoctoral fellows are young researchers and graduates of PhD programs, who continue to work mostly at academic research institutions conducting research to further their expertise in a particular subject before they move into a permanent position in academia, non-profit sector, or industry.

Scientific peer-reviewed publications are vital for training of medical students, especially those who would like to pursue an academic career involving practicing medicine and conducting research, as well as graduate students who are studying for a higher degree such as MSc or PhD in life sciences. Publications keep students informed of current research results, and provide guidance for planning and conducting their experiments. This is also the time when students are introduced to the idea of publishing their own research results and provides opportunities to obtain experience in writing, editing, and submitting peer-reviewed journal articles, abstracts and preparing conference presentations.

Key point: Scientific peer-reviewed publications are vital for training of medical students, especially those who would like to pursue an academic career involving practicing medicine and conducting research.

Physicians, clinicians and other healthcare professionals

Physicians and clinicians largely depend on peer-reviewed, original research or review articles and professional conference presentations to remain well informed of current medical advancements. Indeed, for all healthcare professionals, including nurse practitioners, pharmacists, and physician assistants, publications are an effective way to share experiences and best practices, as well as being a resource for information on medical therapies and the current medical state.

Collaborative practice agreements, specific best practice recommendations, guidelines, and consensus documents are also of great value to all healthcare professionals, and printed or online publications can also help to support their requirements for continuing education.

Patients and caregivers

Today's easy access to medical content in published and online resources opens up a large opportunity for patient-centered care that involves the patients themselves and their caregivers. At any time, about 42 million Americans provide care to adult patients with advanced illness and multiple chronic conditions (Gillick, 2013). Easily accessible publications produced for lay audiences such as patient guides provide guidance to patients and their caregivers during treatment and long-term care and help them manage the treatments safely. However, there are challenges around accountability with increased patient involvement in health care (Lawton & Armitage, 2012). The limitations to the readily accessible clinical knowledge on public domain in terms of extent and reliability need to be carefully considered by patients and their care providers to obtain the safest and most effective option for treatment.

Key point: The participating clinicians, the industry sponsor, and medical publication professionals all share the responsibility to follow the highest standards of data integrity in the development of medical publications.

References for Section 6

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Section 7: Publication Planning

7.1 Why is a Publication Plan Necessary and What Factors Should It Consider?

In order to effectively communicate about any treatment/therapy/device in development, there should be a plan for what data will be generated and discussed, what audience will find the data important, and when this data will be available for publication/presentation. The ultimate goal of medical publication planning is to ensure that there is a complete profile of the treatment/therapy/device in the peer-reviewed scientific literature. Publications describing the characteristics, efficacy, and safety of a treatment/therapy/device provide the evidence that physicians, patients, regulatory agencies, payors, and others in the healthcare industry assess to decide how to use the product and whether it provides a benefit compared with other treatments/therapies/devices for the same condition.

Journal manuscripts

Publications also serve as a forum for public disclosure of data from clinical trials, where the results are put into context and vetted by other scientists/clinicians during the process of peer review at scientific/medical journals, unlike when the basic data from the trial is posted to clinical trial registry databases. The time it takes for a manuscript to be reviewed and accepted by the journal, including responding to the reviewers' requests for changes/additional information, needs to be considered in the publication plan. Journal editors make the first assessment of whether a particular manuscript contains content that is relevant to the focus of the journal and would be of interest to their readership. If the manuscript meets the editor's criteria, it is then sent to two or three experts in the therapy area/research area (peers) for a more in-depth review of the science/data described in the manuscript and a recommendation for acceptance or rejection by the journal. The entire peer review process can take several weeks to months, depending on the journal and on whether or not the manuscript is accepted by the first journal to which it is submitted.

Congress presentations

Although journal manuscripts describing data about the treatment/therapy/device are the enduring materials that result from a publication plan, they often take a significant amount of time to develop and publish. For that reason, presentation of results at appropriate scientific congresses is also an important part of publication planning. Data from trials can be submitted in abstracts to these scientific meetings soon after the results are known and then presented as either oral presentations or posters at the meeting while the data is being written up in a manuscript. These meeting presentations often describe top-line results and go into less detail than is found in a complete manuscript, but they serve an important function by bringing early awareness of the results to a target audience and building anticipation for when a more thorough discussion of the results will appear in the full manuscript. In some cases, if the results are particularly exciting, the manuscript may be published and available at the time of the presentation of a scientific meeting. Timing of when data will be available and when and where it should be presented/published is an important aspect of publication planning. Scientific congresses have deadlines for submission of abstracts, usually 6 months or so before the meeting, to allow time for peer review and decisions on rejection or acceptance as poster or oral presentation and creation of the meeting presentations. In many cases, the study is completed and the data are analyzed and available in plenty of time to submit an abstract to a scientific congress by the submission deadline. Sometimes a study is scheduled to complete a short time before an abstract deadline for a major scientific congress at which the publication team would like to present. This means that the full analysis of the data may not be possible before the submission deadline, so the team needs to work with a statistician before the study ends to determine what data would be needed to create an abstract, so the statistician can prioritize the analyses accordingly and provide the data in time. If the study completion is delayed, the team may decide to submit a placeholder abstract, which tells what data will be included once the analyses are complete, but which does not contain any of the data. Not all scientific congresses will allow placeholder abstracts, so this needs to be investigated early in publication planning for that study, and the team may have to choose another scientific congress at which to present.

Clinical trials registries

Another factor that needs to be considered in publication planning is when clinical trial data will be posted on a public website. In the United States, the Food and Drug Administration (FDA) requires that all interventional clinical trials be registered before enrollment on their clinical trials registry site (ClinicalTrials.gov; <https://www.clinicaltrials.gov>), and the primary results of the trial are required to be posted in this same database within 12 months after the last patient's last visit for a product already approved for marketing or within 12 months of when the product is approved. The European Medicines Agency (EMA) has also created a clinical trials registry and results database (EudraCT; <https://eudract.ema.europa.eu>) for trials conducted in the European Union, and other countries have or are considering their own trial registry and results databases. When results are posted to these sites, there is no discussion of the data: no conclusions, no context of how this data fits into what is already known about the product or therapeutic area as would be found in a publication. In addition to the requirements to register clinical trials and post results, biopharmaceutical companies have committed to post summaries of their clinical study reports, briefly describing the results of the study, on their publically accessible company websites at around the same time as the basic results are posted to regulatory clinical trial databases. In most cases, the ideal situation would be to have a manuscript published before any of the data is available on public websites, to provide a full discussion of the results and what they mean. More information about requirements for clinical trials disclosure can be found in Section 5.2.

Key Point: Publication plans need to consider when data will be available, what audience will be interested in knowing about it, and what venue is best for presentation/publication.

7.2 Evolution of The Publication Plan: Life Cycle Management

Publication planning starts early in the development of a treatment, therapy or device, typically after successful initial testing in human subjects, known as Phase 1. Figure 7.2.1 shows the different phases of development and what information is collected in each

phase, as well as what kind of publications can be produced during that phase. The timing for presentation/publication of the data from each phase is determined by the Publication Team or Committee and is known as life cycle management. Once a Publication Committee is formed, the team looks at all the information about the treatment/therapy/device that has been published so far to see if there are any gaps that need to be addressed in the publication plan. For example, has the description of the mechanism of action been published for a novel first-in-class drug candidate entering Phase 3 in development? If not, this would be considered a gap, and the publication team would make it a priority to get a manuscript with this information published. They also look at what potential competitors in the same therapeutic space have published about their product to learn how and where their data were published and use that knowledge to create a robust publication plan for the new product.

Figure 7.2.1. Phases of Development and Types of Publications that Can Be Produced from Data from Each Phase

Phase	Preclinical	Phase I	Phase II	Phase III	FDA Approval	Phase IV
Purpose	<ul style="list-style-type: none"> Identify how treatment may affect disease targets Initial toxicology 	<ul style="list-style-type: none"> First stage in human subjects Absorption Metabolism Elimination Dose ranging for toxicity 	<ul style="list-style-type: none"> Short-term efficacy, safety, side effects Define target population Dose ranging for efficacy, safety, and tolerability 	<ul style="list-style-type: none"> Large randomized blinded trials to test clinical outcomes, risk-benefit ratio Basis for product labelling 	<ul style="list-style-type: none"> Input from advisory committee of experts Presentation of data by sponsor Decision by FDA 	<ul style="list-style-type: none"> Post-marketing surveillance to assess: <ul style="list-style-type: none"> Side effects Economics Patient reported outcomes Evaluation for new treatment indications, special patient populations
Scope	<ul style="list-style-type: none"> Test tube and animal studies in the laboratory 	<ul style="list-style-type: none"> <100 healthy volunteers or subjects with indications 	<ul style="list-style-type: none"> 100 to 300 subjects with/disease/condition to be treated 	<ul style="list-style-type: none"> 100 to >1000 subjects with disease/condition to be treated 	<ul style="list-style-type: none"> May request additional studies be completed prior to or after approval 	<ul style="list-style-type: none"> >1000 subjects with disease/condition to be treated
Duration	2-5 years	1-2 years	1-3 years	2-4 years	1-2 years	1-15 years
Role of the Professional Medical Writer	<ul style="list-style-type: none"> Review articles: <ul style="list-style-type: none"> Disease Therapy Social impact 	<ul style="list-style-type: none"> Primary analysis Clinical summary reports Congress abstracts Journal manuscripts Slide sets 	<ul style="list-style-type: none"> Primary analysis Clinical summary reports Congress abstracts Journal manuscripts Slide sets 	<ul style="list-style-type: none"> Primary analysis Analyses for specific at-risk populations Clinical summary reports Congress abstracts Journal manuscripts 	<ul style="list-style-type: none"> Preparation of documents to support submission Training materials 	<ul style="list-style-type: none"> Abstracts and manuscripts based on new studies or new analyses of Phase I-III data Patient education materials Systematic reviews and meta-analyses Audience-specific publications

The timing of publications in the plan does not exactly follow the phases of development shown in Figure 7.2.1. The plan is usually more generally divided into three major “buckets”: before the product is approved for general use and marketed, around the time the product is approved by regulatory agencies and launched into the market, and after the product has been on the market for a period of time.

Before a drug or device is approved, data from preclinical studies and sometimes data from basic research that describes any novel characteristic of that compound/device would be included in a publication plan. If the compound/device addresses an unmet need or works through a new pathway, review articles, which summarize the information about the field currently published in the literature, may be appropriate. Such articles can discuss where the new product candidate fits in the field. Usually data from Phase 1 are published at around the same time as data from Phase 2 trials, as some of the information collected in Phase 1 would only be important to publish if the compound/device were to continue being developed after Phase 2. However, sometimes, as in the area of oncology, Phase 1 data is published as soon as it is available, even before the trial is formally completed, because positive results that show an increase in survival for patients using the new therapy may be used to file for early regulatory approval of the drug/device, and publications describing the data are often included in the filing package submitted to the regulatory agency.

Around the time the treatment/therapy/device is approved by regulatory agencies, all of the available Phase 3 trial data should be presented/published to support the regulatory filing as well as to present the efficacy and safety data to the target audience. After the product is launched, additional publications looking at efficacy and safety endpoints in subgroups of patients in the Phase 3 trials would be included in a publication plan, especially if the trials were large.

After the product has been on the market a while, publications describing results of additional studies exploring new indications for its use or evaluating its effects in new populations would be included in a supporting publication plan. Other topics for publications during this part of the product life cycle include patient outcomes,

adherence with medication, health economics, comparative effectiveness, and safety surveillance.

Key Point: An effective publication plan takes into consideration where the product is in its life cycle in clinical development and ensures that publications describing data important during that phase are part of the plan.

7.3 Authorship

Authors should be selected based on their interest, contributions to the study, and expertise (and for primary clinical papers, their ability to work in a timely manner at study completion). The selection of authors, and their roles and responsibilities are discussed in detail in Section 4.

7.4 Publication Steering Committee

When planning the publication of clinical trials it is important that the authors are involved as early as possible in the planning process. GPP3 echoes earlier guidance and recommends formation of a publication steering committee (PSC) for a clinical study (Battisti et al, 2015). The committee's main responsibility is to plan and oversee the production of the publications for the study. This committee can consist of:

- Investigators (PIs and others)
- Members of the study steering committee & protocol development team
- Sponsor clinical team/internal study team
- Publication lead (publication professional/medical writer)
- Statisticians
- Other experts in the field.

This committee should be formed either when the protocol is finalized or at the end of the study/trial enrollment. So that committee members know what is expected of them, roles and responsibilities of each member of the committee should be defined at the very beginning. If possible, authorship should also be discussed for the different publication deliverables before work is begun on them.

7.5 Publication Committees

Study sponsors usually form cross-functional publication committees that are responsible for developing and implementing a scientific publication plan for a specific product or disease area. Publication committees may also play a role in choosing authors. The publication committee can be composed of:

- A publication lead
- External investigators
- Steering committee/Advisory Board members
- Clinical team
- Statisticians
- Preclinical development
- Regulatory
- Legal
- Safety/Pharmacovigilance
- Pharmacokinetics
- Outcomes/pharmacoeconomics
- Managed care
- Medical Affairs

This committee develops the strategic publication plan for the year and meets on a regular basis to discuss implementation and make any changes necessary to the plan based on delays in data, data that are not good, and studies being halted/suspended, etc. They may also be responsible for issuing invitations to authors for the various publications. This is done in a similar manner as described in the individual author section.

7.6 Choosing Journals

When a manuscript is being developed, it is important to select the target journal at an early stage so that the manuscript can be developed based on the guidelines of the chosen journal. The lead author should be asked for journal recommendations for each manuscript, keeping in mind the following:

- **Indexed in MEDLINE**

- One of the most important criteria in choosing a journal is to make sure it is indexed in MEDLINE, a database that contains journal citations and abstracts for biomedical literature from around the world. Journals must meet certain quality criteria in order to be indexed on MEDLINE, including scope and coverage, quality of content, quality of editorial work, production quality, and audience. There are 5,650 journals indexed on MEDLINE, and the articles in these journals are cited on the PubMed website, which is the most commonly used vehicle for article searches.

- **Determining your audience**

- Who will be reading the manuscript? Knowing this will help with the drafting of the article. For example, if the audience is a particular medical specialty, then the manuscript can be more technically specific. If the manuscript is for a more general physician audience, then the manuscript may be broader. Manuscripts focused toward Allied Health Professionals (physician assistants and nurses) often include treatment advice. Once the audience has been determined, the journal list can be refined based on the chosen audience.

- **Impact Factor**

- Impact Factor is defined as the average number of citations received per paper published in that journal during the two preceding years. Journals are ranked according to their Impact Factor. Many authors want to submit to a journal with a high Impact Factor. Although it is desirable to have your data published in a high-tier, high Impact Factor general medicine journal like the *New England Journal of Medicine* or *The Lancet*, it makes more strategic sense to target the journal that is most likely to accept the manuscript.
- Most of the time, the data in a manuscript are not relevant to a general medicine audience but are more suited to an audience in a specific disease area. Specialty journals in different disease areas also have Impact Factors, though generally not as high as for general medicine

journals, and a manuscript could first be submitted to the specialty journal with the highest Impact Factor for that disease area.

- Journal Impact Factor metrics are used in judging the scientific impact of a particular journal but the Impact Factor has recently come under scrutiny as a valid manuscript impact factor. A new Altmetrics (Alternative Metrics) movement is afoot to replace/supplement the Impact Factor as a measure of scientific impact of a paper vs. a measure of a journals' popularity. One alternative method is the Eigenfactor Score (<http://eigenfactor.org>), which seeks to rate a scientific journal on its total importance.

- ***Aim for the appropriate level for the data in the manuscript***

- If data are ground breaking, a new mechanism of action, or will determine new ways to treat a disease, then authors should reach for a higher tier journal (defined as journals with an Impact Factor of 20 and higher).
- If it is interesting data but not earth shattering, then it is better to go for a mid-tier journal (Impact Factor of 8-20)
- If the data are not impactful or statistically significant and will not change the way physicians treat their patients, then it is better to aim for a lower tier journal (Impact Factor of 0-8).
 - Some authors like to start with the higher tiered journals and work their way down, but this can delay publication and be quite expensive. It is better to realistically look at the data and choose the most appropriate journal.

Key Point: Some authors like to start with the higher tiered journals and work their way down, but this can delay publication and be quite expensive. It is better to realistically look at the data and choose the most appropriate journal.

- ***Speed to publication***

- Once a potential journal list has been developed, it is recommended that the speed to publication be reviewed. Often times, the higher impact

journals may have longer lead times, or a particular journal that is being targeted has a very long lead time. This is a good time to balance being published in a higher tiered journal versus getting the data published quickly.

- **Access (*open vs. subscription*)**

- Open access journals give unrestricted access to their articles based on the payment of publication fees by the submitters of the articles. The useful aspect of open access is that it expands the audience and may reach readers who were not originally targeted. The drawback of these journals is that they often have a lower impact factor. The fees that are charged can be quite high and will need to be taken into consideration when the budget for the manuscript is being developed. Subscription journals are limited to those readers who have paid a yearly fee to access the content, but they may be higher tiered than many open access journals and so more desirable to some authors. A good alternative option may be subscription journals with higher impact factors that offer an open-access option for an article with payment of a publication fee.

- **Read the *targeted journal***

- Reading a journal before submitting a manuscript is critical. Knowing the impact factor and the speed to publication does not mean that this is the journal for your manuscript. Be sure to:
 - Read the contents
 - Do a search and see if they publish manuscripts in your disease area
 - Read the guidelines for authors
 - Look at the rate card for the demographics
 - Consider sending a pre-submission inquiry letter to see if the editor is interested in your manuscript

- **Choose one or more *back-up journals***

- Once a journal is chosen, be sure to have a back-up journal option. Therefore, if the manuscript is rejected, it can be sent to the second journal quickly, resulting in less lost time.

Key point: Once a journal is chosen, be sure to have a back-up journal option.

7.7 Congress Planning

Any publication plan should have a timeline that indicates when a study will close and when study data will be ready for submission of an abstract to a scientific congress. Ideally the data will be available a month or more before the abstract deadline, but sometimes the data are late, and timelines need to be accelerated. As with journal manuscripts, it is important to identify the primary audience for the data and then any relevant secondary audiences for encore presentations.

If not already planned, it is useful to look for congresses that target the intended primary audience with submission dates closest to the data release. On average it can take 4-8 weeks to write an abstract and send it through author and internal review. It is essential to read the abstract guidelines on the congress website carefully to ensure that the data is appropriate for this congress. The guidelines also will have instructions for the formatting of the abstract. Once the abstract has been presented to a primary audience, then it is time to look for congresses for your secondary audiences that will accept an encore abstract.

References for Section 7

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Graf C, Battisti WP, Bridges D, Bruce-Winkler V, Conaty JM, Ellison JM, Field EA, Gurr JA, Marx ME, Patel M, Sanes-Miller C, Yarker YE; International Society for Medical Publication Professionals. Research Methods & Reporting. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ* 2009;339:b4330. <http://www.bmj.com/content/bmj/339/bmj.b4330>

Section 8: Best Practices



Guidelines for best practices are needed to address potential challenges during the development of publications, posters, and oral presentations; professional engagement and content review; and presentation of scientific materials. Although best practices continue to evolve, such guidance will help publications professionals to better manage communications and interests as scientific content is developed and delivered, and aid fostering and maintenance of an environment of mutual respect.

8.1 Best Practices – Compliance, Ethics, and Industry Guidance

Clinical trial registration and results posting

The Food and Drug Administration Amendments Act (FDAAA) of 2007 requires that all “applicable clinical trials” be registered before enrollment on their clinical trial registry site (ClinicalTrials.gov), and the primary results of the trial are required to be posted in this same database within 12 months after the last patient’s last visit for a product already approved for marketing or within 12 months of when the product is approved (<https://www.clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered>).

Details of trials considered to be “applicable clinical trials” under the statute are included in Section 3.2.

At this time, FDAAA requires the reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials. However, NIH encourages results reporting for all NIH supported clinical trials registered in ClinicalTrials.gov, regardless of whether or not they are required to do so under FDAAA.

The European Medicines Agency (EMA) has also created the European Clinical Trials Database (EudraCT), a clinical trials registry and results database for trials conducted in

the European Union (<https://eudract.ema.europa.eu>), and other countries have or are considering their own trial registry and results databases. In addition to the requirements to register clinical trials and post results, biopharmaceutical companies have committed to post summaries of their clinical study reports, briefly describing the results of the study, on their publically accessible company websites at around the same time as the basic results are posted to regulatory clinical trial databases.

When results are posted to these sites, there is no discussion of the data, no conclusions, and no context of how this data fits into what is already known about the product or therapeutic area as would be found in a publication. Therefore, it is considered important that trial results are also submitted for peer-review publication.

The Sunshine Act

The US Patient Protection and Affordable Health Care Act was signed into law in March 2010 and includes the Physician Payment Sunshine Act (Sunshine Act). Information on the Sunshine Act and similar laws and regulations in regions outside the US can be found in Section 2.6.

Current industry guidelines

In 1998 members of the academia, journal editors, study investigators and professionals in the pharmaceutical industry met to discuss publications practices and started an initiative to establish principles and guidelines for publications practices (Wager, 1999). Policies and standards were released to encourage transparency, ethics, and the exercise of practical professional judgment in publication planning. The International Committee of Medical Journal Editors (ICMJE) "Uniform Requirements for Manuscripts Submitted to Biomedical Journals (URMs)" and the "Good publication practice for pharmaceutical companies" (GPP guidelines) were initially established to promote ethics and transparency in the publication of pharma-sponsored trials, as well as to encourage practical professional judgment in general publication practices.

The International Society of Medical Publications Professionals (ISMPP) is dedicated to the progress of the profession of medical publications. ISMPP continues to encourage the adoption of policies and procedures to uphold standards of practice in scientific publication through sponsorship of the GPP Steering Committee, which was formed to develop and update guidelines for best practices. Mindful of the need to adapt to a constantly evolving professional landscape, the Steering Committee has recently released another update to the Good Publication Practice guidelines (GPP3; Battisti et al, 2015) that were originally published in 2003 (Wager et al, 2003) and updated in 2009 (Graf et al, 2009).

Checklists and standard reporting of research – tools, tips and guidelines

A number of guidelines and checklists have been developed to help improve reporting of scientific research across all areas of study and research.

The recommendations by the [ICMJE](http://www.icmje.org/recommendations/) represent a gold standard in best practices of conducting and reporting research in scientific journals (Section 8.2).

(<http://www.icmje.org/recommendations/>). According to ICMJE, these recommendations were “... developed to review best practice and ethical standards in the conduct and reporting of research and other material published in medical journals, and to help authors, editors, and others involved in peer review and biomedical publishing create and distribute accurate, clear, unbiased medical journal articles”.

Why is it important to have a standard best practice in reporting research? Clarity and transparency of reporting research can be better achieved through a standard approach based on the principles outlined in the ICMJE. Several journals follow the recommendations and will require authors to comply when submitting scientific work to the journal.

The EQUATOR Network

The EQUATOR (Enhancing the QUALity and Transparency Of health Research) Network (<http://www.equator-network.org>) is an online tool designed to educate the scientific and medical community on the reporting of medical research and “...seeks to improve the quality of scientific publications by promoting transparent and accurate reporting of health research.” Furthermore, the EQUATOR Network provides a library of resources on ethics in research and publications, in addition to a comprehensive collection of good practice guidelines for reporting research. The website includes links to guides and guidelines developed by various stakeholders: editorial groups, government bodies, publishers, medical writing and publication professional organizations (<http://www.equator-network.org/library/research-ethics-publication-ethics-and-good-practice-guidelines/-etguid>).

The EQUATOR Network also offers resources and guidelines for writing research results for publication: experimental studies (including randomized controlled trials), observational studies, diagnostic accuracy studies, systematic reviews and meta-analysis, qualitative research, economic evaluations, and quality improvement studies. Listed in Table 9.1.1 are examples of some key guidelines, however there are additional guidelines for specific research and study groups, and a comprehensive list of reporting guidelines can be found on the EQUATOR Network website (<http://www.equator-network.org/wp-content/uploads/2014/05/Catalogue-of-RG-update-7-May-2014.pdf>).

TABLE 9.1.1: Research Reporting Guidelines*

Guideline	Research Type	Website/Reference
ARRIVE	Animal research	https://www.nc3rs.org.uk/arrive-guidelines
CONSORT Consolidated Standards of Reporting Trials	Randomized controlled trials	http://www.consort-statement.org/
STROBE Strengthening the Reporting of Observational Studies in Epidemiology	Observational studies	http://www.strobe-statement.org/
CARE CAse REports	Case studies	http://www.care-statement.org/
COREQ Consolidated Criteria for Reporting Qualitative Research	Qualitative studies	http://intqhc.oxfordjournals.org/content/19/6/349.long
STARD Standards for Reporting of Diagnostic Accuracy	Diagnostic accuracy studies	http://www.stard-statement.org/
SQUIRE Standards for Quality Improvement Reporting Excellence	Quality improvement studies	http://squire-statement.org/
PRISMA Preferred Reporting Items for Systematic reviews and Meta-Analyses (formerly QUOROM)	Systematic reviews	http://prisma-statement.org/
ENTREQ Enhancing Transparency in Reporting the Synthesis of Qualitative Research	Synthesis of qualitative research	Tong A et al. BMC Med Res Methodol. 2012; 12:181.
SPIRIT Standard Protocol Items: Recommendations for Interventional Trials	Protocol items for clinical trials	http://www.spirit-statement.org/
SAMPL Statistical Analyses and Methods in the Published Literature	Statistical reporting	Lang TA, Altman DG. Science Editors' Handbook, European Association of Science Editors, 2013.
CHEERS Consolidated Health Economic Evaluation Reporting Standards	Health economic evaluations	http://ispor.org/taskforces/EconomicPubGuidelines.asp
MOOSE Meta-analysis of Observational Studies in Epidemiology	Meta-analyses of observational studies	https://www.editorialmanager.com/jognn/account/MOOSE.pdf
Cochrane handbook	Systematic reviews of interventions	http://www.cochrane.org/

*<http://www.equator-network.org/>

Guidelines for reporting assays

Another useful resource for reporting guidelines is the Minimum Information for Biological and Biomedical Investigations (MIBBI) website. This website provides the latest information on data reporting standards and also details on particular assays, for example, minimal information about microarray experiments (MIAME), minimal information about a cellular assay (MIACA), minimal information about a flow cytometry experiment (MIflowCyt), among many others. The EQUATOR Network website provides links to these guidelines.

Reporting randomized controlled trials and industry-sponsored research

The CONSORT (CONsolidated Standards of Reporting Trials) 2010 guideline (<http://www.consort-statement.org/consort-2010>) was developed through collaboration and consensus of a diverse international group, which included clinical trialists, journal editors, guideline developers, and knowledge translation specialists. It is intended to improve the reporting of parallel-group randomized controlled trials (RCTs), thereby enabling readers to better understand the design, conduct, analysis and interpretation of a trial, and the validity of its results. For this goal to be achieved, complete transparency from authors is needed. The guideline, which contains a 25-item checklist and a flow diagram, is freely available to view and download from the CONSORT website.

The GPP2 guidelines present clear and practical recommendations for reporting industry-sponsored medical research, including clarification of roles and criteria for authors, contributors, and sponsors of medical publications (Graf et al, 2009). The guidelines also include details to guide medical publication professionals in the management of specific responsibilities and activities including honoraria and reimbursement, publications focused steering committee development, clarification of roles of medical writers, and publication planning and documentation. GPP3, an update to the GPP2 publication, was published in August 2015 (Battisti et al, 2015). Enhancements include additional guidance on key topics of best practices and clarity

on the roles and responsibilities of medical professionals, among other updated information.

In 2010, the Medical Publishing Insights and Practices (MPIP) convened a roundtable of journal editors and industry representatives, to consider ways of closing the persistent and perceived credibility gap in industry sponsored research. The resulting consensus on a top 10 list of recommendations was published in 2012 (Mansi et al, 2012). The recommendations outlined a number of areas where there are *“opportunities to enhance the transparency and credibility of industry-sponsored clinical research.”*

In 2013, Peter Doshi and colleagues published a *“call for sponsors and investigators of abandoned studies to publish (or republish)”* and, in case of a sponsor's failure to respond, they proposed a system for independent publishing (Doshi et al, 2013). According to the authors, if some studies of a treatment remain unreported (or if they are misreported) this will inevitably weaken or distort the available evidence base, and make it difficult to assess the treatment's true value.

Ethics

Ethics in medical publications may be summarized as a code of standards and principles for professional conduct and business practice that is appropriate for an individual or a group. ISMPP *“promotes high standards for professional ethics and practices, and encourages members to meet such standards”* and has developed a code of ethics (<http://www.ismpp.org/ethics>). Medical publications professionals are expected to uphold ethical standards and principles that should include compliance to laws and regulations, and the rules of professional organizations and government groups.

Some examples of specific topics/areas that might be covered by the 'umbrella' term of ethics include plagiarism, ghostwriting and confidentiality of patient information.

Plagiarism in scientific publications is a challenge and can impact the credibility and integrity of the data, authors, researchers, and contributors, and possibly the journal. Medical writers, authors, researchers, and contributors share the responsibility to avoid, identify and address, plagiarism. Plagiarism, if identified, should be immediately brought to the attention of the medical writers, authors, researchers, and contributors, accompanied by the original source to that verify plagiarism has occurred. Authors, researchers, writers and contributors should determine the proper action to address the instance of plagiarism, and to correct the content with proper citing of sources. Self-plagiarism should also be addressed; copyrights may be involved and it may be necessary to seek/obtain permissions. [Note: Plagiarism is also discussed in Section 3 (Ethics) and Section 6 (Role of Publications).]

Ghostwriting has been defined as "the provision of written material that is officially credited to someone other than the writer(s) of the material", to which ISMPP concurs. Guest authoring describes the case where an individual 'lends' their name to articles despite not fulfilling authorship criteria (Grassley, 2010; Stern & Lemmens T, 2011).

The practices of ghost writing and guest authorship are not condoned and should always be discouraged. [Note: Ghostwriting and ghost authorship are also discussed in Section 1, Subsections 2.4 and 2.8, Subsections 3.3-3.4 and Subsections 4.1 and 4.3.

Best practices in scientific publication require that patient data should be protected and identities kept confidential. Study data involving human subjects should protect patient data, and the study protocol should clearly state that each patient's (or subject's) privacy is to be maintained per the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (<http://www.hhs.gov/ocr/privacy/index.html>).

8.2 Best Practices – Authorship

Key guidelines on authorship

Authors or persons that are responsible for and intellectually contribute to the original evidence-based content of scientific publications should adhere to certain standards. Journals and publishers can provide guidelines for authors that are specific to the publication, and general best practices for authorship include adherence to journal and industry guidelines. Key industry guidelines include the [ICMJE](#) recommendations, revised in December 2015, and the GPP3 guidelines (Battisti et al, 2015). [Note: ICMJE guidelines are also discussed in Sections 1 through 6 and later in this section.]

Comprehensive guidance on authorship, including why authorship matters, and roles and responsibilities of an author, can be found on the ICMJE website. The ICMJE website also provides guidance on reporting author conflict of interest (www.icmje.org/conflicts-of-interest). Reporting conflicts of interest are an important disclosure to ensure transparency and integrity of reported research. According to ICMJE's description of author responsibilities "Public trust in the scientific process and the credibility of published articles depend in part on how transparently conflicts of interest are handled during the planning, implementation, writing, peer review, editing, and publication of scientific work." Best practices with regards to handling conflicts of interest are discussed further in this Section.

ICMJE recommendations represent best practice standards for the publishing of scientific publications, including recommendations for authors and non-author contributors, peer reviewers, and editors and journal staff. Authorship criteria stipulated in the ICMJE guidelines are discussed in more detail in Section 4.

The Council of Science Editors (CSE) is a group of editorial professionals who are dedicated to the education and support of best practices in scientific editing and publishing. The CSE was formed in 1957 by the American Institute of Biological Sciences with funding from the National Science Foundation. To adapt to the evolving scientific publications environment, the organization evolved and as of 2000 includes members

from varied scientific backgrounds and interests in scientific publications. Resources that are available to download from the ([CSE](#)) site include their White Paper on Publication Ethics (updated 2012), sample correspondence for an editorial office, CSE policies, and information related to handling retractions of scientific publications. Areas covered by CSE policies include recommendations for group-author articles in scientific journals and biometric databases, possible solutions to problems with biomedical authorship, and guidance for journals on conflict of interest.

The GPP2 document presents clear and practical guidelines to manage and address key roles and circumstances relative to best practices in scientific publication, including clarification of roles and criteria for authors, contributors, and sponsors of medical publications. The guidelines also include details to guide medical publication professionals in the management of specific responsibilities and activities including honoraria and reimbursement, publications focused steering committee development, clarification of roles of medical writers, and publication planning and documentation (Graf et al, 2009). An overview of the GPP2 document, including updates to the initial GPP1 guidelines, is available [here](#).

Good Publication Practice – 3 (GPP3), published in August 2015, updates the guidelines and directives addressed in GPP2, and provides additional guidance on key topics of best practice and further clarifies roles and responsibilities for medical professionals.

Use of medical writers

Manuscript development may include the use of medical writers to supplement authors' original content and writing. Tasks and activities that medical writers may undertake to support authors with manuscript development should be ethical and transparent. The tasks may include confirmation of the list of authors with each author's contact information, clarification of roles and responsibilities, and receipt of each author's written disclosures, documentation that authorship criteria has been met, conflict of interest statement, and agreement to contribute to manuscript development. They may also include assistance to develop category outlines, conducting literature searches, identifying and obtaining references and providing writing to support evidence-based statements pursuant to the authors' directions.

Medical writers are expected to adhere to best practices in professional publication, such as those described in the ISMPP code of ethics (<https://ismpp.memberclicks.net/code-of-ethics-a>), EMWA guidelines (Jacobs & Wager, 2005), AMWA position statements and code of ethics (http://www.amwa.org/position_statement), WAME policies and recommendations (<http://www.wame.org/policies-and-resources>), and GPP2 guidelines (Graf et al, 2009). In adherence to standards of best practice, and in line with compliance requirements, medical writers should exercise sound professional judgment in the management of tasks that support manuscript development and submission. Indeed, they may be able to advise on compliance requirements and best practices and manage all documentation, as required (often via a specialist database e.g., Datavision, PubStrat, etc). Medical writers can effectively manage version control of the manuscript and supporting materials including charts, graphs, the study protocol, references, and all data analysis (including meta-analysis, as applicable), and ensure all author comments are agreed and addressed. They can also liaise with the journal on behalf of the authors (with appropriate permission from the Corresponding Author), ensure that reporting and journal guidelines have been followed and references cited appropriately.

Key point: Tasks and activities that medical writers may undertake to support authors with manuscript development should be ethical and transparent.

Authorship agreements and company/institute policies

Authorship can often be a complex matter in publication development and requires best practices to be put into place to make certain the roles and responsibility of an author are defined and well understood to those participating in publication development. Multi-center clinical trials often pose particular challenges given the number of contributors and individuals that could qualify for authorship (Rosenberg et al, 2015).

Conditions for authorship should be consistent with [ICMJE guidelines](#). Best practices include: explaining the purpose of the publication, company or institution standards,

and expectations for author collaboration, and establishing clear expectations and responsibilities of each author to facilitate an understanding of company policies, roles, and expectations. Transparency, honesty, professional courtesy, and discretion are examples of the basics for interaction that should be agreed to by each author.

Expectations and responsibilities of each author should be clearly communicated and agreed to in advance of author engagement. An early understanding by each author of the terms of the authorship agreement can define roles, provide goals of the work, and help to minimize conflict. The agreement may be customized for the author and for the lead author. The lead author typically will identify or endorse potential authors, interact with journal editors (in the case the individual is also corresponding author) to ensure adherence to journal guidelines and timelines, and facilitate timely review and responses to reviewers' comments, and manage manuscript submission. For multicenter trials, a biomedical group has developed generic author contracts and manuscript workflow checklists that could be used as reference in the case of multiple study sites and high number of contributors to the study (Rosenberg et al, 2015).

Conditions for authorship should be in compliance with [ICMJE uniform requirements](#). As authors are identified, important factors should be considered to protect against bias and ensure fair balance of the work. [More information on authorship, including authorship criteria and authors' roles and responsibilities, can be found in Section 4.]

Specific information within the authorship agreement should include terms and conditions that each author should acknowledge and adhere to, for the life of the work. Below is a list of key information to include in the agreement:

- ICMJE criteria to qualify as an author
- Type and purpose of the work
- Specific focus and benefit of the work
- Timeline - start of work and expected completion (i.e., within six months)
- List of co-authors (i.e., note preliminary list of authors and confirmed authors)
- Planned publication forum (i.e., journal list, congress)
- Ownership of the work

- Full disclosure and conflict of interest statement (i.e., financial disclosure)
- Confidentiality clause (i.e., assurance to maintain confidentiality until the work is released and published)
- The agreement should encourage cooperation of each author to operate with mutual respect and collaborate to ensure the integrity of the work.

Company or institute policy can refer to the standards of the organization that is a sponsor of the work. Also important to note is an author's institution or professional affiliation may have strict parameters for authorship. Some institutions or author affiliations may require preapproval of the topic in advance of content development, and/or review of the final version prior to release or submission. As authors are identified it may be helpful to inquire about the policies of their affiliations in advance of signing the authorship agreement.

Disclosures / conflict of interest

Full disclosure of funding and professional relationships, including conflict of interest, should be documented by each author, researcher, non-author contributor, and medical writer prior to the start of work for manuscript development. Each journal requires a different level of information and may request additional documents to include financial disclosure and non-financial affiliations as held by the authors, non-author contributors, researchers as well as by immediate family members.

Sponsors should disclose involvement and type of sponsorship relative to the research or manuscript development. Funding sources should specify the type and amount, and if funding was for research, presentation of data, manuscript development, or publication.

Specific verbiage or statements may also be required by the journal and should be included in each version of manuscript development. For example: "Author A is a member of the steering committee and has been an advisor for, and has accepted grant funding for research from ABC Bio-tech company." Journal guidelines should be

adhered to and may require specific statements, forms or documentation to ensure transparency and disclosure of professional relationships and conflict of interest.

GPP2 guidelines recommend transparency and full disclosure as noted above, as well as "contractual relationships or consultancy fees for scientific, government, or legal services, or equity in the company" (Graf et al, 2009). GPP3 (Battisti et al, 2015) enhances this guidance by recommending adherence to ICMJE 's 36-month disclosure window in cases where an institution, company or journal fails to specify a time frame.

ICMJE recommendations on conflict of interest were first published in 1978 and the current version can be viewed on the [ICMJE website](#). These guidelines state, "*A conflict of interest exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain).*" The ICMJE Conflict of Interest form, which is used by many journals, is available for download from the website.

All those involved in the peer-review and publication process, including authors and also peer reviewers, editors, and journal editorial board members should consider their conflicts of interest and disclose all relationships that could be viewed as potential conflicts of interest. Full disclosure should include not only financial relationships, such as employment and consultant relationships, and relationships relative to receipt of funds or grants for research (including data collection and analysis, and writing), but also personal relationships, and professional and academic affiliations, agreements and rivalries. Peer reviewers, editors and journal staff should disclose potential conflicts of interest as reviewers and decision-makers relative to manuscript acceptance or approval. The ICMJE recommendations are discussed further in Section 4: Authorship.

Journal requirements for disclosure and conflict of interest can vary by publication and adherence to journal instructions is crucial. In an article in the Journal of the American Medical Association (Blum et al, 2009), Blum and colleagues stated "*the corresponding author may be the only author of the manuscript to review a conflict of interest policy,*" thus supporting the need for full disclosure and conflict of interest statements from all

contributors. Details of conflict of interest policies are often available on journal websites.

Acknowledgments

GPP3 guidelines recommend that each manuscript include statements to acknowledge those individuals who have assisted in the study or development of the publication, but who do not meet ICMJE authorship criteria or other accepted author guidelines, including medical writers, editors, researchers, sponsors, study investigators, medical directors, department chairs, persons who provided important technical expertise (eg, statisticians), and study participants (as a group).

If a journal or professional organization prohibits or limits inclusion of this information, GPP3 recommends its insertion within the publication or congress presentation or, if necessary in a cover letter; in any case, the involvement of these contributors should be documented in the project file (Battisti et al, 2015).

Depending on the journal, the level of information requested for acknowledged individuals or contributors may vary. Some journals may even request documented proof that individuals agree to the acknowledgment. Thus, it is essential to understand the specific requirements of the target journal during the publication development process.

Copyright and permissions

Protection of original work guards the use, distribution, and reproduction with specific limitations (Copyright Law of the United States, § 106a · Rights of certain authors to attribution and integrity). For the purpose of protecting the advancement of science and art, the protection of copyrights were provided by the Constitution of the United States (Clause 8, Article 1, Section 8 of the United States Constitution) and can be dated to the late 1700's. Copyright terms usually last for the life of the author(s), plus 50 or more years. Authors should complete and file the appropriate forms to protect the

work. Authors may earn permissible use of work, individually and collectively, pursuant to the terms of the authorship agreement. Permissions and use of the work may be requested of the lead author, co-authors, or the company sponsor, dependent on the terms of the authorship agreement. Company or institute policy may not allow an employee to sign copyright license to publish, and the appropriate company/institute department should be consulted to confirm.

8.3 Best Practices – Publication Planning and Development

Key elements of strategic publication planning

Best practices to plan the reporting and dissemination of scientific data should include clear definition of roles and responsibilities. Timelines and tactics should also be clearly defined and key milestones monitored and managed. An outline and timeframes should factor in key data, journal requirements, and the professional audience that will receive the clinical or scientific data.

Key point: Best practices to plan the reporting and dissemination of scientific data should include clear definition of roles and responsibilities.

Publication team structure

Strategic publication planning involves numerous elements – one element in particular is essential to ensure streamlined delivery of data dissemination: the publication planning team. Gathering input from the subject matter experts on these various elements will help ensure that an effective publication plan is created. The establishment of a publication team would be an effective solution to ensure comprehensive and strategic publication planning. A publication team is a cross-functional team whose role is to create the publication plan and modify the plan as part of product life cycle management or assesses plans as the research evolves. The internal team for publication planning should be developed based on skills and the

goal of the publication plan. A publication team may seek input from the publication steering committee of a specific study or advisors on content to disseminate including managing expectations. It is important to include external subject matter experts as part of the publication planning team or publication steering committee for specific studies.

Publication steering committee

For clinical trials, GPP3 recommends that companies form publication steering committees early in the trial process to oversee and develop publications. The publication steering committee should include reliable advocates qualified to review and comment on the scientific or clinical data, key factors relative to the selection of the appropriate forums for dissemination of clinical and scientific data, and able to provide general feedback to improve the quality of writing and further support evidence-based statements. Roles and responsibilities should be clearly defined. Timelines and publication strategy as well as tactics should be clearly communicated to manage expectations and ensure cooperation (Battisti et al, 2015).

Publications team charter

The responsibilities and key deliverables for the Publications Team can be detailed within a charter to help provide direction and guidance to the team. The following are examples of responsibilities to consider include in a Publication Team charter:

- Develop comprehensive strategic publication plan and ensure that the plan is executed
- Ensure that appropriate guidelines and regulations are followed in the development of publications and are shared with functional areas
- Discuss and make decisions regarding publication topics for the product or research area
- Update strategic publication plan as needed to ensure alignment of product life cycle, research or therapeutic area needs.

Tactics

Publication planning involves many steps to ensure accuracy and timeliness of the dissemination of clinical or scientific data (Graf et al, 2009). Key milestones should be managed with transparency, ethics, and completeness. Mapping scientific statements over time can be managed with careful organization and structure. Use of a taxonomy with clear information, keywords, categories, and document classification, can track and manage scientific statements and supporting resourcing.

Clinical data should be efficiently analyzed with clear categories for reporting and manuscript development. Based on key findings the messaging and final analysis should be classified based on the focus of the research and publications. The audience should be profiled to align messages to maximize dissemination of data and supporting documentation. Communication channels including journals, congresses, and websites should be carefully screened to identify the forums that are most appropriate for delivery of key messages and scientific data or publications. A gap analysis should be thoroughly conducted to determine the appropriate platform and tactics to manage competitor presence, current and future plans, and key messages and information). Based on the findings of the gap analysis a needs assessment can identify the appropriate publication for data dissemination. Advisors and advocates should be identified and varied expertise leveraged to develop an advocacy plan to support publication initiatives. Budgets and timelines should be developed and carefully monitored to manage expenses and timing, including submission and journal requirements or fees.

Congresses present forums to present abstracts, posters, and to deliver oral presentations. Scientific or clinical data should be carefully delivered to maximize impact and information to a target audience. Rules and guidelines of the congress should be adhered to including criteria for presenters and presentation materials. Additional factors to manage include the length and style of the presentation, as well as the parameters of data and details to include in abstracts, posters, and presentations.

Journals have procedures and guidelines that must be adhered to for manuscript development and submission, as well authorship and disclosures. Timelines, submissions policies, and timeframes for peer review should be considered publication planners determine the timing of delivery of clinical and scientific data to a target audience. Journal selection should be thorough to identify the appropriate forum to disseminate the data. A publication steering committee is a resource to share input on the appropriate journals and the respective target audiences.

Managing multiple publications requires careful tracking and version control of manuscripts, supporting documents, author forms and statements, and submission guidelines and requirements. Submitted manuscripts may not be accepted and may require modification and resubmission. Resubmissions “*maybe delayed due to the inefficiency of some authors*” (Torgerson et al, 2005) or due to journal delays. Sequential submission must follow journal deadlines for response received from the editor and policies regarding non-permitted submissions during editor or journal review.

Best practice for submissions (original or resubmission) is to notify each journal of the submission or intended submission to alternate journals, including the manuscript titles to each journal.

Managing translations should include services contracted with a reputable translation service or a qualified translator to ensure accuracy and completeness of data and content. Publication development timelines should include additional weeks to allow for the translation and back-translation of the publication.

Management of a publication plan

Tactical measures and milestones should be closely tracked and managed to ensure the timely progression of each component of the publication plan. Manuscript development, budget, timelines, author forms and statements, submission requirements, and journal policies should be tracked with full transparency. Consistency and accuracy of information may be managed with clear communication in regular

intervals, such as weekly status meetings with printable reports to track progress and highlight tasks. Careful meticulous planning is an essential activity and several key factors should be considered.

- Integrating key outcomes to develop a quality publication plan also includes a thorough review and assessment of the value of the data for publication. Practical and manageable strategy and tactics should facilitate effective measures to address transparency and efficient use of technology to assess and disseminate data and key findings.
- Congress abstract submission deadlines may involve frequent monitoring of congress updates and the potential for late-breaker submissions. Keep a careful watch of the congress website for deadlines.
- Coordinating encores, adaptations, and original abstracts per the association and congress policies is essential. Policy details should note criteria for encores if permitted, allowable adaptations, and standards for original abstract submissions.
- Presentations – what data, which audience will help to develop quality presentations for target audiences. Consider the significance of the data to the audience and highlight relevant details. Assist investigators to present study results and key information according to congress policy.

International publication planning – incorporating global publication activities to an effective publication plan or publication delivery

With clinical and basic research being conducted and performed globally, there is an ever-growing need to ensure best publication practices across all regions of the world. A planning process that appropriately considers all regions and accepted cultural norms may be considered the first step to engage in global publication planning and delivery. Critical to the success of publication delivery is ensure that the process is documented, communicated and agreed with the proposed authors, as well as the implementation of an author contract and/or medical writing workflow agreement (if appropriate). Outlining in detail the process may lead to better understanding of best practices and standardized delivery of the publication. Working with authors from

around the globe will demand that the medical writer and/or authors demonstrate a particular sensitivity and calmness throughout the collaboration and negotiate solutions when conflict may arise.

The best practice to implement across all regions is communication – including communication of the publication plan for data (or specific datasets), authorship criteria (roles and responsibilities), discussion with potential authors for author order, discussion (or input) with authors on target journal, and sharing of timings for author reviews/approvals. There may be regional variation in many areas of publication development and it will be important to identify and understand the regional perspective to allow you to develop an ethical, strategic publication and best publication practice aligned process. (Note: the source of reference for this section is an ISMPP U webinar, dated November 10, 2010, 'Publication Planning Best Practices US vs Ex-US'.)

Presenting research at a scientific meeting

Scientific meetings provide an important opportunity for research findings or ideas to be exchanged, discussed or disputed and contribute to the further knowledge sharing within the scientific community.

Abstracts

Guidelines and checklists for abstracts are typically outlined by the congress and can be found on the congress website. The standard abstract includes background, methods, results and conclusion(s) – the congress will provide abstract structure guidelines. Abstract submission requirements such as word count, character count, tables or figures allowed, size limits and author conflict of interest requirements are typically listed on the website with the abstract submission deadlines (general abstract submission and "late-breaker").

There are guidelines available for the development of abstracts when reporting randomized controlled trials (CONSORT abstract; <http://www.consort-statement.org/extensions?ContentWidgetId=562>). These are an extension of the

CONSORT statement for manuscripts and serve a similar purpose – that is to improve transparency of reporting trials.

Generally, the guidelines for the development of manuscripts (e.g., ICMJE authorship criteria) can also be applied to ensure best practices for the development of abstracts.

Publication of an Abstract – journal requirements and published abstracts

The congress will also provide guidance about specific types of abstracts that may be considered for submission and review by the congress scientific committee. If the congress accepts 'encore' abstracts (see definition below), it is advisable to check whether the original abstract was published in a journal or is owned by the society after presentation. If the original abstract was published, copyright permission to use the original abstract should be requested from the journal (or society).

Types of abstracts and copyright

- Original abstract: contains work that has not been previously submitted to, presented at, or is under consideration for any other scientific meeting and that has not been previously published.
- 'Encore' abstract: contains work that has been previously submitted and/or presented at a different meeting.
 - o Some congresses permit submission of 'encore' abstracts if the previous presentation was primarily for a substantially different audience (e.g., in terms of language, geographic area or medical/scientific specialism).
 - o The definition of 'encore' abstract has many interpretations – best to discuss with the authors if any changes will be applied and check with the congress for specifics on definition of an encore abstract.

Oral (podium) presentations and posters

The type of presentation that the congress invites the authors to prepare (oral presentation or poster) will determine the best practices specific to the presentation.

For example:

- Oral presentation: follow ICMJE guidelines for disclosing conflicts of interest, funding disclosures and acknowledgments. Ideally the presenter's conflicts of interest should appear at the start of the presentation to ensure the audience is aware of any conflict (perceived or actual). The last slides should include funding disclosures and acknowledgments.
- Poster presentation: poster presentation formats will vary by congress, the inclusion of certain elements (author contributions/conflict of interests, funding disclosures, and acknowledgment sections) are important to maintain high integrity when communicating research as a poster.

Publishing research in a manuscript

Identifying an appropriate target journal

In the previous sub-sections, good practices for the conduct and reporting of research, and basic authorship requirements and responsibilities have been addressed through the use of applying recommendations and completing checklists. A further area for consideration when publishing your work is identifying the target journal.

To assist with the identification/selection of a suitable target journal to which to submit your work, you could consider the following questions:

- Does the journal publish articles in the research area that will be reported?
- Would the research area be of interest to the readers of the journal?
- What type of geographical reach does the journal have?
 - o Is geography important that my research be accessible to certain regions (i.e., EU, Asia, US etc.)?
- What is the acceptance rate of the journal?
 - o You may need to go to the journal website for this information or contact the publisher of the journal.
- Does the journal accept the type of article that will be prepared (i.e., brief communication, case report, full article, review, clinical experience, editorial, letter to editor)?
- Does the journal offer open access? Would it benefit peers to have full access to the article through open access?

- What type of publishing costs are associated with the journal (i.e., open access, costs for word limits, by page, supplementary material to in be included)?

Ideally these considerations should be discussed amongst the authors and addressed in the early stages of manuscript development. This ensures that the publication will fulfil journal requirements (word count, figures, tables, reference style) and avoids last minute time-consuming rewrites or restyling of the article.

Contacting a journal prior to submission - pre-submission letter

Once a journal has been identified, it may be worthwhile to contact the journal. This is a simple step to the journal's editorial office that could help to avoid rejection and time spent on reformatting and multiple submissions. Often times, manuscripts are rejected because the content is either not novel or not of interest to the readership of the journal. A phone call or email to the journal's editorial office (information found on the journal website) to ask if they would be interested in the subject matter with a brief overview of the work is all that is required.

The cover letter

The cover letter is a key submission component to include with the manuscript for a complete journal submission package. The information that is typically included in a cover letter is described in Section 1.9 (Submission Requirements).

The workplace reality of writing a medical publication

The following table (Table 8.3.1) provides a step-by-step illustration of the process of writing a manuscript and an estimate of the time involved for circumstances when a medical writer is utilized.

Table 8.3.1. Summary of steps involved and estimate of medical writer's hours required for each stage of the manuscript writing process.

Task	Hours
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Kick-off teleconference – client + authors (short concept sheet)	4-6
Generate outline	15-20
Client review of outline	1-2 (follow up, acknowledging receipt of comments, chasing)
Revise outline	2-5
Author review of outline	1-2
Develop draft of manuscript	25-40
Client team review of first draft 5	1-2
Incorporate comments; sends to author(s)	5-8
Author(s) review of first draft	1-2
Incorporate comments; develop second draft	5-8
Author(s)/client team review of second draft	1-2
Incorporates comments; develop final draft	4-5
Approval (company/institute)	Dependent on company/institute approval timing, no medical writing required (i.e. 5–14 days in approval)
Author approval	4-5 (includes assembling all documents for submission, e.g. conflict of interest forms, cover letter, etc.)
Manuscript submitted	2-3 (whether writer submits depends on agency policy and author preferences)
Total	70-110

Kick-off teleconference: Discuss the objective of the publication and obtain authors' input on content; establish authorship, select target journal, clarify roles and responsibilities and agree on a timeline for development of the publication.

Outline: Generally, a fairly detailed outline of the proposed content for the manuscript, based on the author-approved concept sheet, points from kick-off discussion, and intellectual input from the authors.

Drafts: Usually two full drafts with review and comment from authors, followed by a third and final draft that goes through a number of approval processes prior to submission.

Approval: All authors must approve the final version of a manuscript before it is submitted for publication. In addition, the sponsor of the publication also must provide approval. Almost all companies have some version of an LMR (legal, medical, and

regulatory) approval process by which the company assures that the publication is cleared from each of these critical perspectives.

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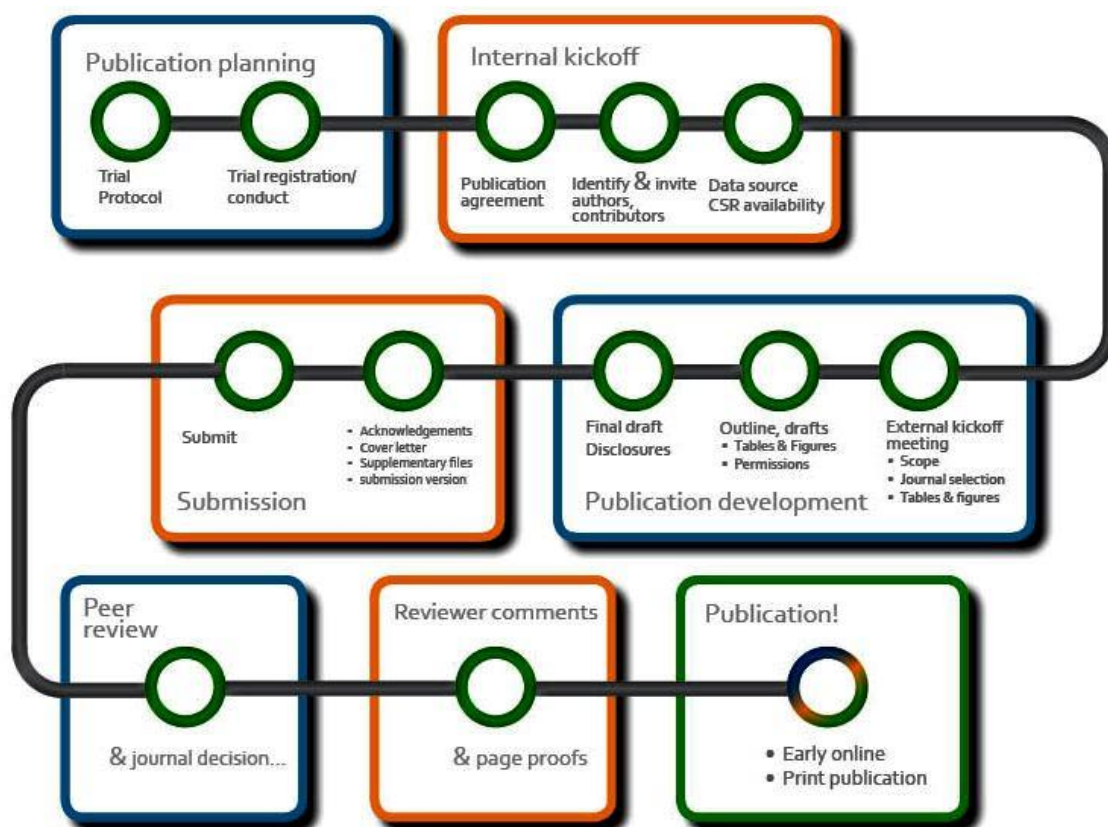
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ISMPP U webinar

Publication Planning Best Practices US vs Ex-US. (Publication planning on a global scale: complications and considerations.) *John Gonzalez, Global Skills Lead for Publications, AstraZeneca; Sarah Feeney, Head of Scientific Direction, Complete Medical Communications*
Presented Wednesday, November 10, 2010

Section 9: Publications Roadmap

This roadmap includes the topline steps that comprise the overall publication process, from study protocol through to publication (initial planning; kickoff; publication development; submission; peer review; reviewer comments; publication), with explanatory comments related to each step. The roadmap is meant to be a very basic illustration of the steps common to the development of every publication; the nature of the clinical study on which the publication is based dictates the complexity of the planning process and defines the scope of the work involved. More comprehensive information can be obtained from other resources (see Figure 8.3.1; [ISMPP Standards Committee Handbook](#)).



Reference for Section 9

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ISMPP Glossary

The glossary section of ISMPP's Standards Committee handbook will be available soon!

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ISMPP U Webinars

Publication Planning Best Practices US vs Ex-US. (Slide deck title – Publication planning on a global scale: complications and considerations.) John Gonzalez, Global Skills Lead for Publications, AstraZeneca; Sarah Feeney, Head of Scientific Direction, Complete Medical Communications

Presented Wednesday, November 10, 2010

Anti-Bribery and Corruption Laws: What Medical Publication Professionals Need to Know. Christopher Rains, Head of Global Publications, Sr. Director, Global Medical Affairs, Shire Pharmaceuticals; Moderator: Michael Platt, President, MedVal Scientific Information Services, LLC; Chair, ISMPP U Committee

Presented Wednesday, October 3, 2012

Publication Steering Committees: What Should Publication Professionals Consider? Kenneth Pomerantz, PhD; Director, Medical Publication Group, Clinical Development and Medical Affairs, Boehringer-Ingelheim Pharmaceuticals, Inc.; Brian Scheckner, PharmD, BCPP, ISMPP CMPPTM; Director, Scientific Publications, Global Medical Affairs, Shire; Moderator: Gary Burd, PhD, ISMPP CMPPTM; Director of Scientific Services, Caudex Medical

Presented Wednesday, November 20, 2013

Other ISMPP Assets

Authorship and algorithms: Assessing contributions at Lilly.

Jeffrey Clemens, PhD, Consultant and Medical Lead for Communications, Eli Lilly.
8th Annual Meeting (April, 2012). General session Day 1.

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