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Preface

Dear Colleagues,

Biomedical journals have seen steady increases in submissions recently, partly owing to the introduction of legislation requiring clinical trial results reporting and to industry sponsors' policies that encourage publication of even early phase studies. Meanwhile, new journals continue to launch every week, providing an ever greater choice of places to publish research. Both factors present challenges when trying to find the right journal for an industry-sponsored study, particularly when authors and publication planners are reticent about communicating with journal editors and some editors may seem wary of direct approaches.

There is already plenty of guidance for authors on writing good manuscripts. In this article, we discuss the Authors' Submission Toolkit, a new resource for authors that tackles practical questions about manuscript preparation and the submission process that are incompletely addressed in existing guidance documents. The toolkit has been produced through the Medical Publishing Insights and Practices (MPIP) initiative, a project co-sponsored by members of the pharmaceutical industry and the International Society for Medical Publication Professionals (ISMPP) to enable open communication between authors and journal editors and to increase trust, transparency, and integrity in the process of peer reviewing and publishing industry-sponsored research.

We hope that the toolkit will provide useful and relevant information for authors, such as how to initiate appropriate collegial dialogue with journals and to help ensure that good research is being published in the right place. The toolkit summarizes tips and "best practices" to increase awareness of editorial requirements, journal selection, submission processes, publication ethics, peer review, and effective communication with editors, much of which has traditionally been seen as mysterious to authors. We also hope that the toolkit will help to increase confidence in disclosing the role of professional medical writers as legitimate contributors to the process.

Finally, we hope that this initiative will help to increase trust between journal editors and the teams who produce industry-sponsored research: industry investigators, authors, publication planners, and medical writers.

Sincerely,

Trish Groves
Deputy Editor
British Medical Journal

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Commentary

Authors' Submission Toolkit: A practical guide to getting your research published

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Abstract

Biomedical journals and the pharmaceutical industry share the goals of enhancing transparency and expanding access to peer-reviewed research; both industries have recently instituted new policies and guidelines to effect this change. However, while increasing transparency may elevate standards and bring benefits to readers, it will drive a significant increase in manuscript volume, posing challenges to both the journals and industry sponsors. As a result, there is a need to: (1) increase efficiency in the submission process to accommodate the rising manuscript volume and reduce the resource demands on journals, peer reviewers, and authors; and (2) identify suitable venues to publish this research. These shared goals can only be accomplished through close collaboration among stakeholders in the process.

In an effort to foster mutual collaboration, members of the pharmaceutical industry and the International Society for Medical Publication Professionals founded a unique collaborative venture in 2008 – the Medical Publishing Insights and Practices initiative (MPIP). At an MPIP roundtable meeting in September 2009, journal editors, publishers and industry representatives identified and prioritized opportunities to streamline the submission process and requirements, and to support prompt publication and dissemination of clinical trial results in the face of increasing manuscript volume. Journal and sponsor participants agreed that more author education on manuscript preparation and submission was needed to increase efficiency and enhance quality and transparency in the publication of industry-sponsored research. They suggested an authors' guide to help bridge the gap between author practices and editor expectations.

To address this unmet educational need, MPIP supported development of an Authors' Submission Toolkit to compile best practices in the preparation and submission of manuscripts describing sponsored research. The Toolkit represents a unique collaboration between the pharmaceutical industry and biomedical journals, and reflects both groups' perspectives on how authors can help raise standards and increase efficiency in publishing industry-sponsored studies. The information provided in the toolkit can be useful to help authors navigate the manuscript preparation and submission process, and should improve the quality and timeliness of publications.

Introduction

Purpose of the toolkit

Industry-sponsored clinical research has become more open and transparent in recent years due to changes in policy, regulation, and technology, as well as a general trend toward increased information access and sharing. The goals of greater transparency and expanded access to data are also driving a significant increase in the volume of manuscripts being developed and submitted to journals, which poses challenges to both the journals and the pharmaceutical industry. As a result, there is a need to improve efficiency in the submission process to accommodate this increased manuscript volume and mitigate resource demands

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Manuscript – Medical Publishing Insights and Practices initiative – MPIP – Submission – Transparency

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on authors and editorial staff. These mutual goals can best be achieved through open dialogue and collaboration among key stakeholders.

The Authors' Submission Toolkit is a compilation of "best practices" in manuscript preparation and submission. It maintains a focus on research sponsored by the pharmaceutical industry, an area where medical publication practices and guidelines are continuing to undergo frequent refinement and evolution. It is intended to elevate transparency and integrity in medical publishing while improving efficiency. Specific objectives are as follows:

- Promote best practices and raise standards in manuscript preparation and submission
- Provide authors with resources to navigate the manuscript preparation and submission process
- Raise awareness of journal options for research data that is negative, confirmatory or of specialized interest
- Provide guidance to facilitate proper ethical collaborations between authors and industry
- Highlight practices that help increase the efficiency of submission and review for all stakeholders
- Increase awareness of guidelines regarding the role and proper acknowledgement of professional medical writers and third-party contributors

While the focus of the initial work is industry-sponsored clinical trials, many of the "best practices" captured may also be useful for authors of any study type. The authors recognize that many useful authors' resources are already available in the public domain and have referenced these sources in this document. The Resources section provided at the end of the article includes key documents and websites that address topics in the toolkit.

Organization

The toolkit, which walks authors through the key stages of the manuscript preparation and submission process, is divided into six sections. Each section is organized into several key sub-topics, and provides practical advice, identified through collaboration between journal editors, publishers, and pharmaceutical industry members.

MPIP & the development of the toolkit

The MPIP initiative was founded in 2008 by pharmaceutical industry members and the International Society for Medical Publication Professionals (ISMPP) to elevate trust, transparency, and integrity in publishing industry-sponsored studies. Current MPIP members include: AstraZeneca, Amgen, GlaxoSmithKline, Pfizer and ISMPP. MPIP's goals are to: (1) improve understanding of the issues and challenges faced by journals that publish industry-sponsored research; (2) identify potential solutions to increase transparency and trust; and (3) promote more effective partnership between sponsors and journals to raise standards in medical publishing and expand access to peer-reviewed data.

In September 2009, the MPIP convened a roundtable meeting to provide a forum for journal editors and publishers to identify and prioritize possible solutions to streamline the submission process, thus supporting prompt publication and dissemination of clinical trial results in the face of increasing manuscript volume. At the MPIP roundtable meeting, journal editors and publishers highlighted the need for an authors' guide to "best practices". A working group of editors and publishers from generalist and specialty journals and MPIP co-sponsor representatives was formed to create the Authors' Submission Toolkit.

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Members of the working group collaborated over a four-month period in early 2010 to clarify the aims, structure and content of the Toolkit and to draft, review and revise it.

Before the study and writing begin

Early preparation can provide guideposts to help streamline the manuscript development and submission process. Even before a study begins, becoming familiar with good publication practices as well as journal publication protocols and requirements will help to ensure that once completed, the manuscript summarizing results of the study is suitable for journal submission. This chapter discusses useful guidelines and publication requirements.

Authorship and contributorship

Authorship decisions and contributor disclosures are explicit ways of assigning responsibility, giving credit for intellectual work, and ensuring transparency. Most journals and industry have adopted the International Committee of Medical Journal Editors (ICMJE) guidelines, which state that authorship credit should be based on the following criteria:

- Authors are those who made a significant contribution to (a) the study concept and design, acquisition of data, or analysis and interpretation of data; (b) drafting/revising the manuscript for important intellectual content; and (c) approval of the final version to be published
- Authors must meet all three criteria
- All other persons making contributions that do not meet all three criteria should be acknowledged, typically by degree, academic or business affiliation, and specific contributions

There are several key considerations regarding authorship that should be discussed early on and during the research with fellow authors, contributors, professional medical writers, and sponsor representatives:

Stakeholder roles. The optimal time to agree upon who will be listed as an author, contributor, or sponsor on the article and who will be acknowledged (if the journal allows acknowledgements) is before study initiation. Keep in mind that guidance will vary among journals and institutions around classification of "author" or "contributor". Some journals and institutions also have specific guidelines about number of authors on a publication, as well as how to handle authorship by multi-site organizations or consortia. For large, industry-sponsored studies that involve many investigators, determining who will be listed as an author early during the research process is critically important. This can help to avoid confusion and reduce the likelihood of offending people involved in the study. For example, while a study investigator might be a high volume enroller for a clinical trial, s/he may not meet all ICMJE requirements for authorship; moreover, collection of data alone does not constitute authorship under the ICMJE criteria (nor does acquisition of funding, or general supervision of the research group). These contributions can, however, be publicly recognized in the Acknowledgements or at the end of a manuscript under a subheading of Trial Members. Therefore, it is important to agree in advance upon authorship guidelines being adhered to or criteria for authorship.

Contributions from professional medical writers, agencies or sponsors. Many journal editors recognize that help from a professional writer can raise reporting standards, improve compliance with guidelines, and elevate overall editorial quality. The World Association of Medical Editors (WAME) therefore states, "Editors should make clear in their journal's information for authors that medical writers can be legitimate contributors." However, it is advisable to check journals' instructions to authors and institutional policies to determine whether involvement from professional medical writers or medical writing agencies is expressly permitted. Guidelines proposed by the European Medical Writers Association (EMWA) and the GATE principles suggest authorship criteria for professional medical writers that can be helpful. If the contributions of a professional medical writer do not meet authorship criteria, these contributions must be disclosed, including the writer's name and any associated third-party organization. The practice of ghostwriting (i.e., the unacknowledged use of writing assistance) for medical publications is deemed unacceptable.

Corresponding author. Most journals recommend designating one author to submit the manuscript and function as primary contact between the journal and other authors/contributors. A corresponding author (who could be selected on the basis of ability to help coordinate the review and revision process) should be designated early to streamline the eventual preparation and submission of materials. Note that the corresponding author does not need to be the lead or first author listed on a manuscript, but should have full access to the study data to ensure the accuracy and completeness of the manuscript and its contents. Many journals will only accept submissions from a correspondent who is an author on the paper. However, in cases where it is permissible for a publication planner or professional medical writer to act as or assist the corresponding author, this role should be clearly explained in the cover letter accompanying a submission.

Publication charter. A publication charter is one tool for prospectively defining who is going to be involved in the process and delineating clear roles for each author.

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Conflict of interest disclosures

Conflict of interest disclosure is critical to enhance transparency and credibility in medical publishing. Current guidelines necessitate the disclosure of any financial or personal relationships that have the potential to inappropriately influence the research design, conduct, reporting or data interpretation, which are also referred to as dual commitments, competing interests, or competing loyalties. Many guidelines and protocols are available to help authors understand what types of information should be disclosed and how this should be disclosed. In 2009, the ICMJE developed a Uniform Disclosure Form for Potential Conflicts of Interest, which many journals may adopt in the future. The form includes instructions to help authors provide the right information. It is also necessary, as part of proper disclosure, to provide a comprehensive account of all financial or non-financial assistance provided by sponsors and participating organizations during the conduct, analysis, or reporting of the study. A list of the various guidelines and protocols is also available through the EQUATOR Network, an umbrella organization that brings together researchers, medical journal editors, peer reviewers, developers of reporting guidelines, and other collaborators with mutual interest in improving the quality of research publications and of the research itself.

Importantly, disclosure by editors, journal staff, and peer reviewers of any commitments or relationships that may influence their consideration of a submission is a requirement for an increasing number of journal editors. This practice complements journals' proper and honest evaluation of individuals who may or may not be suitable reviewer candidates, which has also become standard.

Prior presentation and publication policies

Most journals require that study data have not been previously published, not counting reporting disclosures such as the presentation of tabulated summary data in a trials database such as clinicaltrials.gov. Prior publications can reduce the timeliness of the information, and repeat publications also have the potential to increase redundancy in the academic literature (e.g., when meta-analyses are conducted and incorporate more than one publication from the same dataset). Some journals may prohibit manuscript submissions covering study results that have been previously presented at a local, national, or international conference, and/or for which an abstract has been published. When a journal does accept a manuscript and it is subsequently found that parts or the entirety of the study have been previously published, the journal may opt to retract the article and subsequently include a notice of redundant publication.

Best practices, particularly for industry-sponsored research, include:

- Adhere to the journal's guidance and prior presentation or publication policies
- Disclose all prior presentations, including conference abstracts, media releases, and any disclosures of full or partial study data
- Explain why previous presentations or publications were made, and any likely implications of any full or partial releases of data
- For manuscripts presenting new analyses or data syntheses, list the original data source, including the clinical trial registration number and article reference, and explain the purpose and perceived value of the new analyses

Understanding the publication plan

The publication plan is a useful tool for industry sponsors to chart data release, articulate the publication objectives for each study, identify the target audience(s), and manage the development timeline to avoid rejection on the basis of prior data release (e.g., presentation at a congress or inclusion in another publication). For large studies with multiple endpoints, an overarching publication plan can help provide details on the various publications and how they relate to one another to avoid redundancy. The publication plan should be finalized before study results are known to the investigators or sponsor and can also document the intent to publish study data irrespective of study outcome. It can address several key questions:

- How do the study and intended article relate to other publications from the same or related datasets? Establishing whether there may be multiple publications from the same or related datasets will help pinpoint the distinct purpose, potential significance, and ideal audience for each publication, which can guide journal selection and increase the likelihood of acceptance.
- When are other articles from the same or related datasets expected to be published? When there are multiple ongoing studies examining a related research topic, or arising from the same or related datasets, timing for publication of each respective study has additional implications. The primary manuscript should always be accepted for publication before other papers covering analysis of secondary endpoints from the study. This will help ensure that the pre-specified data endpoints or primary data are disseminated and well understood before secondary analyses become available. Knowing when related articles are expected to be published can help determine the suitable timeframe to reach publication and identify a journal aligned with the publication needs for the paper.

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- Are there any internal processes on the sponsors' end to be aware of? Research sponsors may have internal requirements that will impact the manuscript preparation and submission process. Clarifying key issues (e.g., timing, sponsors' review processes, etc.) will help to set appropriate expectations and implement a process plan between research sponsors and authors.

Other issues to be aware of prior to beginning a study

Journals' instructions and resources are the single most important piece of guidance for authors. Up-to-date resources typically offered by journals on their websites include:

- Summary of journal's scope of coverage, aims, and key audiences to provide guidance on whether the journal is a suitable venue for reporting outcomes from a particular study
- Description of journal policies, including required submission documents, typical review timelines and metrics of acceptance and rejection
- Conditions to be met prior to acceptance, often in "checklist" form (e.g., institutional review board/ethics committee review, reporting guidelines, clinical trial registration, etc.)
- Contact information for editorial staff

Some key issues to address prior to commencing a study include:

Appropriate design. Journal editors place a high premium on appropriate study design; poor or inadequate study design is commonly cited as a reason for manuscript rejection. For guidance, compare the design of one's study against other models from published articles with a similar research topic or scope. Feedback can also be requested from senior investigators, co-contributors or peers, particularly those who have conducted studies in the same practice area or with an analogous research scope. Be sure to review institutional guidelines and contracts before seeking assistance.

Reporting requirements from regulators. Recently, there has been an increase in the requirement from regulatory authorities around the conduct of studies and publication of data. During the manuscript submission process, journals may directly verify and/or request confirmation that regulatory requirements in the country of publication have been met prior to publication. Most recently, confirmation of registration of all trials in a publicly-accessible database, and inclusion of high-level summary data following the study's completion, have been incorporated into regulatory guidance in numerous countries.

Guidelines on reporting research. An increasing number of journals endorse reporting guidelines, statements of advice on how to report research methods and findings. A library of useful guidance documents is available through the EQUATOR Network. For example, it provides links to a number of consensus recommendations for reporting various types of studies, including QUOROM and PRISMA (systematic reviews and meta-analyses), CONSORT (randomized trials), STARD (studies of diagnostic tests), MOOSE (meta-analyses of observational studies), and STROBE (observational epidemiological studies).

Journal selection

In order to ensure that all industry-sponsored research, positive, negative and neutral, is transparently disseminated to advance science and inform good medical practice, identification of suitable venues to publish all results involving human subjects is critical. In selecting a journal, the key consideration should be identifying the most appropriate forum for dissemination of the research findings to the intended target audience. Given all the variables, it is important to prioritize and balance objectives with respect to journal relevance and reputation, target audience, geographical considerations, timing, flexibility and access options. Generalist, specialty, and subspecialty journals offer a range of peer-reviewed options for reaching global, regional, and national audiences. The rise of electronic and open-access publishing has created new options for data dissemination and added a further dimension to the medical journal landscape. Selecting the appropriate journal up front can save valuable time for all parties while ensuring critical research is disseminated in a timely fashion (Figure 1).

Step 1: Conduct an internal assessment

As with any good research, identifying and answering key questions will help to define an appropriate process. Five important questions to consider are:

Whom do I want to reach (target audience)?

- What types of researchers and healthcare practitioners comprise my key audience (e.g., academic clinicians, "front-line" clinicians, or researchers)?
- Are there any specific segments that I want to reach (e.g., insurers, government, etc.)?
- Are there particular geographic regions I wish to reach?

How do I intend to reach the desired audience?

- What are the relative benefits of electronic or print media, or a combination of the two, for dissemination of the final article?
- Are there any institutional or organizational requirements that I need to consider (e.g., if my article is published only electronically or in a non-indexed

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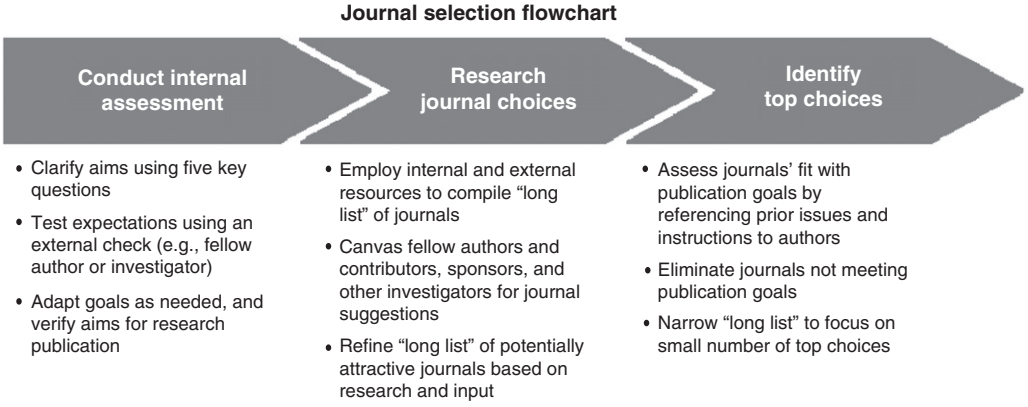

Figure 1. The following is a three-step model for selecting an appropriate journal.

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journal, how would that be perceived by the target audience and will this impact my chances for tenure and academic or professional advancement)?

How will readers access my article?

- How will a subscription, pay-per-view, or open-access format impact who reads my article?
- If I want to consider journals that additionally provide different forms of public "open access" to research data, what type of access would be suitable for my research (e.g., public access to the full dataset vs. high-level summaries)?

What type of journal will best meet my needs?

- Is it general or specialty? Surgical or non-surgical? A society or proprietary journal? Local or international?
- Will the ability to publish supplemental data via the Internet be useful for me?

How soon do I want or need to publish the data?

- Will the data be more or less relevant if they are published today versus a year or two later?
- Is the intention to have the publication available at the same time it is presented at a medical congress to provide further context?

For sponsored and multi-authored studies, strive to obtain input from all key stakeholders, particularly if the type of study, field of research, or submission process is an unfamiliar one. Trusted peers or academic mentors can also help to validate preliminary assumptions.

Step 2: Research journal options

Once an assessment of data and publication needs has been conducted, it is easier to identify target journals that meet pre-specified priorities. Best practices for building a "long list" of potentially suitable journals include:

- Request input from fellow authors, trusted peers, academic mentors and librarians / information specialists. For authors of industry-sponsored studies, sponsors can also be a useful source of input and resources (e.g., publication planning software such as Datavision, Congress Authority, and Journal Selector).
- Research PubMed (MEDLINE) to find journals that have published articles with topics similar to that of the research study.
- Explore journal directories, such as The Directory of Open Access Journals, an online resource that provides a comprehensive list of open-access journals.

Step 3: Identify top choices

Once a "long list" of journals has been compiled, determine how a manuscript arising from a study will "fit" with each potential target journal. A suitable place to start is to review the Instructions to Authors to understand individual journal's expectations, and to help determine whether a specific journal's requirements can be met. Some journals now provide checklists to help evaluate suitability of an article with the journal (e.g., see the "Is the BMJ the right journal for my research article?" checklist included in the Resources section).

Next, read through the entire content of a few recent issues; quickly scanning cover pages or article titles will provide only a limited view of the types of research presented in different journals. Consider whether a journal editor would be likely to recommend that the intended manuscript be published alongside these articles. Be realistic about which journals are the "best fit" and are most likely to accept a particular manuscript. Doing so will save all stakeholders time and energy, and will help to ensure that the article is published without excessive delay.

Finally, evaluate how each target journal might meet the needs of co-authors and research sponsors as appropriate. Some important considerations (many of which can be found in the Instructions to Authors or elsewhere on the journal website) that can help guide the journal search include:

- Rejection rate (which varies widely across journals)
- Indexing (e.g., through Medline)

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- Time to acceptance; time to publication
- Impact Factor™ (a measure of how frequently articles from a journal are cited)
- Article length restrictions
- Types of articles typically published
- Acceptance of industry sponsorship
- Acceptance of acknowledged medical writing assistance
- Receptivity to pre-submission contact
- Opportunity to accept correspondence / feedback from readers
- Charges for pages, publication, color figures or open access
- Expedited peer-review or publication services

Publishing research findings of "specialized interest"

Although it is widely accepted that all biomedical research should be documented and, when appropriate, published (scientific knowledge, after all, can be advanced equally by success, failure, or unexpected results), it can be challenging to publish results that are perceived as being negative, merely confirmatory, or otherwise of "specialized interest." However, many journals accept negative data if it is informative and educational, and several journals specifically note that they are interested in manuscripts describing "negative" trials or results of specialized interest. Examples include *Archives of Drug Information*, *BMC Research Notes*, *Journal of Drug Assessment*, *Journal of Negative Results in Biomedicine*, *PLoS One* and *Trials*. For a more extensive list of journals that accept manuscripts describing "negative" trials or results of "specialized interest," visit the MPIP initiative webpage (www.mpip-initiative.org).

Pre-submission inquiries

Importance of the pre-submission inquiry

According to some journal editors, the pre-submission inquiry is an under-utilized but important tool to streamline the manuscript submission and review process for authors and journals. From the author's perspective, a pre-submission inquiry facilitates receipt of timely and useful feedback on suitability of a manuscript for a particular journal, suggestions for improvement, or recommendations for more suitable venues prior to developing the full manuscript. In addition, a pre-submission inquiry provides an opportunity to clarify important questions about the submission process, such as review timelines and publication policies. And, it prompts the author to consider and articulate the significance of a study within the context of a broader field of study before undertaking the full manuscript preparation.

From the journal's perspective, pre-submission inquiries are useful for pre-screening and identifying suitable manuscripts for review from a vast number of submissions, conserving limited resources and providing quick decisions. They also provide a way to relay constructive feedback to authors about the study's perceived fit and suitability with their journal. Finally, they are useful for soliciting feedback about authors' concerns and questions about submission, all of which can be used to make ongoing enhancements to the editorial guidance provided to authors.

There are certain situations where a pre-submission inquiry can be particularly useful. For example:

- If the study has time-sensitive significance for its research area and should be considered for priority review at the editor's discretion (unless the journal offers a separate expedited review application process) and/or publication
- If studies with a similar topic or scope have not been published in the target journal being considered, but there is reason to believe that a study would be relevant and interesting to the journal's audience
- If there are unusual circumstances (e.g., previous publication of a portion of the study data) that necessitate special editorial review or guidance

Keep in mind that in some cases, particularly in highly specialized fields of study, one may cultivate a close working relationship with specific journal editors and/or editorial staff through repeat submissions. In these instances, initiating and continuing to build a good rapport with the journal is especially important, and this process begins with the pre-submission inquiry.

Completing a pre-submission inquiry

First, check the Instructions to Authors. Some journals explicitly do not accept or discourage the use of pre-submission inquiries. Others provide explicit guidance for pre-submission inquiries, or only accept them for certain types of articles. Where permitted, journals typically provide detailed instructions that may require uploading appropriate documents into an electronic system.

If a journal does not include specific guidance around pre-submission inquiries in their editorial policies, consider e-mailing an editor requesting feedback about the suitability of the research for the journal. Beginning a dialogue with the journal early in the process can not only demonstrate a high level of interest, but will open up a line of communication in case additional guidance from the journal is needed during the manuscript preparation and submission processes.

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A pre-submission inquiry is typically a shorter version of the full manuscript cover letter accompanied by a complete abstract; details on both of these items are given later in this guide. Journals with more formal processes may require names and contacts of authors, as well as additional disclosures (e.g., trial registration confirmation, conflicts of interest disclosure, etc.). Best practices include:

- Lay the foundation for a good relationship with the journal by being judicious, professional and brief in all communications.
- Follow instructions and English usage rules to create a good first impression for journal editors. Failing to obey word limits may be seen as an inability to follow instructions.
- Get clarity on uncertainties about the process to prevent misguided time and energy. Journal editors are often receptive to even very early inquiries about manuscript fit and logistics (e.g., process, costs, etc.).
- Request the editors' feedback by including a statement such as, "If you find this submission not to be suitable for your journal, it would be greatly appreciated if you could provide suggestions for other journals that might be more suitable." Most editors are aware of a wide range of journals, and may be able to provide good recommendations if theirs is not the ideal venue for a particular study.

Manuscript preparation

Important considerations

Many journal editors indicate that non-compliance with guidance around manuscript preparation is a common, but easily avoidable, mistake. The following approaches can help to streamline manuscript preparation and increase the chances of eventual acceptance:

- Adhere to the journal's instructions regarding formats and length, including word limits, graphic sizes, and acceptable document formats. Ensuring adherence to these requirements enables speedy review and helps journals stay within their page budgets. Instructions to authors and/or feedback from editors can help provide clarity around what types of supplemental data, content, etc. can be in included in print and online. Read published articles in the journal for a better idea of the appropriate tone and level of detail.
- Utilize proper grammar, punctuation, and language as it may be difficult for an editor or reviewer to overlook extensive errors, even if the study itself is interesting and significant. Ask senior colleagues, research sponsors and even investigators in other disciplines to help review the manuscript before submission. Authors with limited command of the English language should consider using translation and/or supplementary medical writing assistance services; reference the journal's instructions regarding acknowledgement of contributors.
- Check for internal consistency of data and results within the text and all accompanying materials (e.g., graphics, tables, appendices, etc.); even minor differences in the data presented are viewed unfavorably by editors and reviewers.
- Aim to be as transparent as possible when writing the manuscript and include all necessary information. A clear statement of the research question, an account of how the study was conducted, and what was found should be included. Avoid including non-critical, extraneous information; providing excessive information, such as that found in a full study report written for internal or regulatory use, is not helpful and can slow the review process. Most journals are receptive to requests for help identifying ways to distill key points and to streamline manuscripts (for example by organizing some results in a table rather than in the body of the article).
- Ensure that all authors contribute to and approve the manuscript in accordance with ICMJE guidelines.

Best practices by manuscript section

In Table 1, we provide best practices for each section of the manuscript. In general, remember to follow Instructions for Authors regarding the format and content of all sections of the manuscript.

Of note, editors often cite the methods section as that which most commonly contains flaws in submitted manuscripts.

Cover letters

Purpose

The cover letter is the first summary of the study that will be read by an editor, and provides the first (and sometimes only) chance to convey the study's significance and relevance to the journal's audience. It is helpful to the editor to reference prior communications, including pre-submission inquiries, prior feedback and past reviews/comments, in order to clarify understanding and to streamline the process. The cover letter is also an appropriate place to highlight important considerations for publication, such as the relevant journal section for the manuscript and any key factors around timing, etc. Rigorously following instructions, reinforcing adherence to disclosure guidelines, and addressing any outstanding questions about the suitability of a manuscript for a selected journal will also demonstrate a commitment to making the publication a success.

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Table 1. Best practices in manuscript preparation, organized by section.

Title and abstract	• Ensure title and abstract are consistent with journal guidance regarding structure, form, word/character count • Ensure title and abstract match up and clearly relate to each other • Ensure abstract conclusions accurately represent outcomes and are consistent with study conclusions • As appropriate, include p-values and absolute numbers for key findings in the abstract • Provide key words, as instructed by the journal, to enable database searching of the article
Acknowledgments	• Make all required disclosures consistent with journal policy (i.e. for authorship, contributorship, funding, role of the sponsor, and competing interests) in appropriate format • Explicitly add a statement about what type of assistance, if any, was received from the sponsor (e.g., editorial support, graphics, statistical analysis) or sponsor's representatives (e.g., CROs). • Include the name(s) of any professional writer(s), editorial staff or other contributors, or any third party associations that participated in manuscript development
Introduction	• Clearly articulate the research question addressed by the study (e.g., journal editors mention that the conceptualization of the problem and approach is often not well conveyed), following journal's format for ''hypothesis'' if explicitly provided • State the importance of the research question to the field (e.g., is it new / relevant and does it address an important research question?) • Note relationships to other studies from the same or related datasets • Do not be afraid to acknowledge if a study has been conducted for regulatory purposes • Present the introduction in a straightforward manner, without excessive wordiness
Methods	• Provide a full explanation of the study methodology, including study design, data collection and analysis principles, and underlying rationale, etc., with special attention to: – Sample selection, including inclusion and exclusion criteria, and any ethical considerations that guided the study design – Description of randomization or other group assignment methods used – Description of the pre-specified primary outcome measure(s), as well as secondary and other variables • Describe any unusual statistical methodologies employed, expressed so non-expert editors can understand deviations from standard approaches • Describe how subjects were recruited and compensated (if applicable) • Describe how compliance was measured (if applicable) • For randomized controlled trials, follow journal's guidelines regarding adherence to the current version of the CONSORT (Consolidated Standards of Reporting Trials) statement relevant to the particular study type • Refer to journal instructions as to whether methods and results should remain as separate sections or be combined
Results	• Clearly report patient population characteristics, low response / study continuation rates, missing data, quality control issues or deviations from registered protocol (e.g., inconsistencies in recruiting, compliance, etc.) • Report results for primary outcomes (and secondary, if appropriate), using tables and figures for additional clarity, with rationale for endpoint selection and explanation of why information was not collected on important non-measured variables • Check if the journal allows excess text, figures, tables or references to be included as online supplemental data, which is particularly important if manuscript exceeds specified word limits • Check for consistency in reported data between text and tables / images • Thoroughly report the impact of unusual analytical methods • Explain any changes from the original hypothesis or objectives that occurred before, during, or after the study
Discussion	• Structure the section so that it presents a natural flow of ideas – start with a simple statement of main findings, followed by strengths and limitations of the study, and what the study adds to previous knowledge • Describe briefly how the results are consistent or not consistent with other similar studies • Discuss any confounding factors and their impact • Avoid excessive wordiness – editors and reviewers describe this section as one that is usually too wordy and often contains non-critical information
Conclusion	• Address, but do not ''over-sell'', perceived significance of the study to the field and possible implications for practice/policy • Ensure conclusions relate directly to the stated a priori hypothesis (and not hypotheses from other studies or outside the area of the study) • Avoid excessive generalizations of the implications, including unjustified extrapolations beyond the actual population(s) studied • Remember that except for randomized, controlled trials, there can only be testable hypotheses and observed associations, rather than rigorous proof of cause and effect • Address areas for improvement with future studies
References	• Follow journal's policies and formatting instructions, including for web-based references and obtain clarification from the journal as needed • In most cases, manuscripts ''in submission'' are not appropriate for inclusion in this section. • Particularly note that some journals do not allow use of unpublished ''data on file'', statements from package inserts based solely on such data, or reviews that rely upon ''data on file'' as the only support for claims made; if ''data on file'' references are allowed by the journal, be sure to request the title, nature of the reference, and internal reference number for record-keeping purposes

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Key elements of a good cover letter

In the Appendix, we have provided a cover letter template with guidance on structure and content. Best practices include:

- Avoid factual and typographical errors, especially in the journal or editor's name
- Clearly articulate the study's research purpose, which sufficiently but briefly discusses the study's importance, its significance for its field of study, and how it relates to other studies, including those from the same or related datasets
- Detail prior correspondence and review – many editors value appropriate disclosure of prior submissions to other journals and on the work the author has already done to address any previous reviewer comments
- Confirm that regulatory and good clinical practice requirements have been met, such as by providing registration details for a clinical trial
- Confirm adherence to conflict of interest requirements, ICMJE authorship criteria, and contributor disclosure standards, or journal requirements if different
- Disclose all full and partial prior releases of data, including poster presentations, meeting abstracts, press releases or marketing materials, with details of when and where such content was disseminated
- Where required, suggest independent and unbiased reviewers, and (if requested) individuals who should not review the article due to competing interests (e.g., those conducting closely related studies)
- Mention any simultaneous submissions to other journals (if applicable)

Review, revision and re-submission

Understanding the review process

Journals employ different systems and approaches for reviewing submissions. Some journals make extensive use of internal editorial review, but most depend on external peer reviewers, who are engaged by a journal to assess the merits of submitted manuscripts. Feedback is meant to be constructive and provide valuable suggestions for improving the manuscript.

Specific guidance about a journal's review system (e.g., blinded, non-blinded, multiple reviewers, review by invitation only, etc.), which can often be found in the instructions to authors, can help to set appropriate expectations regarding the review process and a projected timeline.

Although outright acceptance of a new submission is theoretically possible, it is very uncommon. Most journals will provide at most provisional acceptance, and require at least minor revisions prior to publication. Depending on the journal, the extent of the revisions made, and the specific expertise of the editor, revised papers may be reviewed only internally, sent back out to the original reviewers, or sent out to new reviewers following re-submission. Regardless, editors expect that all comments be appropriately addressed, whether a revised manuscript is submitted to that, or any other, journal.

In some cases, a manuscript may be rejected after internal and editorial review only. In these instances, some journals will provide a brief explanation about why they found a manuscript to be unsuitable for publication in their journal. This feedback can help in deciding whether to submit a rebuttal to the journal or to submit the manuscript to another journal. Keep in mind, however, that authors in some cases may only receive a summary of reviewers' comments and may not have access to other confidential feedback provided by the reviewers specifically to the editor. These comments may influence the editor's decision but may not necessarily be disclosed unless more feedback is specifically requested.

Finally, a journal may feel it needs additional information (e.g., about methods or analyses) to reach a decision on the submitted material and will provide specific guidance around what additional clarification is needed.

Best practices in revision and re-submission

The most critical aspect of revision and re-submission is to address all reviewer and editorial comments. These reviews are intended to improve the manuscript, and are not meant as criticism. A significant amount of (usually) unpaid time and effort goes into peer review, so all comments should be valued and addressed point by point. Follow journals' guidelines for submitting revised manuscripts as tracked documents or in summary form, and clarify whether the corresponding author is required to handle the re-submission, or whether another party (e.g., a medical writer or publication professional) may do so. Also ensure that the re-submission cover letter addresses reviewers' comments thoughtfully and in sufficient detail.

When conflicting opinions about reviewer comments arise (e.g., between author and reviewer, between different reviewers, or between reviewers and editors), the handling editor or editor-in-chief will ordinarily take responsibility for making a decision; usually the editor-in-chief has the final say in handling such conflicts. Therefore, if a reviewer's comment is viewed to be incorrect or unjustified, be sure to provide an explanation of why, and supply any available literature references for support.

Avoid using "easy fixes" as a substitute for proper consideration of reviewers' comments – particularly when flaws in study design are identified. Major study design defects cannot be addressed simply by rewriting or reformatting a manuscript. If an author believes a manuscript is

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still appropriate for publication, it is helpful to add an explanation of shortcomings in the study design and incorporate suggestions for improvements in future studies. Importantly, changing or omitting accurate details is in violation of reporting guidelines.

Finally, during the revision process, the author should revisit the publication goals and priorities and determine how revision or re-submission will affect the timeline and ability to meet the publication goals. Set appropriate expectations about how long incorporating revisions will take and how extensive the changes to the manuscript should be to make it suitable for publication. Bear in mind that even if the manuscript will be subsequently submitted to a different journal rather than resubmitted to the original target, all suggested revisions should be addressed before re-submission. Explicitly addressing the comments and changes made to the original manuscript in the cover letter accompanying the re-submission is encouraged.

Defining next steps following a rejection

Following a rejection, authors generally have two choices: appeal the decision, or submit the manuscript to another journal. Whichever route is taken, all authors must concur with the decision.

Appeals are infrequently accepted, and may be even less successful if the paper was rejected without external peer review. Check the journal's instructions to determine if an appeal is a viable option. Whether the journal allows a full and detailed appeal or prefers to see a revised manuscript as part of the appeal, address as many of the reviewers' comments as appropriate and reiterate why the manuscript is believed to fit with the journal and its readership. Appeals are not a priority for journals, and it may take time to receive a response.

If choosing to submit to another journal, refer to the original list of researched journals, and re-consider journals previously or more recently identified as having a strong fit with the publication needs for a study. Some journals, especially ones with more manageable submission volumes, will respond to follow-up questions following rejection, which can guide a more effective new submission strategy. Others participate in cascades or consortia, through which they share submissions (i.e., even if a submission is not well suited for a particular journal's audience, they may be able to suggest or pass along the manuscript to the editor of a partner journal that might be a more appropriate venue for the research). Most journals in cascades or consortia will list partner journals on their website.

Submissions to new journals should follow the best practices of both original submissions and re-submissions. Specifically, consider submitting a pre-submission inquiry to the follow-up journal to gauge initial interest in and suitability of a manuscript for the journal. As mentioned previously, it is important to disclose any prior rejections (and potentially provide a copy of the previous manuscript, any reviewers' comments received, and demonstrate the improvements that have been implemented). Note that in certain highly specialized areas there is a possibility of the manuscript coincidentally being sent to the same reviewer who conducted the original evaluation; this reinforces the need to demonstrate that initial feedback from all reviewers has been valued and considered.

Transparency

Declaration of funding

The Authors' Submission Toolkit has been developed through the Medical Publishing Insights and Practices initiative (MPIP), which is funded by Amgen, AstraZeneca, GlaxoSmithKline and Pfizer. Bristol-Myers Squibb was a previous sponsor of the MPIP, but is no longer involved in the initiative.

Declaration of financial/other relationship

All authors have disclosed that they are members of the Authors' Submission Toolkit Working Group. L. Citrome has disclosed that he has received honoraria for speaking engagements; participated on advisory boards; and performed consulting for AstraZeneca, Azur, Eli Lilly, GlaxoSmithKline, Janssen, Merck/SPC, Novartis and Pfizer. He has also disclosed ownership of stock in Abbott, BMS, Eli Lilly, Johnson & Johnson, Merck and Pfizer. J.C. has disclosed that she is an Amgen shareholder. F.S.D. and M.E. have disclosed that they are employees of Leerink Swann Strategic Advisors, a life sciences consultancy that serves a large number of biopharmaceutical, medical technology, tools and diagnostics companies worldwide. J.G. has disclosed that he is an AstraZeneca shareholder. B.M. and C.M. have disclosed that they are GlaxoSmithKline shareholders. L.M. has disclosed that she is a Pfizer shareholder. J.S. has disclosed that he is the founder/owner of Physicians Postgraduate Press, Inc., which provides educational resources and services for physicians. P.D.W. has disclosed that he has served as a consultant/advisor to Emmes Corporation, Hisamitsu, ICON, Inc Research and sanofi-aventis. A.W. has disclosed that he is a sanofi-aventis shareholder. L. Chipperfield, R.E., T.G., J.T.M. and A.M. have all indicated that they have no disclosures to report.

Peer reviewers: Stan Heimberger has disclosed that he is a trustee of the ISMPP Executive Committee. Rob Matheis has disclosed that he is an employee of sanofi-aventis US and chair of the Board of Trustees of the ISMPP credentialing program. Dimitri Mikhailidis, Editor-in-Chief of this journal, has disclosed that he has received sponsorship for meeting attendance from Merck Sharp and Dohme and AstraZeneca; performed consulting for Merck Sharp and Dohme; and served on speakers' bureaus for Merck Sharp and Dohme, Solvay and AstraZeneca.

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Resources

General

- American Medical Writers Association (AMWA). Available at: http://www.amwa.org/ [Last accessed April 26, 2010]
- BioMed Central. Available at: http://www.biomedcentral.com/ [Last accessed April 26, 2010]
- Committee on Publication Ethics (COPE). Available at: http://publicationethics.org/ [Last accessed April 26, 2010]
- European Medicines Agency (EMA) Good Clinical Practice. Available at: http://www.ema.europa.eu/Inspections/GCPgeneral.html [Last accessed April 26, 2010]
- EQUATOR (Enhancing the Quality and Transparency of Health Research) Network. Available at: http://www.equator-network.org/ [Last accessed April 26, 2010]
- European Medical Writers Association (EMWA). Available at: http://www.emwa.org/ [Last accessed April 26, 2010]
- Food and Drug Administration Amendments Act (FDAAA) of 2007. Available at: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm [Last accessed 26 April 2010]
- International Committee of Medical Journal Editors (ICMJE). Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications. Available at: http://www.icmje.org/ [Last accessed April 26, 2010]
- Wager E. Getting Research Published: An A-Z of Publication Strategy (2nd edition). Oxfordshire, UK: Radcliffe, 2010
- World Medical Association (WMA). Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects Declaration of Helsinki (2008). Available at: http://www.wma.net/en/30publications/10policies/b3/index.html [Last accessed April 26, 2010]
- World Health Organization (WHO). International Clinical Trials Registry Platform (ICTRP). Available at: http://www.who.int/ictrp/en/ [Last accessed April 26, 2010]
- World Health Organization (WHO). Regional Publications Eastern Mediterranean Series 30 – A Practical Guide for Health Researchers. Available at: http://whqlibdoc.who.int/emro/2004/9290213639.pdf [Last accessed April 26, 2010]

Before the study and writing begin

- ASSERT (A Standard for the Scientific and Ethical Review of Trials) initiative. Available at: http://www.assert-statement.org/ [Last accessed April 26, 2010]
- CONSORT Statement 2010. Available at: http://www.consort-statement.org/ [Last accessed April 26, 2010]
- Council of Science Editors. White Paper on Promoting Integrity in Scientific Journal Publications, 2009 Update. http://www.councilscienceeditors.org/editorial_policies/whitepaper/entire_whitepaper.pdf [Last accessed April 26, 2010]
- Daskalopoulou SS, Mikhailidis DP. Exorcising Ghosts and Unwelcome Guests. Annals of Internal Medicine 2006;144(2):149.
- Daskalopoulou SS, Mikhailidis DP. The Involvement of Professional Medical Writers in Medical Publications [Editorial]. CMRO 2005;21:307-10.
- Graf C, Battisti WP, Bridges D, *et al*. Good Publication Practice for Communicating Company Sponsored Medical Research: the GPP2 Guidelines. BMJ 2009;339:b4330. Available at: http://www.bmj.com/cgi/reprint/339/nov27_1/b4330 [Last accessed April 26, 2010]
- Jacobs A. The Involvement of Professional Medical Writers in Medical Publications: Results of a Delphi Study. CMRO 2005; 21(2):311-6. Available at: http://www.emwa.org/MembersDocs/GhostDelphi.pdf [Last accessed April 26, 2010]
- Jacobs A, Wager E. European Medical Writers Association (EMWA) guidelines on the role of medical writers in developing peer-reviewed publications. CMRO 2005; 21(2):317-21. Available at http://www.emwa.org/MembersDocs/GuidelinesCMRO.pdf [Last accessed May 18, 2010]
- PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Statement (previously the QUOROM Statement). Available at: http://www.prisma-statement.org/ [Last accessed April 26, 2010]
- Public Library of Science (PLoS). Available at: http://www.plos.org/ [Last accessed April 26, 2010]
- STARD (Standards for the Reporting of Diagnostic Accuracy Studies) Statement. Available at: http://www.stard-statement.org/ [Last accessed April 26, 2010]

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- STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) Statement. Available at: http://www.strobe-statement.org/ [Last accessed April 26, 2010]
- Stroup DF, Berlin JA, Morton SC, *et al*. Meta-analysis of observational studies in epidemiology: a proposal for reporting. Meta-analysis Of Observational Studies in Epidemiology (MOOSE) group. JAMA 2000;283(15): 2008-2012. Available at: http://jama.ama-assn.org/cgi/reprint/283/15/2008 [Last accessed April 26, 2010]
- von Elm E, Egger M. The Scandal of Poor Epidemiological Research. BMJ 2004;329:868-869. Available at: http://www.bmj.com/cgi/content/extract/329/7471/868 [Last accessed April 26, 2010]

Journal selection

- Archives of Drug Information. Available at: http://www.wiley.com/bw/journal.asp?ref=1753-5174 [Last accessed April 26, 2010]
- BMC Research Notes. Available at: http://www.biomedcentral.com/bmcresnotes/ [Last accessed April 26, 2010]
- British Medical Journal (BMJ). Is the BMJ the Right Journal for My Research Article? Available at: http://resources.bmj.com/bmj/authors/authors/checklists-forms/is-bmj-the-right-journal-for-my-research-article [Last accessed April 26, 2010]
- Directory of Open Access Journals. Available at: http://www.doaj.org/ [Last accessed April 26, 2010]
- Journal of Drug Assessment. Available at: www.informahealthcare.com/jda [Last accessed June 3, 2010]
- Journal of Negative Results in Biomedicine. Available at: http://www.jnrbm.com/ [Last accessed April 26, 2010]
- Medical Publishing Insights and Practices initiative. Available at: http://www.mpip-initiative.org/ [Last accessed June 1, 2010]
- PLoS ONE. Available at http://www.plosone.org/ [Last accessed 1 June 2010]
- PubMed (MEDLINE). Available at: http://www.ncbi.nlm.nih.gov/sites/entrez [Last accessed April 26, 2010]
- Trials Journal. Available at: http://www.trialsjournal.com/ [Last accessed April 26, 2010]

Manuscript preparation

- Bryne D. Common Reasons for Rejecting Manuscripts at Medical Journals: A Survey of Editors and Peer Reviewers. Science Editor 2000:23(2), 39-44. Available at: http://www.councilscienceeditors.org/members/securedDocuments/v23n2p039-044.pdf [Last accessed April 26, 2010]
- Baylé F. How to Get Published: All You Need to Know to Publish in Psychiatry (2nd Edition). Available at: http://www.servier.com/App_Download/Neurosciences/How/How_to_get_published.pdf [Last accessed April 26, 2010]

Review, revision and re-submission

- ▶Woolley K, Barron J. Handling Manuscript Rejection. CHEST 2009:135(2),573-577. Available at: http://chestjournal.chestpubs.org/content/135/2/573.full.pdf+html [Last accessed April 26, 2010]

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Appendix

Cover Letter Template

Author's Name
Mailing Address (Suite #)
City, State, Zip Code
Phone Number
Fax Number
Email Address

[Date]
Journal Editor-in-Chief (or the editor who has been the journal contact during previous correspondence) [including title]
Journal Name
Mailing Address (Suite #)
City, State, Zip Code

Dear Dr. / Mr. / Ms. XXX:

First paragraph:

- Introduce the manuscript, including the title, type of article (e.g., original research article, review article, case report, etc.), journal category (depending on the type of journal) – mention that you intend to submit to [insert journal name].
- If you are the principal author and are submitting on behalf of yourself and colleagues, this should be declared (e.g., "On behalf of my colleagues, I would like to submit to [insert journal name] this manuscript of original clinical research entitled "[insert article name]").

Second paragraph:

- This paragraph is usually a 3-5 sentence synopsis of the Introduction, and should address key points that are of likely interest to the editor and the reviewers.
- Describe the purpose, content, findings, and value of the manuscript, which will often relate to the current state of the field, for example:
  - This disease/condition has no current standard of care and this manuscript reports the first randomized clinical findings for this disease, etc.
  - New guidelines have recently been published describing updated standard therapies for disease/condition "X"
  - Disease/condition "X" is lacking in data and this manuscript provides clinical data.
- Discuss current hot topics/ controversies in the field and how this manuscript addresses these topics
- Include at least 1 sentence summarizing the key findings of the research study.
- If original research has been conducted, denote whether all national and international regulatory guidelines for clinical trial research have been met (Declaration of Helsinki, EMEA, FDA, etc.).
- Often, this paragraph ends with addressing the value of the information in this manuscript to the specific readership of the journal.

Third paragraph:

- Indicate that the manuscript has been read and approved by all authors. Stipulate that all persons listed as authors have contributed to preparing the manuscript and/or that International Committee of Medical Journal Editors (ICMJE) criteria for authorship have been met, and that no person or persons other than the authors listed have contributed significantly to its preparation. The intent of these statements is to forestall the participation of outside parties ("ghostwriters") who may stand to benefit by attempting to influence the content of a study or its results.
- Specify whether the manuscript or any significant part of it is under consideration for publication, has been published or was submitted for publication elsewhere, or has appeared elsewhere in a manner that could be construed as a prior or duplicate publication of the same, or very similar, work. For example, including a statement such as the following can

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be useful: "The contents of this manuscript are my/our original work and have not been published, in whole or in part, prior to or simultaneous with my/our submission of the manuscript to [journal name]."

- Also describe any NIH/Wellcome Trust funding and any issues regarding copyright transfer/open access requirements.

Fourth paragraph:

- Detail any funding of the work reported, as well as financial or other support in the preparation of the manuscript (including editorial/writing assistance). For example (from GPP2), "The study was funded by YZ Pharmaceuticals, the manufacturer of Drug F. Medical writing services from WX Medical Writing were funded by YZ Pharmaceuticals."
- When appropriate, the cover letter should contain a brief summary of any potential conflict of interest (both financial or otherwise) arising from relationships with commercial or corporate interest in connection with the work submitted and attestation that these relationships have been addressed in the appropriate section of the manuscript. For example, "This study was funded by a grant from [company]. Authors AA, BB, and CC are or were employees of [company] when this study was conducted and own stock in [company #2], of which [company] is a subsidiary. Authors DD, EE, and FF received research funding from [company]. Author GG has no conflict of interest to report. We attest that we have herein disclosed any and all financial or other relationships that could be construed as a conflict of interest and that all sources of financial support for this study have been disclosed and are indicated in the acknowledgments."

Fifth paragraph:

- Describe the contents of the submission package, usually per journal instructions (e.g., "per journal's instructions, 3 hard copies of the manuscript and figures, study protocol, author checklist, journal submission form, are included").
- Depending on the journal, if color figures are included, some journals may request a statement indicating that the authors are willing to assume the cost of color separations and reproduction is requested. Denote if there has been any prior publication of figures or tables in the manuscript, in which case documentation of written permission from the publisher should be included.
- Journals may accept suggestions for included and excluded reviewers, which can either be listed here or indicate that this list is also provided on a separate sheet. Provide the name, title, institution, address, contact telephone number, and email of all mentioned reviewers.

Sixth paragraph:

- Graciously thank the editor for his/her time in reviewing this submission. Remind him/her of your interest in the journal's review of your manuscript. Provide the editor with contact information if any questions should arise regarding this submission or during the review process.

Salutation

Signature

Author's name [title]

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