CLINICAL THERAPEUTICS
The International Peer-Reviewed Journal of Drug Therapy

AUTHOR INFORMATION PACK

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.5

DESCRIPTION

Clinical Therapeutics provides peer-reviewed, rapid publication of recent developments in drug and other therapies as well as in pharmacoeconomics, 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

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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 pharmacoeconomics, 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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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 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.)

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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](http://dx.doi.org/10.1016/j.clinthera.2013.03.003); Huserau 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](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.

**Currency values**

*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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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.

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