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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 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. Submit your manuscript at 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.
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GUIDE FOR AUTHORS

Introduction

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, 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 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 double-blind review process.

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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.

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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 (e.g., providing language help, writing assistance or proof reading the article, etc).

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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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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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