TABLE OF CONTENTS

- Description p.1
- Audience p.1
- Impact Factor p.2
- Abstracting and Indexing p.2
- Editorial Board p.2
- Guide for Authors p.4

DESCRIPTION

*Clinical Therapeutics* is dedicated to the dissemination of reliable and evolving evidence regarding therapeutics to an international audience of scientists and clinicians working in a variety of research, academic, and clinical practice settings. This goal is especially important in an era of harmonization and globalization of drug development. *Clinical Therapeutics* strives to achieve its mission by providing peer-reviewed, rapid publication of recent developments in drug therapies, as well as in-depth review articles on specific agents, treatment strategies, and disease states. Articles are published online within 20 business days after acceptance. Articles appearing in *Clinical Therapeutics* are indexed by all major biomedical abstracting databases.

Published articles range from pivotal studies exploring new molecules in large, multicenter trials to those exploring new indications for approved agents. Additionally, reports that assess drug safety and tolerability in all phases of development; new routes of administration and new formulations; pharmacokinetic, bioavailability, bioequivalence and biosimilarity; and changes in practice guidelines and standards, are all of interest for publication. *Clinical Therapeutics* also understands the importance of strengthening the body of evidence surrounding particular agents through the publication of replication studies, negative trials, and failed trials. Beyond the clinic, we seek reports that examine the real-world implications of therapeutics such as comparative effectiveness and pharmacoeconomics studies. Commentaries, perspectives, and contemporary issues are sought to offer a balance of viewpoints and scholarly opinion on a broad array of drug-related topics. Case reports, which remain a vital part of our mission, offer clinically valuable lessons.

In addition to feature articles published monthly, each issue of *Clinical Therapeutics* features a specific theme section dedicated to an annual update of a specific topic area. A special guest editor will comprise each update with reviews, commentaries, and original research highlighting what's new or controversial in the topical specialty. Authors are invited to submit manuscripts for consideration in the topic updates, identifying submissions as such in their cover letters. Submissions not selected for the updates will be considered for general publication. [2015 ISSUE UPDATE CALENDAR](The link is http://www.clinicaltherapeutics.com/content/CFPMore)Submit your manuscript at [http://www.ees.elsevier.com/clinther](http://www.ees.elsevier.com/clinther)

AUDIENCE

Research Clinicians in Academia and Industry, Practicing Physicians, Pharmacologists, and Specialists in Pharmacoeconomics, Outcomes Research and Health Policy.
IMPACT FACTOR

2017: 3.185 © Clarivate Analytics Journal Citation Reports 2018

ABSTRACTING AND INDEXING

Current Contents/Clinical Medicine
Chemical Abstracts
Current Opinion Series
Cancerlit
BIOSIS
De Haen Drug Data
EMBASE
International Pharmaceutical Abstracts
SCISEARCH
Cambridge Scientific Abstracts
Martindale: The Extra Pharmacopeia (Martindale Online)
MEDLINE®
Medical Documentation Service
Nursing and Allied Health
Smoking and Health
Research Alert
CINAHL
Current Awareness in Biological Sciences
PsycINFO
Iowa Drug Information Service (IDIS)
Derwent Drug File
Sociedad Iberoamericana de Informacion Cientifica (SIIC) Data Bases
Science Citation Index
Pharmacoeconomics and Outcomes News
MUST
Scopus

EDITORIAL BOARD

Editor-in-Chief
Richard I. Shader, MD, Tufts University School of Medicine, Boston, MA, USA

Editor Emeritus and Topic Editor-at-Large
Philip D. Walson, MD, University Medical Center Göttingen, Hannover, Germany

Topic Editors

Allergy, Asthma, and Immunology
Theoharis Theoharides, MS, PhD, MD, Tufts University School of Medicine, Boston, MA, USA

Cardiology and Cardiovascular Diseases
Peter L. Thompson, MD, University of Western Australia, Crawley, WA, Australia

Drugs and Biologics Development
Kenneth Kaitin, PhD, Tufts Center for the Study of Drug Development, Boston, MA, USA

Endocrinology, Diabetes, and Other Endocrine Disorders
John G. Ryan, DrPH, University of Miami, Miami, FL, USA

Geriatric Therapeutics
William Hung, MD, MPH, The Mount Sinai Medical Center, New York, NY, USA

Infectious Diseases
Ravi Jhaveri, MD, University of North Carolina School of Medicine, Chapel Hill, NC, USA
Neurology and Neuroscience
Huned S. Patwa, MD, Yale University, New Haven, CT, USA

Oncology and Hematology
Andrea Bullock, MD, MPH, Beth Israel Deaconess Medical Center, Boston, MA, USA

Pharmacoeconomics, Outcomes, and Health Policy
Patrizio Armeni, PhD, Università Bocconi, Milano, Italy
Giuditta Callea, PhD, Università Bocconi, Milano, Italy
Carlo Federici, MSc, Università Commerciale Luigi Bocconi, Milano, Italy

Pharmacology, Pharmacokinetics, and Pharmacodynamics
John S. Markowitz, PharmD, University of Florida, Gainesville, FL, USA

Pharmacovigilance
Paul Beninger, MD, MBA, Tufts University School of Medicine, Boston, MA, USA

Rheumatology
Tommy Cheung, MBBS (HK), The University of Hong Kong, Hong Kong, China

Women’s Health and Gender Medicine
Alyson McGregor, MD, MA, Alpert Medical School at Brown University, Providence, RI, USA

Youth and Children
Jill L. Maron, MD, MPH, Tufts University School of Medicine, Boston, MA, USA

Contributing Editors
Kevin Dale Deane, MD, PhD, University of Colorado School of Medicine, Aurora, CO, USA
Seetal Dodd, PhD, Deakin University, Victoria, Australia
Linda R. Duska, MD, University of Virginia Health System, Charlottesville, VA, USA

Consulting Editor, Cardiology and Cardiovascular Diseases
Anna Franzone, MD, PhD, Bern University Hospital, Bern, Switzerland

Consulting Editor, Nephrology
David Drew, MD, MS, Tufts Medical Center, Boston, MA, USA

Consulting Editor, Ophthalmology
Elias Reichel, MD, Tufts University School of Medicine, Boston, MA, USA

Consulting Editor, Pain Management and Treatment
Jason B. Hack, MD, Warren Alpert Medical School, Brown University, Providence, RI, USA

Consulting Statistical Editor
Janet Forrester, PhD, Tufts University School of Medicine, Boston, MA, USA

Consulting Editor, Women’s Health
Megan L. Evans, MD, MPH, Tufts University School of Medicine, Boston, MA, USA

Consulting Editor at Large
Karthik Venkatakrishnan, PhD, Takeda Pharmaceuticals International Co., Cambridge, MA, USA
Haojie Zhu, PhD, University of Michigan College of Pharmacy, Ann Arbor, MI, USA

International Consulting Editors
Romuald Bellman, Innsbruck Medical University, Innsbruck, Austria
Marie Besson, Geneva University Hospitals, Geneva, Switzerland
Bernard Cheung, Queen Mary Hospital, Hong Kong
Emilio Clementi, University of Milan, Milan, Italy
Jozef Glasa, Slovak Medical University, Bratislava, Slovakia
Sinem Ezgi Gulmez, University of Bordeaux, Bordeaux, France
Maria Theresa Herdeiro, University of Aveiro, Aveiro, Portugal
Alexander Khokhlov, Clinical Hospital, Yaroslavl State Medical University, Russia
Adrian Llerena, Clinical Research Center University Hospital, Badajoz, Spain
Stefan Oswald, University of Greifswald, Greifswald, Germany
Donald Singer, Fellowship of Postgraduate Medicine, London, UK
GUIDE FOR AUTHORS

Introduction

*Clinical Therapeutics* is dedicated to the dissemination of reliable and evolving evidence derived from clinical pharmacology and other therapeutic approaches to an international audience of scientists and clinicians working in a variety of research, academic, and clinical practice settings. Providing such information is especially important in this era of harmonization and globalization of drug development. *Clinical Therapeutics* strives to achieve its mission by providing peer-reviewed, rapid publication of recent developments in drug therapies, as well as in-depth review articles on specific agents, treatment strategies, and disease states. Most articles are available online within 20 business days after acceptance. Articles appearing in Clinical Therapeutics are indexed by all major biomedical abstracting databases.

Published articles range from pivotal studies exploring new chemical entities in large, multicenter trials to those exploring repurposing of marketed agents. Additionally, pilot studies; reports that assess drug safety and tolerability in all phases of development; new routes of administration and new formulations; pharmacokinetic, bioavailability, and biosimilarity; and changes in practice guidelines and standards, are all of interest for publication. *Clinical Therapeutics* also understands the importance of strengthening the body of evidence surrounding particular agents through the publication of replication studies, negative trials, and failed trials. Beyond the clinic, we seek reports that examine the real-world implications of therapeutics such as comparative effectiveness and pharmacoeconomics studies as well as work that has implications for health policy. Commentaries, which include perspectives, and contemporary issues, are sought to offer a balance of viewpoints and scholarly opinion on a broad array of drug-related topics. Case reports, which remain a vital part of our mission, offer clinically valuable lessons. All manuscripts are peer reviewed by independent clinicians or scientists for clinical relevance, technical accuracy, methodological rigor, clarity, and objectivity using a double-blind review process.

**Pre-submission Inquiries**

*Clinical Therapeutics* is delighted to respond to pre-submission inquiries. Please send a letter of inquiry together with your proposed manuscript title and abstract for consideration to the editorial office at clinther@elsevier.com; all queries will be dealt with promptly.

**Types of submissions**

All types of submissions with the exception of Commentaries, Research Letters, and Case Reports must include a structured abstract of 400 words or less, as directed by the extension to the CONSORT statement for abstracts (http://www.consort-statement.org/extensions/data/abstracts/), followed by 4 to 6 carefully chosen keywords for indexing.

The abstract should be formatted as follows:

**Purpose:** Briefly provides the frame of reference for the reader and identifies the knowledge gap that the article seeks to address: clearly states the purpose of the research; and identifies the scientific hypotheses and questions being asked.

**Methods:** Succinctly outlines study methodology, including detailed study design, exclusion and inclusion criteria, statistical approaches, and adverse event assessment methodology.

**Findings:** Includes study demographics, adverse events, principle data and statistical analyses.

**Implications:** Covers any limitations or problems in interpretation or generalization from the study findings as well as implications and future directions: must be strictly limited to what can be supported directly by the Findings, and what was identified in the Purpose section.

**Study registry identification number should be included immediately following the Implications section of the abstract.**

Abstracts are often presented separately from the article; therefore, an abstract must be brief and able to stand alone. References should be avoided (if essential, the complete reference per AMA style must be given with the lines of text). Non-standard or uncommon abbreviations should be avoided (when necessary, they must be defined at their first use in the abstract).
Additionally, all manuscript types should also include an Acknowledgements section and a Conflict of Interest statement as described below:

**Acknowledgements**

Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or otherwise. List here those individuals who provided help during the research (eg, providing language help, writing assistance or proof reading the article, etc).

**Conflicts of Interest**

At the end of the text and preceding the references section, under a subheading “Conflict of interest statement” all authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors should declare the role of study sponsors, if any, in the study design, in the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. If the study sponsors had no such involvement, the authors should state so. As a guideline see the ICMJE form for disclosure of Potential Conflicts of Interest at: http://www.icmje.org/coi_disclosure.pdf. In order to maintain the double-blind peer review process, we recommend that first and last initials are used in place of author names within this section.

**Original Research**

**Review Articles and Commentaries**

**Brief Reports**

**Pilot Study**

**Research Letters**

**Case Reports**

**Letters to the Editor**

**Manuscript fees and page charges**

Please note: the manuscript fees and page charges described below are completely separate from the optional Open Access fee. Manuscript fees and page charges are not optional unless the author is approved for a fee waiver (see waiver information below).

Corresponding authors of manuscripts accepted for publication will be charged the following rates:

- For **Original Research** papers: $600 USD per composed journal page
- For **Review articles**: A flat fee of $2500 USD
- For **Commentaries, Brief Reports, Pilot Studies, and Case Reports**: A flat fee of $2000 USD
- For **Research Letters**: A flat fee of $1000 USD

Upon article acceptance and delivery of a composed article proof, payment instructions will be provided to corresponding author with a link to a payment portal (“Submission Start”). Author is expected to complete payment with 48 hours, and to do so, prior to returning article proofs. Please note: author’s article will not be published until such time payment has been satisfied.

Standard page charges do not include publication of color figures. Consult the editorial office for color figure fees after article acceptance.
Express track submission fees

Clinical Therapeutics offers Express Track peer review service for time-sensitive manuscripts, for a fee of $1000 USD per submitted manuscript for Original Research. This fee is nonrefundable and noncancellable. Payment instructions are provided at the time of submission. Express Track submission fee guarantees you:

• High-quality peer review, completed within 5-10 business days.

• A reject or revise decision provided to the author within 3 business days of receipt of reviewers' comments by the editorial office.

• A final decision on revised manuscripts within 15 business days of receipt (excluding requests for subsequent revisions).

A fee of $750 per printed journal page is charged for accepted Express Track papers. Upon article acceptance and delivery of a composed article proof, payment instructions will be provided to corresponding author with a link to a payment portal (“Submission Start”). Author is expected to complete payment with 48 hours, and to do so, prior to returning article proofs.

Accepted manuscripts are published online in advance of print within 20 days from acceptance (pending author approval of finished proof and payment of page charges), and are scheduled for publication in the next available issue.

If you would like to use Express Track peer review service, please request this in your cover letter.

Submission checklist

You can use this list to carry out a final check of your submission before you send it to the journal for review. Please check the relevant section in this Guide for Authors for more details.

Ensure that the following items are present:

One author has been designated as the corresponding author with contact details:
• E-mail address
• Full postal address

All necessary files have been uploaded:

Manuscript:
• Include keywords
• All figures (include relevant captions)
• All tables (including titles, description, footnotes)
• Ensure all figure and table citations in the text match the files provided
• Indicate clearly if color should be used for any figures in print

Graphical Abstracts / Highlights files (where applicable)

Supplemental files (where applicable)

Further considerations
• Manuscript has been ‘spell checked' and ‘grammar checked’
• All references mentioned in the Reference List are cited in the text, and vice versa
• Permission has been obtained for use of copyrighted material from other sources (including the Internet)
• A competing interests statement is provided, even if the authors have no competing interests to declare
• Journal policies detailed in this guide have been reviewed
• Referee suggestions and contact details provided, based on journal requirements

For further information, visit our Support Center.


**Waiver Policy**

If you have no funding for page charges, you **MUST state the reason at the time of submission**, and provide appropriate formal documentation which supports your request, and clearly indicates that your research/study/grant does not support funds for publication. Such documentation may include a copy of the grant proposal, or an official letter from institution or sponsor which clearly states there is no money for publication fees.

Please complete the **Waive Fee Request** form and upload it with your manuscript and formal documentation at the time of submission. Waive Fee Requests that are not supported by formal documentation will not be considered. Please note: **No fee waiver or reduction in fees will be granted after a manuscript is submitted.**

The ability to pay the fee does not influence decisions regarding the acceptance of a paper, which is solely dependent on the peer-review process. Please note: **Express Track** manuscripts are not eligible for a reduced or waived fee.

**BEFORE YOU BEGIN**

**Ethics in Publishing**

For information on Ethics in publishing and Ethical guidelines for journal publication see http://www.elsevier.com/publishingethics and http://www.elsevier.com/journal-authors/ethics.

Prospective authors are encouraged to read the Authors' Submission Toolkit: A practical guide to getting your research published (available at http://informahealthcare.com/doi/pdfplus/10.1185/03007995.2010.499344). The Author 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.

**Policy & Ethics**

The work described in your article must have been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-invol; EC Directive 86/609/EEC for animal experiments http://ec.europa.eu/environment/chemicals/lab_animals/legislation_en.htm; Uniform Requirements for manuscripts submitted to Biomedical journals http://www.icmje.org. This must be stated at an appropriate point in the article.

**Case Reports**

Because case reports (CRs) place patient-specific information into the public domain, CT requires that authors obtain written consent. In the United States, CRs must comply with the Health Insurance Portability and Accountability Act of 1996 (HIPPA) regulations. This means that written consent is required when any patient-specific identifiers are part of the CR. Some institutions exempt CRs that de-identify the patient completely. CT requires that the patient’s age and sex be correctly reported. CT does not allow inclusion of other information such as the patient's name, initials, case number or any other identifying material that could allow the patient to be recognized. CT requires written assent by children and youth as well as written consent from a parent or guardian. Some institutions require potential CR authors to use consent forms developed by the institution.

CRs cover past experiences and as such most institutions do not require review or approval by Ethics Committees or Institutional Review Boards (IRBs). However, some institutions do require IRB approval when four or more cases are involved and their data are aggregated and analyzed. CT concurs with this requirement because when four or more patients are involved and analyzed such findings are best reported as a Brief Report or Pilot Study.

**Pharmacology, Pharmacokinetics, and Pharmacodynamics**

For submissions to the Pharmacology, Pharmacokinetics, and Pharmacodynamics section of Clinical Therapeutics, all manuscripts must include a complete description of the bioanalytic assay(s) and methodology utilized in the generation of the data presented. **It is not acceptable to simply state**
that a validated method was used. Although the complete information included in a pure "Methods" paper is not necessary here, required items at minimum should include: type of instrumentation used, method of extraction, HPLC column and mobile phase, internal standard, type of detection used (e.g. ultraviolet), mass spectrometer settings, m/z monitored, and basic quality control information such as within- and between-day variability, and lower limits of sensitivity. Finally, if the assay(s) have been previously published, or are based upon a published method, appropriate citations must be provided.

Safety and Tolerability
For submissions to Clinical Therapeutics, a statement about safety should explicitly include the time period and only when there is a clear absence of harm as determined by relevant questioning, observation, and testing. It is possible that a drug or biologic may be considered tolerable at the same time that tests show it to be unsafe (e.g., a lengthened QTc interval). Conversely, a drug may be considered safe by all objective assessments, and yet produce side effects that can contribute to high degrees of dose interruption or discontinuation. Furthermore, a drug may also be considered prima facie unsafe when pharmacogenomic information suggests it will yield unwanted metabolites in certain individuals or be highly prone to clinically significant drug interactions with frequently used additional agents or foods. Safety assessments may need to be different for different age groups (e.g., effects on growth and development in children and youth, increased propensity to falls in the elderly, effects on life style for active adults). It is also important to remember that safety concerns may stem from excipients added during the manufacturing process rather than from the drug or biologic per se.)

CHEERS/Health Economic Evaluations
To optimize the quality, consistency, and transparency of health economic and outcomes research reporting and dissemination, Clinical Therapeutics endorses the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement. Authors submitting economic evaluations of pharmacotherapies and other treatment interventions for publication should consult with the CHEERS statement and follow its 24-item checklist of recommendations. Please refer to the statement published in Clinical Therapeutics (http://dx.doi.org/10.1016/j.clinthera.2013.03.003; Husereau D, Drummond M, Petrou S, Carswell C, Moher D, Greenberg D, Augustovski F, Briggs AH, Mauskopf J, Loder E, CHEERS Task Force. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement. 2013;35:356-363) or the CHEERS statement website at http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp for more information. For this purpose, health economic evaluation is defined as the comparative analysis of alternative pharmaceutical and health interventions in terms of their costs and their consequences. All health economic evaluations assess costs, but approaches to measuring consequences of health interventions may differ and can be valued in terms of monetary units; natural units, such as life years gained or disability days avoided; and preference-based health measures, such as quality-adjusted life years or disability-adjusted life years.

Declaration of interest
All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential competing interests include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors must disclose any interests in two places: 1. A summary declaration of interest statement in the title page file (if double-blind) or the manuscript file (if single-blind). If there are no interests to declare then please state this: 'Declarations of interest: none'. This summary statement will be ultimately published if the article is accepted. 2. Detailed disclosures as part of a separate Declaration of Interest form, which forms part of the journal's official records. It is important for potential interests to be declared in both places and that the information matches. More information.

Submission declaration and verification
Submission of an article implies that the work described has not been published previously (except in the form of an abstract, a published lecture or academic thesis, see 'Multiple, redundant or concurrent publication' for more information), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder. To verify originality, your article may be checked by the originality detection service Crossref Similarity Check.
Author contributions
For transparency, we encourage authors to submit an author statement file outlining their individual contributions to the paper using the relevant CRediT roles: Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Resources; Software; Supervision; Validation; Visualization; Roles/Writing - original draft; Writing - review & editing. Authorship statements should be formatted with the names of authors first and CRediT role(s) following. More details and an example

Authorship
Each author is required to declare his or her individual contribution to the article: all authors must have materially participated in the research and/or article preparation, so roles for all authors should be described. The statement that all authors have approved the final article should be true and included in the acknowledgments. Please add the information regarding each author's individual contribution to the manuscript on the title page after the corresponding author's address.

Changes to Authorship
This policy concerns the addition, deletion, or rearrangement of author names in the authorship of accepted manuscripts:

Before the accepted manuscript is published in an online issue: Requests to add or remove an author, or to rearrange the author names, must be sent to the editorial office from the corresponding author of the accepted manuscript and must include: (a) the reason the name should be added or removed, or the author names rearranged and (b) written confirmation (e-mail, fax, letter) from all authors that they agree with the addition, removal or rearrangement. In the case of addition or removal of authors, this includes confirmation from the author being added or removed. Note that publication of the accepted manuscript in an online issue is suspended until authorship has been agreed.

After the accepted manuscript is published in an online issue: Any requests to add, delete, or rearrange author names in an article published in an online issue will follow the same policies as noted above and result in an erratum.

Reporting and registration of clinical trials
All randomized controlled trials submitted for publication should include a completed Consolidated Standards of Reporting Trials (CONSORT) flow chart. Please refer to the CONSORT statement website at http://www.consort-statement.org for more information. This journal has adopted the proposal from the International Committee of Medical Journal Editors (ICMJE) which require, as a condition of consideration for publication of clinical trials, registration in a public trials registry such as https://clinicaltrials.gov/, which can be used by all countries. Please note that requirements for registration may change so authors should always check that they are consulting an up-to-date site. Trials must register at or before the onset of patient enrollment. The clinical trial registration number should be included at the end of the abstract of the article. For this purpose, a clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example drugs, surgical procedures, devices, behavioral treatments, dietary interventions including vitamin or herbal supplements, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration. Further information can be found at http://www.icmje.org.

Studies that were initiated without registration can be registered retrospectively and will be considered for publication on a subjective basis.

Prospective, Observational, or Interventional Pre- and Post-Marketing Studies
Pre- or post-marketing studies must undergo review by an institutional review board (IRB) or ethics committee. Patients must give written informed consent unless a waiver of consent is allowed by the IRB. Patients must be informed of any real or potential conflicts of interest, including compensation of the investigator and potential costs to the patient that may result from their participation in the study. The amount of the remuneration of the investigators for their participation in pre- or post-marketing studies must be approved by the IRB/ethics committee. If the design of a prospective
pre- or post-marketing study calls for a treatment intervention such as a switch or withdrawal, then criteria must be established a priori for patient selection, the implementation of the intervention, and assessment of success/failure of such intervention. Such criteria must be scientifically justified, documented, uniformly applied and enforced, and clearly reported in the study report. Additionally, the patient or his/her insurance provider will not be required to pay for costs related to prospective interventions, such as those that may result from a drug switch or withdrawal.

All other studies that involve identifiable human subjects, including retrospective studies, chart reviews, post-marketing surveillance studies, or government mandated phase IV trials require IRB or ethics committee approval or waiver. In each case, detailed IRB or ethics committee information should be clearly stated in the Methods section.

Studies that only utilize pre-existing, de-identified (according to HIPAA standards) patient data are not required to seek IRB approval.

**Placebos in Clinical Trials**

A full description of any placebo (PBO) or matched control used in a clinical trial must be given in the Methods section. It will no longer be sufficient to simply indicate that a PBO was used. This means that color; type (capsule or pill or liquid); contents (e.g., lactose) including dyes; taste (if there is any); and packaging (e.g., double-dummy) must be noted. For solid PBOs, shape must also be described, as well as whether the PBO is active or inactive. In addition, any efforts to study the success of matching should be included. For example, could subjects/patients or evaluating/rating clinicians guess assignments? Sham procedures must also be described in detail. We are instituting this change as part of our ongoing effort to facilitate replication of findings from trials. All too often this valuable information is omitted from published trial results. When appropriate these descriptions may be designated as Supplemental Digital Content.

**Copyright**

Upon acceptance of an article, authors will be asked to complete a 'Journal Publishing Agreement' (see more information on this). An e-mail will be sent to the corresponding author confirming receipt of the manuscript together with a 'Journal Publishing Agreement' form or a link to the online version of this agreement.

Subscribers may reproduce tables of contents or prepare lists of articles including abstracts for internal circulation within their institutions. Permission of the Publisher is required for resale or distribution outside the institution and for all other derivative works, including compilations and translations. If excerpts from other copyrighted works are included, the author(s) must obtain written permission from the copyright owners and credit the source(s) in the article. Elsevier has preprinted forms for use by authors in these cases.

For gold open access articles: Upon acceptance of an article, authors will be asked to complete an 'Exclusive License Agreement' (more information). Permitted third party reuse of gold open access articles is determined by the author's choice of user license.

**Author rights**

As an author you (or your employer or institution) have certain rights to reuse your work. More information.

Elsevier supports responsible sharing
Find out how you can share your research published in Elsevier journals.

**Role of the funding source**

You are requested to identify who provided financial support for the conduct of the research and/or preparation of the article and to briefly describe the role of the sponsor(s), if any, in study design; in the collection, analysis and interpretation of data; in the writing of the report; and in the decision to submit the article for publication. If the funding source(s) had no such involvement then this should be stated.
Funding body agreements and policies
Elsevier has established a number of agreements with funding bodies which allow authors to comply with their funder's open access policies. Some funding bodies will reimburse the author for the gold open access publication fee. Details of existing agreements are available online. After acceptance, open access papers will be published under a noncommercial license. For authors requiring a commercial CC BY license, you can apply after your manuscript is accepted for publication.

Open Access
This journal offers authors a choice in publishing their research. Regardless of how you choose to publish your article, the journal will apply the same peer review criteria and acceptance standards.

Subscription
• Articles are made available to subscribers as well as developing countries and patient groups through our universal access programs.
• No open access publication fee payable by authors [see "Manuscript Fees and Page Charges," section. These fees are separate from the gold Open Access fee].
• The Author is entitled to post the accepted manuscript in their institution's repository and make this public after an embargo period (known as green Open Access). The published journal article cannot be shared publicly, for example on ResearchGate or Academia.edu, to ensure the sustainability of peer-reviewed research in journal publications. The embargo period for this journal can be found below.

Gold open access
• Articles are freely available to both subscribers and the wider public with permitted reuse.
• A gold open access publication fee is payable by authors or on their behalf, e.g. by their research funder or institution.

For gold open access articles, permitted third party (re)use is defined by the following Creative Commons user licenses:

Creative Commons Attribution-NonCommercial-NoDerivs (CC BY-NC-ND)
For non-commercial purposes, lets others distribute and copy the article, and to include in a collective work (such as an anthology), as long as they credit the author(s) and provided they do not alter or modify the article.

The gold open access publication fee for this journal is **USD 3100**, excluding taxes. Learn more about Elsevier's pricing policy: [https://www.elsevier.com/openaccesspricing](https://www.elsevier.com/openaccesspricing).

Green open access
Authors can share their research in a variety of different ways and Elsevier has a number of green open access options available. We recommend authors see our green open access page for further information. Authors can also self-archive their manuscripts immediately and enable public access from their institution's repository after an embargo period. This is the version that has been accepted for publication and which typically includes author-incorporated changes suggested during submission, peer review and in editor-author communications. Embargo period: For subscription articles, an appropriate amount of time is needed for journals to deliver value to subscribing customers before an article becomes freely available to the public. This is the embargo period and it begins from the date the article is formally published online in its final and fully citable form. Find out more.

This journal has an embargo period of 12 months.

Elsevier Researcher Academy
Researcher Academy is a free e-learning platform designed to support early and mid-career researchers throughout their research journey. The "Learn" environment at Researcher Academy offers several interactive modules, webinars, downloadable guides and resources to guide you through the process of writing for research and going through peer review. Feel free to use these free resources to improve your submission and navigate the publication process with ease.

Language (usage and editing services)
Please write your text in standard, grammatically correct English. If English is not your first language, authors are encouraged to consult with a colleague or professional whose native language is English to improve grammar and syntax prior to submission. Alternatively, authors may wish to visit Elsevier's language editing and copyediting services which are available both pre- and
Informed consent and patient details
Studies on patients or volunteers require ethics committee approval and informed consent, which should be documented in the paper. Appropriate consents, permissions and releases must be obtained where an author wishes to include case details or other personal information or images of patients and any other individuals in an Elsevier publication. Written consents must be retained by the author but copies should not be provided to the journal. Only if specifically requested by the journal in exceptional circumstances (for example if a legal issue arises) the author must provide copies of the consents or evidence that such consents have been obtained. For more information, please review the Elsevier Policy on the Use of Images or Personal Information of Patients or other Individuals. Unless you have written permission from the patient (or, where applicable, the next of kin), the personal details of any patient included in any part of the article and in any supplementary materials (including all illustrations and videos) must be removed before submission.

Submission
Our online submission system guides you stepwise through the process of entering your article details and uploading your files. The system converts your article files to a single PDF file used in the peer-review process. Editable files (e.g., Word, LaTeX) are required to typeset your article for final publication. All correspondence, including notification of the Editor's decision and requests for revision, is sent by e-mail.

Submit your article
Please submit your article via http://ees.elsevier.com/clinther.

Additional Information
Drugs should be referred to by their universally accepted generic names, not by company trademarks. US adopted names (USANs) are acceptable. If unnamed compounds are referred to, as much information as possible (e.g., class of compound) should be included and published references to the compound should be provided. If this is not possible because of intellectual property reasons then this should be stated.

Footnotes and uncommon abbreviations should be avoided whenever possible. When abbreviations or symbols are used, they should be defined in the text the first time they appear as well as in the tables and figures.

Any material that has been published elsewhere must be accompanied by written consent from the original author and publisher for print and electronic reproduction.

PREPARATION
Double-blind review
This journal uses double-blind review, which means the identities of the authors are concealed from the reviewers, and vice versa. More information is available on our website. To facilitate this, please include the following separately:
Title page (with author details): This should include the title, authors' names, affiliations, acknowledgements and any Declaration of Interest statement, and a complete address for the corresponding author including an e-mail address.
Blinded manuscript (no author details): The main body of the paper (including the references, figures, tables and any acknowledgements) should not include any identifying information, such as the authors' names or affiliations.

Article structure
Structured abstract (see Types of submissions)

Essential title page information
• Title. Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.
• Author names and affiliations. Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. You can add your name between parentheses in your own script behind the English transliteration. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lower-
case superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.

• **Corresponding author.** Clearly indicate who will handle correspondence at all stages of refereeing and publication, also post-publication. This responsibility includes answering any future queries about Methodology and Materials. **Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.**

• **Present/permanent address.** If an author has moved since the work described in the article was done, or was visiting at the time, a 'Present address' (or 'Permanent address') may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main, affiliation address. Superscript Arabic numerals are used for such footnotes.

• **Author declaration of individual contribution.** All authors must have materially participated in the research and/or article preparation, so individual roles for all authors must be described.

**Graphical abstract**
Although a graphical abstract is optional, its use is encouraged as it draws more attention to the online article. The graphical abstract should summarize the contents of the article in a concise, pictorial form designed to capture the attention of a wide readership. Graphical abstracts should be submitted as a separate file in the online submission system. Image size: Please provide an image with a minimum of 531 × 1328 pixels (h × w) or proportionally more. The image should be readable at a size of 5 × 13 cm using a regular screen resolution of 96 dpi. Preferred file types: TIFF, EPS, PDF or MS Office files. You can view Example Graphical Abstracts on our information site. Authors can make use of Elsevier's Illustration Services to ensure the best presentation of their images and in accordance with all technical requirements.

**Highlights**
Highlights are mandatory for this journal. They consist of a short collection of bullet points that convey the core findings of the article and should be submitted in a separate editable file in the online submission system. Please use 'Highlights' in the file name and include 3 to 5 bullet points (maximum 85 characters, including spaces, per bullet point). You can view example Highlights on our information site.

**Keywords**
Immediately after the abstract, provide 4–6 keywords, using American spelling and avoiding general and plural terms and multiple concepts (avoid, for example, 'and', 'of'). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

**Abbreviations**
Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in the footnote. Ensure consistency of abbreviations throughout the article.

**Acknowledgements (see Types of submissions)**

**Formatting of funding sources**
List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions on the program or type of grants and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

If no funding has been provided for the research, please include the following sentence:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

**Conflict of Interest statement (see Types of submissions)**
Units
Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

Footnotes
Footnotes should be used sparingly. Number them consecutively throughout the article. Many word processors can build footnotes into the text, and this feature may be used. Otherwise, please indicate the position of footnotes in the text and list the footnotes themselves separately at the end of the article. Do not include footnotes in the Reference list.

Artwork
Electronic artwork
General points
• Make sure you use uniform lettering and sizing of your original artwork.
• Embed the used fonts if the application provides that option.
• Aim to use the following fonts in your illustrations: Arial, Courier, Times New Roman, Symbol, or use fonts that look similar.
• Number the illustrations according to their sequence in the text.
• Use a logical naming convention for your artwork files.
• Provide captions to illustrations separately.
• Size the illustrations close to the desired dimensions of the published version.
• Submit each illustration as a separate file.
A detailed guide on electronic artwork is available.

You are urged to visit this site; some excerpts from the detailed information are given here.

Formats
If your electronic artwork is created in a Microsoft Office application (Word, PowerPoint, Excel) then please supply 'as is' in the native document format. Regardless of the application used other than Microsoft Office, when your electronic artwork is finalized, please 'Save as' or convert the images to one of the following formats (note the resolution requirements for line drawings, halftones, and line/halftone combinations given below):
EPS (or PDF): Vector drawings, embed all used fonts.
TIFF (or JPEG): Color or grayscale photographs (halftones), keep to a minimum of 300 dpi.
TIFF (or JPEG): Bitmapped (pure black & white pixels) line drawings, keep to a minimum of 1000 dpi.
TIFF (or JPEG): Combinations bitmapped line/half-tone (color or grayscale), keep to a minimum of 500 dpi.

Please do not:
• Supply files that are optimized for screen use (e.g., GIF, BMP, PICT, WPG); these typically have a low number of pixels and limited set of colors;
• Supply files that are too low in resolution;
• Submit graphics that are disproportionately large for the content.

Color Artwork
Please make sure that artwork files are in an acceptable format (TIFF [or JPEG], EPS [or PDF]), or MS Office files) and with the correct resolution. If, together with your accepted article, you submit usable color figures then Elsevier will ensure, at no additional charge, that these figures will appear in color on the Web (eg, ScienceDirect and other sites) regardless of whether or not these illustrations are reproduced in color in the printed version. For color reproduction in print, you will receive information regarding the costs, if any, from Elsevier after receipt of your accepted article. Please indicate your preference for color: in print or on the Web only. For further information on the preparation of electronic artwork, please see http://www.elsevier.com/artworkinstructions.
Please note: Because of technical complications which can arise by converting color figures to 'gray scale' (for the printed version should you not opt for color in print) please submit in addition usable black and white versions of all the color illustrations.

Figure captions
Ensure that each illustration has a caption. Supply captions separately, not attached to the figure. A caption should comprise a brief title (not on the figure itself) and a description of the illustration. Keep text in the illustrations themselves to a minimum but explain all symbols and abbreviations used.
Tables
Number tables consecutively in accordance with their appearance in the text. Place footnotes to tables below the table body and indicate them with superscript lowercase letters. Avoid vertical rules. Be sparing in the use of tables and ensure that the data presented in tables do not duplicate results described elsewhere in the article. Submit each table as a separate file.

References
Permissible Sources
References should include only published works or articles in press. Citation of a reference as 'in press' implies that the item has been accepted for publication and a DOI number must be included. Abstracts, unpublished data, and personal communications are not permitted in the reference list. Unpublished results and data published in abstract form may be mentioned in the text only if the methodological details and data are made available in supplemental digital content. Research datasets that have been assigned a global persistent identifier number are permitted.

Citation in Text
In-text citations should be indicated sequentially by superscript number(s) or in brackets. The authors can be referred to, but the reference number(s) must always be given. Please ensure that every reference cited in the text is also present in the reference list (and vice versa).

Reference List Format
There are no strict requirements for formatting the reference list at submission. References can be in any style or format as long as the style is consistent. Where applicable, author(s) name(s), journal title/book title, chapter title/article title, year of publication, volume number/book chapter and the pagination must be present. Use of DOI is highly encouraged. The reference style used by the journal will be applied to the accepted article by Elsevier at the proof stage. Note that missing data will be highlighted at proof stage for the author to correct. Journal names should be abbreviated according to the list of title word abbreviations: http://www.issn.org/2-22661-LTWA-online.php.

Data references
This journal encourages you to cite underlying or relevant datasets in your manuscript by citing them in your text and including a data reference in your Reference List. Data references should include the following elements: author name(s), dataset title, data repository, version (where available), year, and global persistent identifier. Add [dataset] immediately before the reference so we can properly identify it as a data reference. The [dataset] identifier will not appear in your published article.

Data Reference

Reference management software
Most Elsevier journals have their reference template available in many of the most popular reference management software products. These include all products that support Citation Style Language styles, such as Mendeley and Zotero, as well as EndNote. Using the word processor plug-ins from these products, authors only need to select the appropriate journal template when preparing their article, after which citations and bibliographies will be automatically formatted in the journal's style. If no template is yet available for this journal, please follow the format of the sample references and citations as shown in this Guide. If you use reference management software, please ensure that you remove all field codes before submitting the electronic manuscript. More information on how to remove field codes.

Users of Mendeley Desktop can easily install the reference style for this journal by clicking the following link:
http://open.mendeley.com/use-citation-style/clinical-therapeutics
When preparing your manuscript, you will then be able to select this style using the Mendeley plug-ins for Microsoft Word or LibreOffice.

Supplementary material
Supplementary material such as applications, images and sound clips, can be published with your article to enhance it. Submitted supplementary items are published exactly as they are received (Excel or PowerPoint files will appear as such online). Please submit your material together with the article and supply a concise, descriptive caption for each supplementary file. If you wish to make changes to
supplementary material during any stage of the process, please make sure to provide an updated file. Do not annotate any corrections on a previous version. Please switch off the 'Track Changes' option in Microsoft Office files as these will appear in the published version.

**Research data**
This journal encourages and enables you to share data that supports your research publication where appropriate, and enables you to interlink the data with your published articles. Research data refers to the results of observations or experimentation that validate research findings. To facilitate reproducibility and data reuse, this journal also encourages you to share your software, code, models, algorithms, protocols, methods and other useful materials related to the project.

Below are a number of ways in which you can associate data with your article or make a statement about the availability of your data when submitting your manuscript. If you are sharing data in one of these ways, you are encouraged to cite the data in your manuscript and reference list. Please refer to the "References" section for more information about data citation. For more information on depositing, sharing and using research data and other relevant research materials, visit the research data page.

**Data linking**
If you have made your research data available in a data repository, you can link your article directly to the dataset. Elsevier collaborates with a number of repositories to link articles on ScienceDirect with relevant repositories, giving readers access to underlying data that gives them a better understanding of the research described.

There are different ways to link your datasets to your article. When available, you can directly link your dataset to your article by providing the relevant information in the submission system. For more information, visit the database linking page.

For supported data repositories a repository banner will automatically appear next to your published article on ScienceDirect.

In addition, you can link to relevant data or entities through identifiers within the text of your manuscript, using the following format: Database: xxxx (e.g., TAIR: AT1G01020; CCDC: 734053; PDB: 1XFN).

**Mendeley Data**
This journal supports Mendeley Data, enabling you to deposit any research data (including raw and processed data, video, code, software, algorithms, protocols, and methods) associated with your manuscript in a free-to-use, open access repository. During the submission process, after uploading your manuscript, you will have the opportunity to upload your relevant datasets directly to Mendeley Data. The datasets will be listed and directly accessible to readers next to your published article online.

For more information, visit the Mendeley Data for journals page.

**Data statement**
To foster transparency, we encourage you to state the availability of your data in your submission. This may be a requirement of your funding body or institution. If your data is unavailable to access or unsuitable to post, you will have the opportunity to indicate why during the submission process, for example by stating that the research data is confidential. The statement will appear with your published article on ScienceDirect. For more information, visit the Data Statement page.

**Upon Revision - Promotion of Your Article**
At the time you submit the revised version of your article, please compose a question for which your paper's subject, topic or title is an answer. We will take your question, attach your paper's web address, and use it for social media promotion on Twitter. See example, below: Author composed question: How common are adverse events after corticosteroid treatment?

The answer is the author's paper, "Incidence and US Costs of Corticosteroid-Associated Adverse Events: A Systematic Literature Review," which the Clinical Therapeutics editorial office will translate to a bit.ly URL, http://bit.ly/sFmbgF (a shortened web address) and attach it to the question:

The final product, the question and the shortened web address, is the message we will promote on Twitter, to boost awareness and drive traffic to the published content. What you will see on Twitter:
How common are adverse events after corticosteroid treatment? http://bit.ly/sFmbgF

AFTER ACCEPTANCE

Proofs
One set of page proofs (as PDF files) will be sent by e-mail to the corresponding author (if we do not have an e-mail address then paper proofs will be sent by post) or, a link will be provided in the e-mail so that authors can download the files themselves. Elsevier now provides authors with PDF proofs which can be annotated; for this you will need to download the free Adobe Reader, version 9 (or higher). Instructions on how to annotate PDF files will accompany the proofs (also given online). The exact system requirements are given at the Adobe site.

If you do not wish to use the PDF annotations function, you may list the corrections (including replies to the Query Form) and return them to Elsevier in an e-mail. Please list your corrections quoting line number. If, for any reason, this is not possible, then mark the corrections and any other comments (including replies to the Query Form) on a printout of your proof and scan the pages and return via e-mail. Please use this proof only for checking the typesetting, editing, completeness and correctness of the text, tables and figures. Significant changes to the article as accepted for publication will only be considered at this stage with permission from the Editor. We will do everything possible to get your article published quickly and accurately. It is important to ensure that all corrections are sent back to us in one communication: please check carefully before replying, as inclusion of any subsequent corrections cannot be guaranteed. Proofreading is solely your responsibility.

AUTHOR INQUIRIES
For inquiries relating to the submission of articles (including electronic submission) please visit this journal's homepage or contact the editorial office (clinther@elsevier.com). For detailed instructions on the preparation of electronic artwork, please visit http://www.elsevier.com/artworkinstructions. Contact details for questions arising after acceptance of an article, especially those relating to proofs, will be provided by the publisher. You can track accepted articles at http://www.elsevier.com/trackarticle. You can also check our Author FAQs at http://www.elsevier.com/authorFAQ and/or contact Customer Support via http://support.elsevier.com.

© Copyright 2018 Elsevier | https://www.elsevier.com