

FUTURESCIENCE



Author Guidelines *Clinical Investigation*

This document outlines how to prepare articles for submission. We recommend you read these guidelines in full before submitting your article or making an article proposal. Authors are also advised to read the separate **journal policy** document here: <http://www.future-science.com/page/authors.jsp>

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Aims and scope: *Clinical Investigation*

Clinical Investigation is dedicated to systematic coverage of the methodology, progress and outcomes of clinical trials. As a peer-reviewed, monthly publication *Clinical Investigation* provides a forum for the rapid publication of original research and critically reviews the latest developments in medical research, from Phase 1 trials through to post-marketing studies and pharmacoeconomic research.

The fully-loaded costs involved in bringing a new medicine to market can be as high as \$1.3 billion dollars, and much of this cost is incurred during clinical evaluation. Although dozens of new therapeutic entities enter clinical use each year, only one of every 10,000 potential medicines survives the development and approval process. The process of clinical development is therefore highly expensive, involved and complex, with huge demands placed on investigators to deliver robust, reproducible data and to meet the exacting requirements of regulatory authorities.

Clinical Investigation assimilates the wealth of information resulting from the clinical development of new medicines into concise yet comprehensive formats. The journal addresses contemporary issues in clinical drug development and methodology, and also provides a platform for the rapid publication of new drug data from human studies. Coverage spans all therapeutic areas and relates to conventional small-molecule drugs as well as biotech-derived therapeutic entities, including vaccines, monoclonal antibodies, antisense, cell and gene therapies and recombinant proteins. The journal publishes review articles, original papers, perspectives, commentaries, meeting reports, news, views and more.

Principal themes include:

- Clinical study design and methodology
- Overviews of the clinical progress of new drugs or drug classes
- Clinical progress for specific diseases or therapeutic areas
- Findings in Phase I to IV clinical studies
- Healthcare outcomes and pharmacoeconomics
- Patient stratification and individualised therapies
- Commentary on trials in progress
- Drug safety issues and adverse event monitoring
- Biomarkers in clinical trials
- Regulatory issues
- Clinical trial data management and statistics

Audience

Clinical Investigation provides a systematic program of peer-reviewed coverage relating to the clinical evaluation of new and established therapies. The audience for *Clinical Investigation* includes clinical investigators, healthcare decision makers, formulary managers, clinicians, regulatory personnel and medical affairs professionals. Future Science articles have been engineered specifically for the time-

constrained professional. The structure is designed to draw the readers' attention directly to the information they require.

At-a-glance article formatting checklist

Authors should consult the below checklist before formatting their manuscript. Further details on all article sections are given in 'Article Sections'.

Sections Article type	Word limit (excluding abstract and references)	Abstract	Key words	Future Perspective and Executive Summary	Reference limit	Figures and tables permitted (Combined limit of eight in total – additional will be made supplementary (online-only))	Supporting cover letter
Editorial	1500	✗	✓	✗	20	✗	✗
Opinion	1500	✗	✓	✗	20	✗	✗
Commentary	3000	✗	✓	✗	20	✗	✗
Letter to the Editor	1500	✗	✗	✗	20	✗	✗
Conference Report	3000	✓	✗	✗	20	✓	✗
Research Update	3000	✓	✓	✓	20	✗	✗
Special Report	5000	✓	✓	✓	50	✓	✗
Perspective	8000	✓	✓	✓	150	✓	✗
Review	8000	✓	✓	✓	150	✓	✗
Research Article	8000	✓	✓	✓	150	✓	✓
Preliminary Communication	5000	✓	✓	✓	50	✓	✓
Methodology	5000	✓	✓	✓	50	✓	✓

Article types

Clinical Investigation publishes a range of article types, descriptions of which are outlined below. Authors are encouraged to consult the '**At-a-glance article formatting checklist**' for details on word counts and other formatting requirements.

Editorials, Opinions and Commentaries

Editorials are short articles that provide an insight into, or snapshot of issues of topical importance to the journal's target audience or researchers and other professionals. The intention is that the article should offer an expert perspective on a topic of recent interest. More detailed discussions can take the form of Commentary articles.

Opinion articles should typically be informed, agenda-setting and authoritative. If addressing a problem, they should also present coherent argued solutions. They can address issues relating to scientific research, or peripheral areas of debate affecting industry and academia of concern to the journal's scope.

Published example:

Billingham L, Malottki K, Steven N. Small sample sizes in clinical trials: a statistician's perspective. *Clin. Invest.* 2(7), 655–657 (2012).

www.future-science.com/doi/pdf/10.4155/cli.12.62

Conference Reports

Conference reports aim to summarise the most important research presented at a recent relevant meeting or event. It is not usually feasible to attempt comprehensive coverage of the conference; authors should therefore focus on those presentations that are most topical, interesting or thought-provoking.

Published example:

Fallon JK, Gulley JL. World Vaccine Trials Congress 2012. *Clin. Invest.* 2(8), 765–767 (2012).

www.future-science.com/doi/pdf/10.4155/cli.12.69

Research Updates

Research Updates aim to summarise the development and undertaking of a clinical research network or initiative, discussing how the network/initiative was set up, highlighting what progress it has made to date and presenting new avenues for future research and/or collaboration.

Published example:

Gnant M, Piccart-Gebhart M, Goldhirsch A *et al.* Developing an international network for breast cancer research: the BIG experience. *Clin. Invest.* 1(5), 623–628 (2011).

www.future-science.com/doi/pdf/10.4155/cli.11.44

Reviews

Reviews aim to highlight recent significant advances in research, ongoing challenges and unmet needs; authors should be concise and critical in their appraisal of the subject matter, and strive for clarity. The focus should be on key, defining developments rather than providing a comprehensive literature survey. Reviews should provide balanced coverage of the field and not focus predominantly on the author's own research. Authors are encouraged to include their own perspective on current trends and future directions.

Please note **two** types of Review article feature in *Clinical Investigation*:

Clinical Trial Outcomes articles aim to highlight recent significant advances in clinical research, ongoing challenges and unmet needs, and could be in the format of a review of a specific condition/disease, a therapeutic class, a collection of trials/single trial or an individual drug/therapy.

Clinical Trial Methodology articles present recent findings and developments in the design and undertaking of clinical research. Authors should critically assess the latest available literature, discussing new considerations in the design, performance, analysis, reporting and interpretation of clinical trials and how these new approaches may improve clinical investigation.

Published example:

Karikios DJ, Boyer MJ. Irreversible EGFR inhibitors in advanced non-small-cell lung carcinoma: rationale and clinical evidence. *Clin. Invest.* 2(3), 317–325 (2012).

www.future-science.com/doi/pdf/10.4155/cli.12.7

Alhathal N, Al-Qaoud T Carrier S. Considerations in the design of clinical trials for erectile dysfunction *Clin. Invest.* 2(7), 733–745 (2012).

www.future-science.com/doi/pdf/10.4155/cli.12.54

Perspectives

Perspectives have the same basic structure and length as review articles; however, they should be more speculative and forward-looking, even visionary. They offer the author the opportunity to present criticism, address controversy or provide a personal

angle on a significant issue. Authors of perspectives are encouraged to be opinionated, with all positions concisely and clearly argued and referenced. Referees will be briefed to review these articles for quality and relevance of argument only. They will not necessarily be expected to agree with the author's position.

Please note that two types of Perspective article feature in *Clinical Investigation*:

Clinical Trial Perspective articles provide authors with the opportunity to discuss challenges and opportunities in clinical research and how new thinking in clinical trial methodology may influence future drug development strategies.

Therapeutic Perspective articles allow the authors to discuss the rationale and potential clinical outcome of new drug classes and therapeutic approaches.

Published example:

Melvin GA, Gordon MS, Freake BM. Assessment of suicidal ideation and behavior in clinical trials: challenges and controversies. *Clin. Invest.* 2(3), 265–273 (2012).

www.future-science.com/doi/pdf/10.4155/cli.12.10

Aftab BT, Rudin CM. Therapeutic potential of Hedgehog signaling inhibitors in cancer: rationale and clinical data. *Clin. Invest.* 2(4), 371–385 (2012).

www.future-science.com/doi/pdf/10.4155/cli.12.20

Special Reports

Special reports are short review-style articles that highlight a particular niche area, be it a specific emerging field, novel hypotheses or method. Articles are categorised as Special Reports at the discretion of the Editorial team.

Published example:

Bartlam B, Crome P, Lally F. The views of older people and carers on participation in clinical trials: the PREDICT Study. *Clin. Invest.* 2(3), 327–336 (2012).

www.future-science.com/doi/pdf/10.4155/cli.12.4

Research Articles

Authors of original research **must** provide a supporting Cover Letter on submission briefly detailing:

- relevance to the journal's audience;
- where the novelty in the study lies;
- how the study advances understanding in the field;
- direct and potential implications of the findings.

Experimental details and data

Only where a novel experimental procedure has been employed full details must be provided. Details of routine or previously reported experimental procedures should be provided via references only.

Experimental procedures and/or data running to more than two Word document pages should be placed in a supplementary information file.

Published example:

Hennekens CH, Hetzel S, Pfeffer M *et al.* Low-dose enteric-coated aspirin does not inhibit thromboxane B2 and prostaglandin E2: data-derived hypothesis formulation. *Clin. Invest.* 2(7), 747–752 (2012).

www.future-science.com/doi/pdf/10.4155/cli.12.56

The journal publishes **three** categories of research article:

Research Article

Research articles should present novel work that makes a significant impact within the scope of the journal, and which represents an important advancement in knowledge or understanding. Routine or incremental work is not suitable for full research papers. Research should be reported succinctly; the inclusion of detailed background discussion is to be avoided. Supporting data or further experimental details can be submitted as Supplementary Information. If requested by the Editor or reviewers, authors should be able to provide additional relevant original data underpinning their research.

Preliminary Communications

Preliminary communication articles are intended for short reports of studies that present promising improvements or developments on existing areas of research. The significance and potential implications of the developments must be explicit.

Methodologies

Methodology articles should provide a clinical trial protocol for proposed or ongoing Phase I–IV clinical research. The protocol should describe both study design and rationale, indicating the importance of such research.

Letters to the Editor

Readers may submit Letters to the Editor, commenting on an article published in the journal. Where appropriate, Letters to the Editor will be sent to the author of the original article, who will have 28 days to provide a response for publication.

Acceptance of Letters to the Editor for publication is at the discretion of the Editor and Editorial Board.

Article sections

The following list provides notes on the key article sections; authors should consult the '**At-a-glance article formatting checklist**' to determine which sections are required for their submission.

Title: Concisely and clearly conveys the scope/novelty of the article; not more than 120 characters.

Author(s) names and affiliations: Including full name, postal address, phone and fax numbers, and e-mail address.

Abstract: Not more than 120 words; no references should be cited in the abstract. The abstract should highlight the importance of the field under discussion within the journal's scope, and clearly define the parameters of the article.

For all **Research Articles only**, the abstract must be structured into three sections:

- **Background:** Brief overview of the context, purpose and novelty of the study. Trial registration details should be provided, where appropriate;
- **Results/Methods (for Research Articles and Preliminary Communications only):** a summary of the clinical trial protocol and key findings; detailed discussion of data analysis should be submitted as supplementary information;
- **Methods (for Methodologies only):** A succinct summary of the clinical trial protocol;
- **Summary:** A summary of the main conclusions of the study and any clinical implications.

Author photographs: Required for **Editorials** and **Opinion** articles only. The corresponding author plus **one** other author, if desired, can provide a suitable high-resolution head shot for inclusion.

Key words: Required for; a selection of 5-10 words that encapsulate the scope of the article.

Body of the article: The article content should be arranged under relevant headings and subheadings to assist the reader.

Future perspective: A speculative viewpoint on how the field will evolve in 5–10 years' time.

Executive summary: Bulleted summary points that illustrate the main conclusions made throughout the article.

Figures, tables and boxes

The use of figures and diagrams is encouraged wherever relevant. The author should include illustrations and tables to condense and illustrate the information they wish to convey. Commentary that augments an article and could be viewed as ‘stand-alone’ should be included in a separate box. All figures, tables and boxes should be submitted in an editable format.

Figures, tables and boxes should be numbered consecutively according to the order in which they have been first cited in the text. All abbreviations used within them should be defined in the legend.

If any of the figures or tables used in the manuscript requires **permission** from the original publisher, it is the author’s responsibility to obtain this. More details on obtaining permissions can be found in the **copyright section** below.

Supplementary information

Tables, figures and boxes larger than one A4 page will be included as online-only supplementary information. At the Editor’s discretion data or experimental details can also be included.

References

- Authors should focus on recent papers; those older than 5 years should not be included except for an over-riding purpose.
- Primary literature references, and any patents or websites, should be numerically listed in the reference section in the order that they occur in the text, using Arabic numerals placed in square brackets, e.g., [12].
- Any references that are cited in figures, tables or boxes that do not appear in the text should also be numerically listed in the reference section in the order that they occur in the text.

Reference formatting

All references should be formatted according to the house style given in the below examples:

Journals

Aftab BT, Rudin CM. Therapeutic potential of Hedgehog signaling inhibitors in cancer: rationale and clinical data. *Clin. Invest.* 2(4), 371–385 (2012).

Journal supplements

Hauser RA, Freeman TB, Snow BJ *et al.* Long-term evaluation of bilateral fetal nigral transplantation in Parkinson disease. *Arch. Neurol.* 56(Suppl. 1), 179–187 (1999).

Books

De Groat WC, Booth AM, Yoshimura N. Neurophysiology of micturition and its modification in animal models of human disease. In: *The Autonomic Nervous System (Volume 6)*. Andrews WR (Ed.), Harwood Academic Publishers, London, UK, 227–289 (1993).

Meeting abstracts

Smith AB, Jones CD. Recent progress in the pharmacotherapy of diseases of the lower urinary tract. Presented at: *13th International Symposium on Medicinal Chemistry*. Atlanta, GA, USA, 28 November–2 December 1994.

Patents

Pfiser Global R&D: US5623352 (2012).
Cook N: US5623463 (2011).

Please use the following formats for patent numbers issued by the World, US and European patent offices, respectively: WO1234567, US1234567, EP-123456-A.

Reference annotations

Authors can highlight 6–8 references that are of particular significance to the subject under discussion as “* of interest” or “** of considerable interest”, and provide a brief (1–2 line) synopsis.

Example:

- 59 Asante-Appiah E, Patel S, Desponts C *et al.*
Conformation-assisted inhibition of
protein-tyrosine phosphatase-1B elicits
inhibitor selectivity over T-cell protein-
tyrosine phosphatase. *J. Biol. Chem.* 281(12),
8010–8015 (2006).
- Reveals a new strategy for achieving PTP1B selectivity over TCPTP.

Reference Manager style

1. Download the Future Science Reference Manager Style [here](#).

2. Once the file is downloaded to your desktop, copy the file to the appropriate folder in your program directory (usually located in C:\Program Files\Reference Manager\Styles).

EndNote style

Follow the instructions that are appropriate for your version of EndNote as listed below:

Installing the style into EndNote X2 and later versions

1. Download the Future Science EndNote style for references [here](#) (compatible with Mac EndNote 9).
2. In Windows, or using your Macintosh Finder, browse to the location where you downloaded the style. Double-click on the style file to open it. It should open in the EndNote program.
3. In EndNote, go to the "File Menu" and choose "Save as."
4. Remove the word "copy" from the end of your style's name, and then click the Save button.
5. Click on the "File Menu" and choose "Close Style."

Installing the style into EndNote 8, 9, X, or X1

1. Download the Future Science EndNote style for references [here](#) (compatible with Mac EndNote 9).
2. Using Windows, or using your Macintosh Finder, browse to the location where you downloaded the style. Right-click on the style file and select Copy.
3. Browse to your Endnote Styles folder. This will typically be in following location: Windows: C:\Program Files\EndNote #\Styles (Where # is the version number for EndNote) Mac OS: Applications\EndNote #\Styles (Where # is the version number for EndNote) Note: If you modify the EndNote preferences, you can set this to another location. To check this setting, go to the "Edit" menu or EndNote menu on the Mac and select "Preferences." Click on the Folder Locations option to see the custom Style folder location and modify as needed. Keep in mind that the default location for the Styles folder may cause problems when trying to save or edit in Windows Vista and 7 with versions prior to EndNote X2. Please see this article for more information on this issue.
4. Right-click in this folder and choose Paste. Your style should now be installed in the EndNote program.

If you require further assistance or have any questions, please contact the Editor.

Chemical and biological structures

Authors should submit chemical structures in ISISDraw or Chemdraw formats. Please use the following conventions:

- Always indicate stereochemistry where necessary – use the wedge and hash bond convention for chiral centers and mark cis/trans bonds as such;
- Draw small peptides (up to five amino acids) in full; use amino acid abbreviations (Gly, Val, Leu, etc.) for larger peptides;
- Refer to each structure with a number in the text.

Displaying 3D structures in online version of article

The journal website has functionality to support the Jmol viewer for the display of dynamic, 3D chemical and biological structures. We encourage authors to submit their relevant figures in any of the file formats supported by Jmol - including as MOL and CIF - to take advantage of this on-line functionality. More information on Jmol and the files supported by it, can be found here: <http://jmol.sourceforge.net/>

A published example can be viewed here: http://www.future-science.com/doi/suppl/10.4155/fmc.10.282/suppl_file/figure6.htm

For more guidance, please contact the Editor.

Copyright

If a figure or table has been published previously (even if you were the author), acknowledge the original source and submit written permission from the copyright holder to reproduce the material where necessary.

As the author of your manuscript, you are responsible for obtaining permissions to use material owned by others. Since the permission-seeking process can be remarkably time-consuming, it is wise to begin writing for permission as soon as possible.

Future Science is a signatory to the STM Permissions Guidelines produced by the International Association of Scientific, Medical and Technical Publishers (<http://www.stm-assoc.org/>). Permission is, or in the case of an express permission requirement should be, granted free of charge by signatory organizations, with respect to a particular journal article or book being prepared for publication, to:

- Use up to three figures (including tables) from a journal article or book chapter, but:
 - not more than five figures from a whole book or journal issue/edition;
 - not more than six figures from an annual journal volume; and
 - not more than three figures from works published by a single publisher for an article, and not more than three figures from works published by a single publisher for a book chapter (and in total not more than thirty figures from a single publisher for re-publication in a book, including a multi-volume book with different authors per chapter).
- Use single text extracts of less than 400 words from a journal article or book chapter, but not more than a total of 800 words from a whole book or journal issue/edition.

Permission to go beyond such limits may be sought although in such instances the permission grant may require permission fees. **Important:** although permission may be granted without charge, authors must ensure that appropriate permission has nevertheless been obtained. Co-signatories of the permissions agreement can be found on the following website: <http://www.stm-assoc.org/stm-permission-guidelines/>.

Please send us photocopies of letters or forms granting you permission for the use of copyrighted material so that we can see that any special requirements with regard to wording and placement of credits are fulfilled. Keep the originals for your files. If payment is required for use of the figure, this should be covered by the author.
