



CLINICAL THERAPEUTICS

The International Peer-Reviewed Journal of Drug Therapy

AUTHOR INFORMATION PACK

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DESCRIPTION

Clinical Therapeutics provides peer-reviewed, rapid publication of recent developments in drug and other therapies as well as in pharmacoconomics, health policy, treatment outcomes, and innovations in drug and biologics research. In addition **Clinical Therapeutics** features updates on specific topics collated by expert Topic Editors. **Clinical Therapeutics** is read by a large international audience of scientists and clinicians in a variety of research, academic, and clinical practice settings. Articles 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, bio-availability, 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 pharmacoconomics 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 blind review process.

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. [2019 TOPIC UPDATE CALENDAR](#) Submit your manuscript at <http://www.ees.elsevier.com/clinther>

AUDIENCE

Research Clinicians in Academia and Industry, Practicing Physicians, Pharmacologists, and Specialists in Pharmacoconomics, Outcomes Research and Health Policy.

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Clinical Therapeutics provides peer-reviewed, rapid publication of recent developments in drug and other therapies as well as in pharmacoconomics, health policy, treatment outcomes, and innovations in drug and biologics research. In addition *Clinical Therapeutics* features updates on specific topics collated by expert Topic Editors. *Clinical Therapeutics* is read by a large international audience of scientists and clinicians in a variety of research, academic, and clinical practice settings. Articles are indexed by all major biomedical abstracting [databases](#).

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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).

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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-involving-human-subjects>; 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.

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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 (HIPAA) 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.

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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.

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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.)

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Clinical Therapeutics endeavors to make all manuscripts readily understandable by using universally accepted chemical names, structures, spelling, abbreviations, and formatting. For Pharmacoeconomics submissions, results are sometimes reported in the currency of the author(s)'s country. The relative value of currencies from some countries may not be obvious to some readers. Therefore, we now require that equivalencies in US dollars (USD) and European Union euros (EUR) be added in parentheses after other currencies. For example, 68 Indian rupees or INRs would be followed by (\$1.00 USD/0.85 EUR). We recognize that currency values fluctuate. Therefore, equivalencies should reflect values at the time of submission.

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