

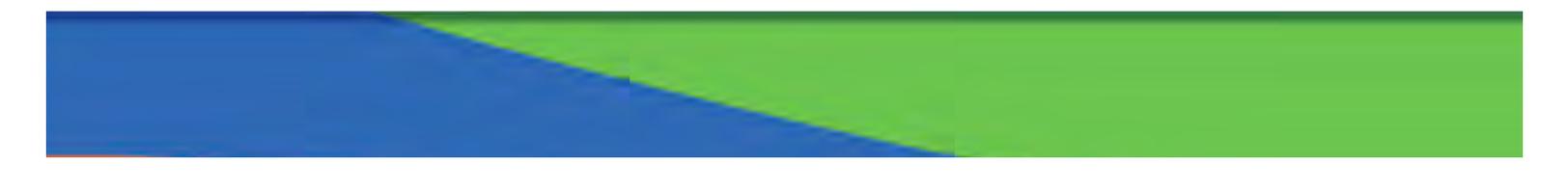
**ISMPP STANDARDS HANDBOOK**

**BEST PRACTICES IN  
MEDICAL PUBLICATION PLANNING**





\*Additional module topics are in development. The Standards Handbook table of contents will be updated periodically to reflect these additions.



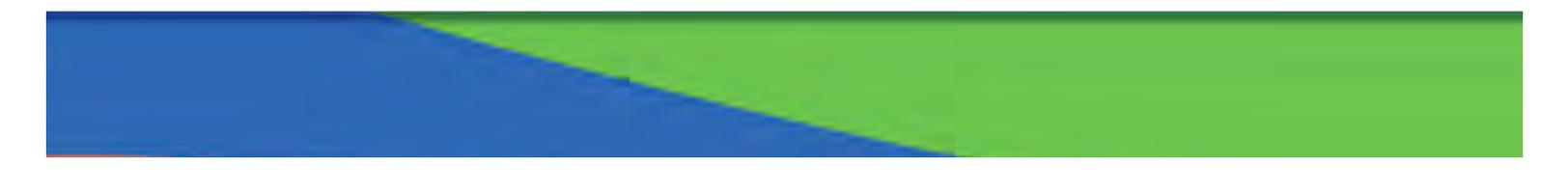


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## FOREWORD

In response to member requests, the International Society for Medical Publication Professionals (ISMPP) tasked the Standards Committee to develop a handbook on medical publication planning and implementation to serve as a reference for medical publication professionals. The ISMPP Standards Handbook: Best Practices *in Medical Publications* is the result. The *Handbook* is designed as a modular system, which allows for the release of information in a rolling fashion, and allows for the updating of individual modules as new information becomes available and/or as practices in a particular area change.

## PROCESS

The Standards Committee worked diligently over the course of several years to first develop an outline for the *Handbook*, which was reviewed within the Committee and then presented to the membership at the 2009 ISMPP Annual Meeting. The outline was revised and submitted to the ISMPP Board of Trustees for approval.

Based on the approved outline, the Committee assigned modules to members for development. Each module submitted was sent out to at least two Committee members for review and comment. The reviewer comments were discussed with the author on a teleconference moderated by the Committee Chair. The author then revised the module and the Committee Chair reviewed the changes. If further review was necessary, the original reviewers were asked to contribute. In some cases, when the topic required specialized knowledge, the Committee requested independent reviewers to participate.

Prior to the release of each module, Committee members, working with module authors, identified any required changes to ensure currency of content. Revisions were reviewed by another Committee member, and approved by the Chair and a senior member of the ISMPP staff.

Each module has been re-reviewed before release to ensure it is current. A periodic review and revision of the modules will be conducted to ensure that modules present current best practices.

## STYLE AND FORMAT

Due to the number of Committee members involved in the creation of the *Handbook*, the need to write multiple modules simultaneously, and the desire to allow the voice of the author to resonate with the reader, the Committee took the decision to allow some flexibility in writing style. All modules are edited according to the American Medical Association (AMA) Manual of Style 11<sup>th</sup> Edition (2009; <http://www.amamanualofstyle.com/oso/public/index.html>).

We hope that you find this *Handbook* helpful, and we welcome comments and suggestions (you may even want to write a module!). If you have any questions or comments, please email us at [ismpp@ismpp.org](mailto:ismpp@ismpp.org) with “Handbook” in the [subject heading](#).

—ISMPP Standards and Best Practices Committee

DISCLAIMER

The International Society for Medical Publication Professionals (ISMPP) initiated the development of this *Handbook* and its contents. The opinions expressed herein do not necessarily represent those of the authors' employers.

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## TYPES OF TACTICS: CONGRESSES

This chapter outlines the various tactics that can be developed for presentation at association and society congresses and meetings. Development of these tactics is addressed in a separate module. Congresses offer a variety of opportunities for communication of key data to highly engaged audiences. Presentations take a variety of formats.

***Larger congresses may ask the author to indicate a category or categories within which the data should be***

### ABSTRACT SUBMISSION

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 (eg, basic or clinical research, protocol, survey, post hoc analysis) presenting the objectives, methods, results, and main conclusions.

Guidelines for abstract submission and subsequent presentation in slide or poster form vary by congress. Abstracts are often restricted by word limits, character count, or size limits (must fit within a specified space). Abstracts for national and international congresses are typically limited to a total word count of 300 to 350 words or ~2500 characters. Submission is generally done online through the congress Web site and may require payment of a fee to the congress.

The congress will announce a deadline for submitting abstracts; deadlines include the general submission date, which usually occurs months prior to the congress, and a “late-breaker” date. The latter provides for submission of late-breaking data that will not be available by the general submission date but that is of great interest to attendees. Congresses usually restrict the number of late-breaker abstracts to preserve the focus on discovery (rather than procrastination). There may also be strict criteria to be met to ‘qualify’ for the late breaker category. Some congresses allow the submission of the methodology and study design of a clinical trial without any data to raise awareness of clinical trials in progress.

***Some congresses now present posters in electronic format... on plasma screens and make them available for download from***

The congress may have a policy for embargo of data to be presented at the meeting, meaning that the author may be restricted as to whether/when he or she can announce the data before the congress takes place or in conjunction with the presentation. Authors should check these policies carefully before committing to any other activities related to their data, such as press releases, interviews, or similar.

Larger congresses may ask the author to indicate a category or categories within which the data should be presented. The congress may also ask the author to indicate his or her preference for presentation of the data, ie, poster or oral presentation (slides).

The congress will have strict requirements for authorship and disclosure of potential conflict of interest. The abstract typically

is required to contain work that is original and has not been previously submitted to, presented at, or is under consideration for any other scientific meeting and that has not been previously published. Smaller regional meetings and nonphysician meetings (eg, nurse or pharmacy) may allow for presentation of slides or posters that have been presented at other meetings, also known as “encore” presentations.

The congress abstract committee will review the submitted abstract for relevance to the planned program and then accept or reject the abstract submission. Some congresses accept abstracts only from their society members. In accepting an abstract, the committee will assign the format for presentation of the data, either in the form of a scientific poster or a slide (oral or platform) presentation. Generally, fewer abstracts are accepted for a slide presentation than for a poster.

Some societies publish their annual meeting abstracts in their sponsored journal, online, or both. In general, presentation of data at a congress is not considered “publication” of results. Therefore, authors will not generally jeopardize submission of the full data in manuscript form to a scientific journal. Journals do not typically count abstracts, posters, or oral presentations at congresses as “prior publication” of data; however, the author should discuss any concerns about preemptive publication with the journal editor before presentation of data at a congress. Again, the presentation may be subject to the congress embargo policy. Finally, because congress presentations are not generally defined as “publications” and are not peer-reviewed, they are not usually cited in journal publications.

## SCIENTIFIC 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 and on specified board. Some congresses now allow posters to be presented in electronic format on plasma/LCD screens and may make them available for download from Web sites through the use of Quick Response (QR) code technology. Posters should include tables, charts, illustrations, and figures to present data and to complement the text.

Some congresses also offer poster discussion sessions, where a presenter offers a brief overview or critique of a group of posters on a similar theme. In this case, the poster presenter may also be asked to provide a few slides of key points from their poster.

The congress usually designates a period of time during the poster session when one of the authors of the poster must attend and stand adjacent to the poster to discuss the data and answer questions from attendees grouped around the poster. The presenter can also provide handouts of the poster (smaller reproductions of the poster). To safeguard the confidentiality of data, attendees are usually not allowed to take photographs of posters.

## PLATFORM/ORAL PRESENTATION

A platform or oral presentation is a brief (5- to 15-minute) slide presentation of the study discussed 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. Not all scientific meetings accept abstract submissions for oral presentation. Those that do offer oral presentations typically limit them to breakthrough data that will generate significant interest.

## 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 and be in compliance with the company's medical/legal guidelines and those of US FDA and/or other governing regulatory authority, depending on the location of the symposium and the affiliation of the presenters. The content can comprise information on a specific brand or a disease state (disease awareness), or both, depending on the company and congress guidelines.

To sponsor a symposium, the pharmaceutical company or its agent will submit an application to the congress specifying the objectives, content, and faculty for the program. The deadline for submission of a symposium application is typically different from the abstract deadline. If accepted, the congress organizers will provide the sponsor with a time, date, and location to hold the symposium. The society will then review all materials developed for the symposium. Sponsorship of the program and the fact that it is a “promotional” program will be clearly advertised.

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## TYPES OF TACTICS: JOURNALS

**J**ournals provide a key venue for publications in a variety of formats. Following is a discussion of the various available formats for publication of primary and secondary research, literature reviews, and other communications. For guidance on developing data publications and review publications, please see the corresponding modules on stages of development.

### PRIMARY RESEARCH

**Primary Manuscript.** A “primary” or “original research” manuscript generally reports the results of a clinical study. The authors report the purpose of the study, the methods used, and the results, and provide a discussion to place the findings in context with current therapeutic practice. The primary manuscript can communicate results of a variety of study end points, including clinical pharmacology, pharmacodynamics, pharmacokinetics, safety, efficacy, outcomes, and quality of life (QoL).

**Secondary Research.** A number of secondary articles may be developed based on subsets of data or different analyses or exploratory end points from a clinical study. A secondary manuscript draws on the findings of the primary manuscript to further highlight significant aspects of the study that were not reported in detail

***The primary manuscript can communicate results of a variety of study endpoints, including clinical pharmacology, pharmacodynamics, pharmacokinetics, safety, efficacy, outcomes, and quality of life (QoL).***

in the primary manuscript. Some of the most familiar types of secondary publications are review articles or articles based on subset data analyses. Secondary publications may contain data or end points that were excluded from the primary publication because of journal word count or space limitations. It is important to cite the primary publication in the 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.

**Meta-Analysis.** Meta-analysis is a statistical analysis in which data from similar studies (identified by systematic review [see below]) are pooled to produce the most precise estimate of the magnitude of effect of a given treatment; it is also a means of assessing 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.

**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.

## REVIEWS OF THE LITERATURE

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. Done well, a review article provides perspective on a certain disease state and its treatment and any unmet needs in terms of diagnosis and treatment. Some journals commission all review articles and do not accept unsolicited manuscripts or consider review manuscripts sponsored by pharmaceutical companies or written by pharmaceutical company employees.

Systematic reviews, such as those done by the Cochrane Collaboration ([www.cochrane.org](http://www.cochrane.org)), seek to collate all evidence that fits prespecified eligibility criteria to address a specific research question. Systematic reviews aim to minimize bias by using explicit, systematic methods.

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## OTHER

**Short Communication.** Many journals provide space for short communications of important research findings. Usually, these reports do not require the amount of space needed for a full report of study findings and have a higher level of urgency. The objective is to communicate key findings from a smaller data set segment in a rapid fashion.

**Editorial.** An editorial or commentary provides the author's unique perspective on a key area of interest. In many journals, the editorial is invited by the editorial staff and accompanies a key primary research article in that same issue. The author, usually not affiliated with the study, will provide context and perspective on findings of the study.

**Letters to the Editor.** Letters to the editor provide an opportunity for brief communication stating an opinion regarding a controversial aspect of therapy or a recent publication; a "research letter" may report new findings. If the letter addresses a recent publication, a response from the author or authors of that publication may accompany the letter to the editor. Letters can be published in the printed version of the journal, online, or both.

**Case Study.** Many journals publish case studies or case reports, which comprise a review of a patient case or series of related cases and commentary from the practitioner author with a short review of relevant literature. Cases are usually unique or provide an example of a key point.

**Supplement.** Many journals publish supplements, which are separate from the regularly published journal issue. Supplements are self-contained and the contents comprise one set of review articles. The supplement can focus on a specific topic or a variety of topics or report the proceedings of a symposium or other types of meeting. The supplement will have a guest editor or chair, who develops the contents with a panel of authors. The supplement manuscript is then submitted to the journal for review and

eventual publication. Supplements can be sponsored by a pharmaceutical company but this practice is evolving; individual journal guidelines will provide more detail.

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### [Value of Publications and Presentations](#)

Drafted by Gordon Muir-Jones; reviewed by Anna Geraci, Thomas C. Holland, Kathy Krueger, and Peter Rittenhouse

[Types of Tactics: Congress](#)

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[Types of Tactics: Journals](#)

Drafted by Thomas C. Holland; reviewed by Marla Mathias and Gordon Muir-Jones.

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WE APPRECIATE YOUR FEEDBACK.

