



# Tips for Authors of Original Research

## *Clinical Therapeutics, Current Therapeutic Research, The American Journal of Geriatric Pharmacotherapy, and Gender Medicine*

The editors of *Clinical Therapeutics, Current Therapeutic Research, The American Journal of Geriatric Pharmacotherapy, and Gender Medicine* expect all manuscripts to conform to the “Uniform Requirements for Manuscripts Submitted to Biomedical Journals,” also known as Vancouver style (*N Engl J Med.* 1997;336:309–315). Authors are encouraged to refer to the latest edition of the *AMA Manual of Style: A Guide for Authors and Editors*. The journals’ specific styles can be found in the “Information for Authors” printed in the back of each issue.

**The following are selected tips for authors of original research from the editors-in-chief, section editors, editors, and peer reviewers of the journals.**

### **GENERAL REMARKS**

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- Define in a quantitative manner or eliminate subjective words and phrases such as: high, low, mild, moderate, severe, good, poor, few, many, most, increased, greater, less, vast majority, usually, young, elderly, quick, rapid, short, long, standard, generally, commonly, and randomly selected.
- Reference or provide data for all statements of fact (even those that appear obvious). Observations without a reference or data should be identified as personal opinion to prevent others from interpreting these statements as fact.
- *P* values, confidence intervals, or other statistics should be included whenever statistical significance is claimed. (Approaching significance or a trend toward significance is not acceptable).
- The term “safety” may be used in the title, section heading, or study objective, but not in the results or conclusion, because studies in select populations cannot prove safety. Only long-term use can determine safety. When presenting results, please use “tolerability,” “safety profile,” or “well tolerated in the population studied.”

### **ABSTRACT**

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- Provide a structured abstract of ~300 words or less with background, objective, methods, results, and conclusion sections, and 4 to 6 key words.

- Study design must be included (eg, randomized, placebo-controlled, double-blind, uncontrolled, open-label) in the Methods section. In addition, briefly indicate the population studied (including age range for eligibility and severity of disease), setting, and methods used.
- Results should indicate the number of patients included in the analyses and their sex and mean age.
- Efficacy and adverse effects should be summarized in detail and balanced without bias. Please provide data and *P* values.
- Everything mentioned in the abstract should be contained in the body of the paper. All data and *P* values should match between the abstract, body text, tables, and figures.

## **INTRODUCTION**

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- Include background information and the objectives of the study.
- Details of background studies should include study design, sample size, dose and duration of treatment, and relevant data and *P* values.

## **MATERIALS AND METHODS**

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- Indicate number and location of study site(s) and protocol approval (or waiver) by an institutional review board or ethics committee.
- Inclusion/exclusion criteria: Include sex, age range for eligibility (eg, 18–65 years), and disease severity (with blood levels, if applicable). Indicate written or oral informed consent.
- Postmarketing studies should conform to the requirements for publication of the journal.
- Study drug administration: Indicate method of randomization, and route and duration of administration. Describe blinding/unblinding procedures and parties involved. Indicate whether and how compliance was assessed.
- For pharmacokinetic/pharmacodynamic studies, indicate whether study drug was given with water/food, standardization of meals, duration of fast, and range for bioavailability.
- Laboratory analysis: Include collection method and volume, handling, centrifugation (*g* or rpm, duration, and temperature), and storage. Detail all concentrations measured and indicate normal values, citing references as necessary. Provide the lab's coefficients of variation.
- Tolerability: Indicate how adverse events (AEs) were determined (eg, lab analysis, patient questioning, spontaneous reporting), and whether AE severity and treatment association was determined. Describe how vital signs were measured (eg, resting blood pressure, heart rate, respiratory rate), and at what intervals and by whom.
- Statistical analysis: Include power analysis and provide a reference for statistical methods used (even if only a book). Define intent-to-treat and per-protocol populations. Indicate the name, version number, and manufacturer of the software used.

## RESULTS

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- Provide all pertinent patient demographic characteristics and numbers of patients in each group. Use both numbers (n/N) and percentages of patients for clarity.
- Provide detailed data on efficacy and all AEs. These results should be presented in a balanced, objective fashion. Provide compliance results.
- Avoid including comments that belong in the Discussion section, such as possible reasons for results.
- Tables should be included after the reference list; figures should be provided as a separate .pdf or .eps file. All figures are redrawn by the journal to achieve uniformity.

## DISCUSSION

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- Compare your results to those of other published studies, and include the study design, sample size, dose and duration of treatment, and relevant data and *P* values for each study cited.
- Extrapolations should be reasonable and conclusions should be justified by the data and/or material presented.
- Include limitations of the study and, if appropriate, discuss why improvements were not incorporated. If applicable, acknowledge that the study design (eg, inclusion/exclusion criteria) may limit the generalizability of the conclusions.
- Include suggestions for future research.

## CONCLUSIONS

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- Reflect the objectives and include only conclusions from the present study.

## ACKNOWLEDGMENTS

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- Indicate the role of the sponsor in the design, conduct, analysis, and publication of your research, as well as any other financial support or editorial assistance (eg, writing, editing, fact checking, statistical analysis) received.
- Any current or previous support that the authors received from industry or institutions (including grants, honoraria, consultancies, speakers' bureau or advisory board positions, and significant stockholdings) for the present or any other research/work must be acknowledged.

## REFERENCES

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- Should be comprehensive and current (<5 years old).
- Follow AMA style. "Data on file" or unpublished references are unacceptable. If the results of an internal company report must be cited, include the manufacturer's unique internal study number, investigators, and year of the study. Referencing a statement as "personal communication" is acceptable, but the date of the communication should be included.