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 pharmacoconomics 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

AUDIENCE

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

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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.

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

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

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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.

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