

Clinical Trials

Impact Factor: 2.2

5-Year Impact Factor: 2.3

Submission guidelines



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Please read the guidelines in full before submitting your manuscript. Manuscripts not conforming to these guidelines may be returned.

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This Journal is a member of the [Committee on Publication Ethics](#)

This Journal recommends that authors follow the [Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals](#) formulated by the International Committee of Medical Journal Editors (ICMJE).

Please read the guidelines below then visit the Journal's submission site <http://mc.manuscriptcentral.com/clinicaltrials> to upload your manuscript. Please note that manuscripts not conforming to these guidelines may be returned.

Only manuscripts of sufficient quality that meet the aims and scope of *Clinical Trials* will be reviewed.

There are no fees payable to submit or publish in this Journal. Open Access options are available - see section 3.3 below.

As part of the submission process you will be required to warrant that you are submitting your original work, that you have the rights in the work, and that you have obtained and can supply all necessary permissions for the reproduction of any copyright works not owned by you, that you are submitting the work for first publication in the Journal and that it is not being considered for publication elsewhere and has not already been published elsewhere.

For more information, please see our guidelines on prior publication.

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1. What do we publish?

1.1 Aims & Scope

Before submitting your manuscript to *Clinical Trials*, please ensure you have read the [Aims & Scope](#).

Clinical Trials is an international peer reviewed scholarly journal that addresses topics of interest to individuals involved in the design and conduct of clinical trials. The primary aim is the dissemination of generalizable knowledge about the design, conduct, analysis, synthesis, history, ethics, regulation and clinical or policy impact of all types of clinical trials. Topics that fall within the aims and scope of Clinical Trials include data management, trial logistics, design and conduct of trials, statistical methods, impact of trials on practice and policy, ethics, law and regulation, synthesis and evidence evaluation, history, education and training, patient-related issues, decision analysis, and commentaries on current or controversial issues in clinical trials. The journal does not publish articles that essentially reproduce the protocol for an individual clinical trial. Articles that simply report the results of a completed clinical trial are also not considered, unless the trial is evaluating or comparing methodologic innovations.

1.2 Article Types

The editor of *Clinical Trials: Journal of the Society for Clinical Trials* will consider manuscripts containing original material providing neither the article nor any part of its essential substance, tables, or figures has been or will be published or is currently submitted elsewhere other than *Clinical Trials*. This restriction does not apply to abstracts published in connection with scientific meetings.

In addition to original research papers (maximum 3,500 words excepting abstract, references, tables and figures; maximum 6 tables or figures), *Clinical Trials* also welcomes Short Communications (manuscripts of 2000 or fewer words, excepting references, tables and figures; maximum 3 tables/figures), Research Letters (1000 or fewer words, 12 or fewer references, 1 table or figure) and letters to the Editor (500 or fewer words) for possible publication. Submissions exceeding the word limits will be “un-submitted” and returned without review to the corresponding author. Note that it is possible to publish additional material as supplementary text, tables and/or figure, but such material may not be reviewed carefully and its content is the responsibility of the author.

1.3 Writing your paper

The Sage Author Gateway has some general advice and on [how to get published](#), plus links to further resources. [Sage Author Services](#) also offers authors a variety of ways to

improve and enhance their article including English language editing, plagiarism detection, and video abstract and infographic preparation.

1.3.1 Make your article discoverable

When writing up your paper, think about how you can make it discoverable. The title, keywords and abstract are key to ensuring readers find your article through search engines such as Google. For information and guidance on how best to title your article, write your abstract and select your keywords, have a look at this page on the Gateway: [How to Help Readers Find Your Article Online](#).

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2. Editorial policies

2.1 Peer review policy

The journal's policy is to obtain at least two independent reviews of each article under serious consideration for publication. It operates a reviewing policy in which the reviewer's name is always concealed from the submitting author. Referees are encouraged to provide substantive, constructive reviews that provide suggestions for improving the work and distinguish between mandatory and non-mandatory recommendations.

All manuscripts accepted for publication are subject to editing for presentation, style and grammar. Any major redrafting is agreed with the author but the Editor's decision on the text is final.

2.2 Authorship

Papers should have no more than 20 authors and only be submitted for consideration once consent is given by all contributing authors. Those submitting papers should carefully check that all those whose work contributed to the paper are acknowledged as contributing authors.

The list of authors should include all those who can legitimately claim authorship. This is all those who:

- (i) Made a substantial contribution to the concept or design of the work; or acquisition, analysis or interpretation of data,
- (ii) Drafted the article or revised it critically for important intellectual content,
- (iii) Approved the version to be published,
- (iv) Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Authors should meet the conditions of all of the points above. When a large, multicentre group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship.

Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship, although all contributors who do not meet the criteria for authorship should be listed in the Acknowledgments section. Please refer to the International Committee of Medical Journal Editors (ICMJE) authorship guidelines for more information on authorship.

Please note that AI chatbots, for example ChatGPT, should not be listed as authors. For more [information see the policy on Use of ChatGPT and generative AI tools](#).

2.3 Acknowledgements

All contributors who do not meet the criteria for authorship should be listed in an Acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, or a department chair who provided only general support.

2.3.1 Third party submissions

Where an individual who is not listed as an author submits a manuscript on behalf of the author(s), a statement must be included in the Acknowledgements section of the manuscript and in the accompanying cover letter. The statements must:

- Disclose this type of editorial assistance – including the individual’s name, company and level of input
- Identify any entities that paid for this assistance
- Confirm that the listed authors have authorized the submission of their manuscript via third party and approved any statements or declarations, e.g. conflicting interests, funding, etc.

Where appropriate, Sage reserves the right to deny consideration to manuscripts submitted by a third party rather than by the authors themselves.

2.3.2 Writing assistance

Individuals who provided writing assistance, e.g. from a specialist communications company, do not qualify as authors and so should be included in the Acknowledgements section. Authors must disclose any writing assistance – including the individual’s name, company and level of input – and identify the entity that paid for this assistance.

It is not necessary to disclose use of language polishing services.

Any acknowledgements should appear first at the end of your article prior to your Declaration of Conflicting Interests (if applicable), any notes and your References.

2.4 Funding

Clinical Trials requires all authors to acknowledge their funding in a consistent fashion under a separate heading. Please visit the [Funding Acknowledgements](#) page on the Sage Journal Author Gateway to confirm the format of the acknowledgment text in the event of funding, or state that: This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

2.5 Declaration of conflicting interests

It is the policy of *Clinical Trials* to require a declaration of conflicting interests from all authors enabling a statement to be carried within the paginated pages of all published articles.

Please ensure that a 'Declaration of Conflicting Interests' statement is included at the end of your manuscript, after any acknowledgements and prior to the references. If no conflict exists, please state that 'The Author(s) declare(s) that there is no conflict of interest'. For guidance on conflict of interest statements, please see the ICMJE recommendations [here](#).

2.6 Research ethics and patient consent

Medical research involving human subjects must be conducted according to the [World Medical Association Declaration of Helsinki](#)

Submitted manuscripts should conform to the [ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals](#), and all papers reporting animal and/or human studies must state in the methods section that the relevant Ethics Committee or Institutional Review Board provided (or waived) approval. Please ensure that you have provided the full name and institution of the review committee, in addition to the approval number.

For research articles, authors are also required to state in the methods section whether participants provided informed consent and whether the consent was written or verbal.

Information on informed consent to report individual cases or case series should be included in the manuscript text. A statement is required regarding whether written informed consent for patient information and images to be published was provided by the patient(s) or a legally authorized representative. Please do not submit the patient's

actual written informed consent with your article, as this in itself breaches the patient's confidentiality. The Journal requests that you confirm to us, in writing, that you have obtained written informed consent but the written consent itself should be held by the authors/investigators themselves, for example in a patient's hospital record. The confirmatory letter may be uploaded with your submission as a separate file.

Please also refer to the [ICMJE Recommendations for the Protection of Research Participants](#).

All research involving animals submitted for publication must be approved by an ethics committee with oversight of the facility in which the studies were conducted. The Journal has adopted the [ARRIVE](#) guidelines.

2.7 Clinical trials

Clinical Trials conforms to the [ICMJE requirement](#) that clinical trials are registered in a WHO-approved public trials registry at or before the time of first patient enrolment as a condition of consideration for publication. The trial registry name and URL, and registration number must be included at the end of the abstract. Since *Clinical Trials* in general only considers for publication clinical trials that evaluate methodological innovations we expect these trials to be registered, even though the primary endpoint may or may not be a "health outcome".

2.8 Reporting guidelines

The relevant [EQUATOR Network](#) reporting guidelines should be followed depending on the type of study. For example, all randomized controlled trials submitted for publication should include a completed [CONSORT flow chart](#) as a cited figure and the completed [CONSORT checklist](#) should be uploaded with your submission as a supplementary file. Systematic reviews and meta-analyses should include the completed [PRISMA](#) flow chart as a cited figure and the completed PRISMA checklist should be uploaded with your submission as a supplementary file. The [EQUATOR wizard](#) can help you identify the appropriate guideline.

Other resources can be found at [NLM's Research Reporting Guidelines and Initiatives](#)

Please be aware that the journal does not publish articles that essentially reproduce the protocol for an individual clinical trial and articles that simply report the results of a completed clinical trial are also not considered.

2.9 Research Data

The journal is committed to facilitating openness, transparency and reproducibility of research, and has the following research data sharing policy. For more information,

including FAQs please visit the [Sage Research Data policy pages](#).

Subject to appropriate ethical and legal considerations, authors are encouraged to:

- share your research data in a relevant public data repository
- include a data availability statement linking to your data. If it is not possible to share your data, we encourage you to consider using the statement to explain why it cannot be shared.
- cite this data in your research

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3. Publishing Policies

3.1 Publication ethics

Sage is committed to upholding the integrity of the academic record. We encourage authors to refer to the Committee on Publication Ethics' [International Standards for Authors](#) and view the Publication Ethics page on the [Sage Author Gateway](#).

3.1.1 Plagiarism

Clinical Trials and Sage take issues of copyright infringement, plagiarism or other breaches of best practice in publication very seriously. We seek to protect the rights of our authors and we always investigate claims of plagiarism or misuse of published articles. Equally, we seek to protect the reputation of the journal against malpractice. Submitted articles may be checked with duplication-checking software. Where an article, for example, is found to have plagiarised other work or included third-party copyright material without permission or with insufficient acknowledgement, or where the authorship of the article is contested, we reserve the right to take action including, but not limited to: publishing an erratum or corrigendum (correction); retracting the article; taking up the matter with the head of department or dean of the author's institution and/or relevant academic bodies or societies; or taking appropriate legal action.

3.1.2 Prior publication

If material has been previously published it is not generally acceptable for publication in a Sage journal. However, there are certain circumstances where previously published material can be considered for publication. Please refer to the guidance on the [Sage Author Gateway](#) or if in doubt, contact the Editor at the address given below.

3.2 Contributor's publishing agreement



Before publication, Sage requires the author as the rights holder to sign a Journal Contributor's Publishing Agreement. Sage's Journal Contributor's Publishing Agreement is an exclusive licence agreement which means that the author retains copyright in the work but grants Sage the sole and exclusive right and licence to publish for the full legal term of copyright. Exceptions may exist where an assignment of copyright is required or preferred by a proprietor other than Sage. In this case copyright in the work will be assigned from the author to the society. For more information please visit the [Sage Author Gateway](#).

3.3 Open access and author archiving

Clinical Trials offers optional open access publishing via the Sage Choice programme and Open Access agreements, where authors can publish open access either discounted or free of charge depending on the agreement with Sage. Find out if your institution is participating by [visiting Open Access Agreements at Sage](#). For more information on Open Access publishing options at Sage please [visit Sage Open Access](#). For information on funding body compliance, and depositing your article in repositories, please [visit Sage's Author Archiving and Re-Use Guidelines](#) and [Publishing Policies](#).

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4. Preparing your manuscript for submission

4.1 Formatting

The preferred format for your manuscript is Word. LaTeX files are also accepted. Word and (La)Tex templates are available on the [Manuscript Submission Guidelines page](#) of our Author Gateway.

Summary of manuscript structure

When preparing your paper:

- Double-space manuscript.
- Use the minimum formatting.
- Roman, bold and italic type can be used, but use only one typeface and size.
- Capitals should be used only where they are to appear in the finished text.
- The text should be ranged left and unjustified, with hyphenation cancelled.
- Indents, underlining and tabs should be avoided unless absolutely necessary.
- Headings and paragraphs should be separated by two carriage returns.
- There should be only one space between words and only one space after any punctuation.
- Acronyms are strongly discouraged except for those that will be recognizable to essentially all readers without explanation.

Title page

The title page should include the following information:

- the title of the paper;
- a running head (short title) of 40 or fewer letter spaces;
- the total number of words;
- the name of each author, including first name;
- long authorship lists are strongly discouraged; contributions of each author should satisfy ICMJE guidelines:- see Br Med J (Clin Res Ed). 1985 September 14; 291(6497): 722;
- the institutional affiliation (including city, state and country) of each author;
- the name, address, e-mail address and telephone number of the corresponding author;
- any grant support that requires acknowledgment;
- and, for manuscripts describing or using data from a controlled trial, the trial registration number and trial register.

Abstract and key words:

On a separate page, provide an abstract of 425 or fewer words.

Utilize the following headings:

- Background/Aims
- Methods
- Results
- Conclusions

Following the abstract, provide three to ten keywords or short phrases.

Tables:

All tables must be cited in the text. Do not paste tables into the text but provide them on separate sheets at the end of your paper. Number tables using Arabic numerals sequentially in order of appearance. Put explanatory notes and other details relating to the body of a table in footnotes identified by superscript, lowercase letters.

Figures:

All illustrations and figures must be cited in the text. Number illustrations and figures using Arabic numerals sequentially in order of appearance. Computer-generated figures produced by a 300 dpi laser printer are acceptable. Symbols, lettering and numbering must be clear and large enough to remain legible after the figure has been reduced. Include titles, figure or illustration numbers, and legends on a separate sheet. The titles, figure or illustration number, and legends should not appear on the figures and illustrations. The cost of colour reproduction must be met by the author.

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Prepare acknowledgments on a separate page. Obtain permission from all individuals

named.

4.2 Artwork, figures and other graphics

For guidance on the preparation of illustrations, pictures and graphs in electronic format, please visit Sage's [Manuscript Submission Guidelines](#).

Figures supplied in colour will appear in colour online regardless of whether or not these illustrations are reproduced in colour in the printed version. For specifically requested colour reproduction in print, you will receive information regarding the costs from Sage after receipt of your accepted article.

4.3 Supplemental material

This journal is able to host additional materials online (e.g. datasets, podcasts, videos, images etc) alongside the full-text of the article. For more information please refer to our [guidelines on submitting supplementary files](#).

4.4 Reference style

Clinical Trials adheres to the Sage Vancouver reference style. View the [Sage Vancouver](#) guidelines to ensure your manuscript conforms to this reference style.

If you use [EndNote](#) to manage references, you can download the [Sage Vancouver EndNote output file](#).

4.5 English language editing services

Authors seeking assistance with English language editing, translation, or figure and manuscript formatting to fit the journal's specifications should consider using Sage Language Services. Visit [Sage Language Services](#) on our Journal Author Gateway for further information.

4.6 Accessibility Guidelines

Authors should familiarize themselves with [Sage's Accessibility Guidelines](#) to ensure their manuscripts meet recognized accessibility standards.

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5. Submitting your manuscript

Clinical Trials is hosted on Sage Track, a web based online submission and peer review system powered by ScholarOne™ Manuscripts. Visit <https://mc.manuscriptcentral.com/clinicaltrials> to login and submit your article online.

IMPORTANT: Please check whether you already have an account in the system before trying to create a new one. If you have reviewed or authored for the journal in the past year it is likely that you will have had an account created. For further guidance on submitting your manuscript online please visit ScholarOne Online Help.

5.1 ORCID

As part of our commitment to ensuring an ethical, transparent and fair peer review process Sage is a supporting member of [ORCID](#), the Open Researcher and Contributor ID.

ORCID provides a persistent digital identifier that distinguishes researchers from every other researcher and, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between researchers and their professional activities ensuring that their work is recognised.

The collection of ORCID iDs from corresponding authors is now part of the submission process of this journal. If you already have an ORCID iD you will be asked to associate that to your submission during the online submission process. If you don't already have one you can create one [here](#).

5.2 Information required for completing your submission

You will be asked to provide contact details and academic affiliations for all co-authors via the submission system and identify who is to be the corresponding author. These details must match what appears on your manuscript. The affiliation listed in the manuscript should be the institution where the research was conducted. If an author has moved to a new institution since completing the research, the new affiliation can be included in a manuscript note at the end of the paper. At this stage please ensure you have included all the required statements and declarations and uploaded any additional supplementary files (including reporting guidelines where relevant).

5.3 Permissions

Please also ensure that you have obtained any necessary permission from copyright holders for reproducing any illustrations, tables, figures or lengthy quotations previously published elsewhere. For further information including guidance on fair dealing for criticism and review, please see the Copyright and Permissions page on the [Sage Author Gateway](#).

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n acceptance and publication

6.1 Sage Production

Your Sage Production Editor will keep you informed as to your article's progress throughout the production process. Proofs will be made available to the corresponding author via our editing portal Sage Edit or by email, and corrections should be made directly or notified to us promptly. Authors are reminded to check their proofs carefully to confirm that all author information, including names, affiliations, sequence and contact details are correct, and that Funding and Conflict of Interest statements, if any, are accurate.

6.2 Online First publication

Online First allows final articles (completed and approved articles awaiting assignment to a future issue) to be published online prior to their inclusion in a journal issue, which significantly reduces the lead time between submission and publication. Visit the [Sage Journals help page](#) for more details, including how to cite Online First articles

6.3 Access to your published article

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6.4 Promoting your article

Publication is not the end of the process! You can help disseminate your paper and ensure it is as widely read and cited as possible. The Sage Author Gateway has numerous resources to help you promote your work. Visit the [Promote Your Article](#) page on the Gateway for tips and advice.

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7. Further information

Any correspondence, queries or additional requests for information on the manuscript submission process should be sent to the Clinical Trials editorial office as follows:

Katherine Wong, Assistant Editor
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Journal of the Society for *Clinical Trials*
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