CLINICAL THERAPEUTICS
The International Peer-Reviewed Journal of Drug Therapy

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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

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Introduction

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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.

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

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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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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.

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Currency values

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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 (eg, lactose) including dyes; taste (if there is any); and packaging (eg, 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.

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