

Clinical Drug Investigation

Additional Information for Authors

PLEASE READ THIS INFORMATION IN CONJUNCTION WITH THE JOURNAL INSTRUCTIONS FOR

AUTHORS (found at <https://www.springer.com/journal/40261>)

Title Page

Title/subtitle – if using a subtitle, please separate this from the main title with a colon. Titles and subtitles of manuscripts reporting the results of original research should describe the intervention/methodology/setting, rather than describe the study results.

Running heading – a running heading (short version of the title), of up to 100 characters, should be provided.

Abstract – for narrative reviews, abstracts should be unstructured (i.e. no headings). For original research articles, abstracts should be structured (e.g. following the guidance of the CONSORT statement for manuscripts reporting the results of randomized clinical trials, the PRISMA Statement for systematic reviews, with or without a meta-analysis, and the STROBE statement for observational studies).

Plain language summaries (PLSs) - PLSs are not mandatory. If provided, they should be up to 250 words in length and placed after the abstract of the article under the heading 'Plain Language Summary'.

Keywords – a list of keywords is not required.

Key points – two to three short bullet points should be provided summarizing the key findings and implications of the paper. These should be presented in non-technical language and not repeat verbatim text found in the abstract. Key points should not describe the objectives or methods of the paper. They should be placed beneath the abstract under the heading of 'Key Points'.

Declarations – a section entitled 'Declarations' should be provided that contains the following subsections (if any of these sections is not applicable, state "Not applicable" under the subsection heading):

- I. Funding – a statement is required for all manuscripts that outlines whether or not any sources of financial assistance were used to conduct the study/analysis described in the manuscript and/or used to assist with the preparation of the manuscript. If no funding was received, this should be stated. In addition, for papers published open access, authors should include a statement that outlines the sponsor(s) of the open access fee.
- II. Conflicts of Interest – a statement is required for all manuscripts that clearly outlines all potential author conflicts of interest. If there are no conflicts of interest for specific or individual authors, this should be stated.

- III. Availability of data and material – a statement is required for all manuscripts that provides information on where data supporting the results reported in the article can be found, including, where applicable, hyperlinks to publicly archived datasets analysed or generated during the study/analysis. Data availability statements can also indicate whether data are available on request from the authors and where no data are available, if appropriate.
- IV. Ethics approval – for manuscripts that report the results of a study that involved human participants, their data or biological material, a statement is required to confirm that the study was approved (or granted exemption) by the appropriate institutional and/or national research ethics committee (including the name of the ethics committee) and certify that the study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.
- V. Consent to participate – for manuscripts that report the results of a clinical study, a statement should be included that outlines the type of consent obtained to participate in the study.
- VI. Consent for publication - if an identifiable clinical photo of a patient is published, or if an article contains patient data that could be identifiable, a statement should be included to confirm that consent of patients was obtained to publish their data.
- VII. Code availability – for manuscripts that use a software application or custom code in the study.
- VIII. Author contributions – a statement is required for all manuscripts that provides a precise and verifiable account of the contribution each author made to the manuscript/work described in the manuscript, bearing in mind the International Committee for Medical Journal Editors (ICMJE) authorship criteria. A statement should also be added to clarify that all authors read and approved the final version.

Acknowledgements – this section should be used to acknowledge the assistance of individuals who do not meet the criteria for authorship but who have made a substantial contribution to the manuscript/study. Acknowledgment of any medical writing support should include the nature of the support, the name of the medical writer and their employer, and the funding sources for the support. You must obtain written permission from any individual you acknowledge.

Text

Please use double-spaced text, page numbering (starting with the title page) and line numbering.

Headings – the headings of the sections/subsections should be numbered using the decimal system (e.g. 1; 2, 2.1, 2.2, 2.2.1, 2.2.2; 3; 4; etc.), starting with the Introduction and finishing with the Conclusions.

Language - the journal does not have a preference for British vs US English, but whichever style is used, it must be consistently applied throughout the manuscript.

Tables and figures

Abbreviations - all abbreviations used in a table or figure should be defined in an abbreviations list placed beneath the table body, or in the figure legend. Abbreviations in the abbreviations list should be presented in alphabetical order.

References

Authors should ensure that material cited in their article was published in peer-reviewed scholarly publications; citation of non-peer-reviewed material (such as conference posters/abstracts, unpublished data on file, and preprints) should be clearly identified and kept to a minimum. If information from preprints is presented in a manuscript, it can be included in the reference list, but it should be made clear in the text where the data are mentioned that they originate from a preprint, e.g. "A recent study on drug x (currently only available as a non-peer reviewed preprint [1]) has suggested ...". The reference citation in the reference list should include the name and location of the preprint server and the DOI of the preprint.

Authors should assess carefully whether an article published by a "predatory" journal should be used as a reference to support statements made in their article. "Predatory" journals are usually open access publications that publish articles with little or no peer review, and do not apply the editorial standards and publishing ethics of scholarly journals. "Predatory" journals often have very similar names to those of well-established journals. Please note that several abstracting and indexing services, including Clarivate Analytics, are taking ethical publication seriously by examining the content, practices and websites of these "predatory" journals. If you would like to learn more about learned (open access) publishers and publications, please visit the websites of the OASPA (Open Access Scholarly Publishers Association), DOAJ (Directory of Open Access Journals) or COPE (Committee on Publication Ethics).

Supplementary information

Material that is not considered essential to a manuscript but that provides useful additional content can be hosted as supplementary information (SI), which will appear online only. SI files (preferably a single file in pdf format) should be uploaded into Editorial Manager as 'Other' files.

Ethical responsibilities of authors

General - the journal endorses the 'Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly work in Medical Journals' issued by the International Committee for Medical Journal Editors (ICMJE) and is a member of the Committee on Publication Ethics (COPE).

Duplicate publication – although the journal will not, in general, publish manuscripts that have been published previously, the journal will consider republication of a paper previously published in a language other than English, or simultaneous publication of a paper in multiple journals with different audiences, if the specific circumstances warrant this action. This will be done with full and prominent disclosure of the original source and with any necessary permissions. The journal does not consider posting of study protocols and results in clinical trial registries, posting of preprints, presentation of study results as an abstract or poster, or publication of study protocols to be prior publication. Press releases of studies presented at scientific meetings are also not considered prior publication and will not compromise an author's ability to write up a full study provided the release does not disclose results beyond those presented in the meeting abstract or poster.

Research reporting

Clinical trial registration - the journal requires, as a condition of consideration of original clinical research for publication, registration of clinical trials in a public trials registry before or at the time of recruitment of the first patient. This applies to trials which began enrolment on or after 1 July 2008: for older trials, retrospective registration will be acceptable, but only if completed before submission of the manuscript to the journal. Authors should list the registration number of the trial at the end of the abstract and in the methods section of the main text. Purely observational studies do not require registration. The journal reserves the right to reject manuscripts that do not comply with these requirements.

Health research reporting guidelines - the journal requests that the reporting of studies follows current best practice, and authors are advised to adhere to the appropriate health research reporting guideline for the type of research being submitted. The journal recommends that authors refer to the EQUATOR Network for up-to-date information on all health research reporting guidelines. In all cases, authors must provide a completed study flowchart and, to aid editorial assessment of the manuscript, are encouraged to provide a completed guidelines checklist.

Systematic reviews, with or without a meta-analysis, should address a novel and clinically relevant research question. The journal encourages prospective registration of systematic review protocols on a registry such as PROSPERO. If the review has been registered, the registration number should appear in the methods section of the main text, and at the end of the abstract.

Surveys - ethics review/approval is generally required for all studies that involve human participation, including survey research. Investigators/authors are advised to ensure that any surveys used to generate data submitted to the journal were assessed by an Institutional Review Board prior to the initiation of the survey. While some survey research may be eligible for ethics approval exemption, the determination of exempt status rests with an Institutional Review Board, not with the investigators.

For clinical pharmacokinetic studies, authors should complete and submit the Clinical Pharmacokinetic Study checklist along with the manuscript to make sure that all the required information is included in the manuscript.

Use of personal communications and unpublished data - authors must include a signed statement of permission from each individual identified as a source of information in a personal communication or as a source for unpublished data (this includes papers that have been submitted, but not yet accepted for publication), and specify the date of communication and whether the communication was written or oral.

Preprint sharing

The Adis journals follow the Springer Nature preprint sharing policy, which encourages posting of preprints (an author's version of a manuscript prior to formal peer review at a journal) of primary research manuscripts on preprint servers or authors'/institutional websites. Posting of preprints is not considered prior publication and will not jeopardize consideration in the Adis journals. If a preprint of your manuscript is available, this should be declared in the Acknowledgements section, along with the location of the preprint server and preprint DOI. Once the preprint is published, it is the author's responsibility to ensure that the preprint record is updated with a publication reference, including the DOI and a URL link to the published version of the article on the journal website. Full details of the Springer Nature preprint sharing policy are available at: <https://www.springer.com/gp/editorial-policies/preprint-sharing>.