

ABOUT THE JOURNAL SCOPE

Clinical and Translational Science (CTS), an official journal of the American Society for Clinical Pharmacology and Therapeutics, highlights original translational medicine research that helps bridge laboratory discoveries with the diagnosis and treatment of human disease. Translational medicine is a multi-faceted discipline with a focus on translational therapeutics. In a broad sense, translational medicine bridges across the discovery, development, regulation, and utilization spectrum. Research may appear as Full Articles, Brief Reports, Commentaries, Phase Forwards (clinical trials), Reviews, or Tutorials. *CTS* also includes invited didactic content that covers the connections between clinical pharmacology and translational medicine. These additional features provide context for research articles and facilitate understanding for a wide array of individuals interested in clinical and translational science. *CTS* welcomes high quality, scientifically sound, original manuscripts focused on clinical pharmacology and translational science, including animal, *in vitro*, *in silico*, and clinical studies supporting the breadth of drug discovery, development, regulation and clinical use of both traditional drugs and innovative modalities.

Topics of interest include:

- Translational medicine, including studies focused on Interrogation/evaluation of mechanism-of-action, human physiology, and interruption of disease pathophysiology
- Hypothesis generating non-clinical and clinical studies, including small clinical trials
- Clinical pharmacology studies with a focus on translational research in discovery, development, regulation and use of pharmacologic agents to improve clinical outcome, and inform optimal use of therapeutics in patients
- Evaluation of various biomarkers as well as assessing the linkage between biomarker response and clinical endpoints in patients, including studies that identify or support biomarkers that can be used at any stage of drug development
- Studies of response to a therapeutic intervention in a particular disease that may translate to a response in another disease, as well as translation of safety signals across species and/or patient populations
- The science and practice of translational medicine, including topics such as models of human disease and their therapeutic implications as well as practical aspects like improvements to study design or conduct and translational medicine methods.
- Studies that guide Phase 2 dose selection
- Studies that demonstrate effective translation between basic and clinical science
- Precision medicine
- Genomic medicine, including pharmacogenomics, next generation sequencing, pharmacometabolomics, and functional genomics
- Electronic and mobile health applications as well as wearables
- Regulatory and public health policy implications of translational studies
- Quantitative and systems pharmacology, PK/PD model-based and mechanistic understanding of disease biology and pharmacology, as these relate to translational medicine

CTS is an official journal of the American Society for Clinical Pharmacology and Therapeutics (ASCPT).

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ABSTRACTING

This journal is covered by: Academic Search (EBSCO Publishing), Academic Search Alumni Edition (EBSCO Publishing), Biological Abstracts (Thomson Reuters), BIOSIS Previews (Thomson Reuters), Biotechnology & Bioengineering Abstracts (ProQuest), CSA Biological Sciences Database (ProQuest), Embase (Elsevier), MEDLINE/PubMed (NLM), Science Citation Index

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EDITORIAL PROCESS

Criteria for Publication

The principal criteria for publication of papers in *CTS* are that they:

- Report original scientific research (the main results and conclusions must not have been published or submitted elsewhere)
- Are of outstanding scientific importance
- Reach a conclusion of interest to an interdisciplinary readership

Selection Process of Submitted Papers

Upon submission, the manuscript is assigned to an Associate Editor covering the subject area, who makes the initial decision on whether to send it out for peer-review. The journal receives many more high-quality submissions than it can publish and the Associate Editors strive to identify maximally impactful papers. Papers not chosen for peer-review are quickly returned to the authors to minimize unproductive delays and allow sufficient time to prepare the manuscript for submission to another journal.

If selected for peer review, referees are chosen by the Associate Editor based upon subject expertise and ability to evaluate the paper fully and fairly, and in a timely manner. The ideal referee report indicates who will be interested in the new results and why, and will be used by the Associate Editor to help determine the impactfulness of publication in *CTS*. If a paper is selected for further consideration, authors are required to address the comments of the referees in a revised version of the paper.

The Associate Editor assigned to the paper is responsible for making a decision recommendation in light of the referees' reports. All recommendations are then considered by the Editor-in-Chief, who determines the final disposition for all papers.

OPEN ACCESS PUBLICATION

All articles selected for acceptance in *CTS* will be published open access. Articles will be made freely available immediately upon publication. For accepted papers, the author identified as the formal corresponding author for the paper will receive an email prompting them to login into Author Services; where via the Wiley Author Licensing Service (WALS) they will be able to complete the license agreement on behalf of all authors on the paper.

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NEGATIVE RESULTS

In recognition of innovative clinical and translational research that asks an important scientific question, executes high quality experimental design, conducts rigorous data analysis, and disproves a hypothesis or produces negative results, *CTS* will consider for publication manuscripts highlighting negative results. As with all *CTS* content, submitted research will be subject to careful peer scientific review, specifically to ensure that negative results are not secondary to limitations in study design, execution or analysis, and truly reflect the null hypothesis and its relevance to clinical and translational works and research.

PREPARATION OF MANUSCRIPTS

CONTENT TYPES

Author Submissions (1) Article, (2) Review, (3) Phase Forward, (4) Commentary, (5) Book Review, (6) Letter to the Editor, (7) Tutorial, (8) Brief Report Submissions that do not adhere to the guidelines provided in this document will be returned to the author prior to consideration. Material that cannot fit within the allowed limit may be submitted as supplementary information.

(1) Article

Word Limit: 4,000 words excluding abstract, references, tables, and figures

Abstract: 150 words maximum

References: 50 maximum

Figures/Tables: 7 maximum

Substantial novel research

(2) Review

Word Limit: 8,000 words excluding introduction, references, tables, and figures

Abstract: 150 words maximum

References: 100 maximum

Figures/Tables: 8 maximum

High-quality, timely reviews covering important topics in the entire field of translational medicine

(3) Phase Forward

Word Limit: 5,000 words excluding abstract, references, tables, and figures

Abstract: 150 words maximum

References: 60 maximum

Figures/Tables: 8 maximum

Manuscripts developed from well-conducted, well reported, and relevant clinical trials with a particular focus on first-in-human, first-in-patient, and proof-of-concept.

(4) Commentary

Word Limit: 1,600 words excluding introduction, references, tables, and figures

Abstract: no abstract for this article type; should include a 75-word Introduction

References: 10 maximum

Figures/Tables: 2 maximum

Typically highlights findings of a paper in the same issue, presented in a wider scientific and clinical context

(5) Book Review

Word Limit: 700 words

Abstract: no abstract for this article type

References: no references for this article type

Figures/Tables: Cover image will be secured prior to publication by the Editorial Office

(6) Letter to the Editor

Word Limit: 400 words excluding references, tables, and figures

Abstract: no abstract for this article type

References: 5 maximum

Figures/Tables: 1 maximum

Letters must be submitted within 6 months of publication of the subject article. A Letter to the Editor must reference the original source, and a Response to Letter must reference the Letter to the Editor in the first few paragraphs. Letters to the Editor can use an arbitrary title, but a Response must cite the title of the Letter: e.g., Response to [title of Letter]

(7) Tutorial

Word Limit: 8,000 excluding introduction, references, tables, and figures

Abstract: no abstract for this article type; should include a 75-word introduction

References: 100 maximum

Figures/Tables: 8 maximum

Educational article providing practical tutorial on tools, methodologies and approaches in translational medicine.

(8) Brief Report

Word Limit: 2,000 excluding abstract, references, tables, and figures. Results and Discussion sections may be combined.

Abstract: 150 words maximum

References: 25 maximum

Figures/Tables: 2 maximum

Brief Reports are intended as short and complete reports of novel research findings of high importance to the field. Reports of preliminary experiments are unacceptable. Brief reports should be especially significant and timely and reach a clear conclusion.

FORMAT OF MANUSCRIPTS

General format Manuscripts must be typed in English and be in a single column, double-spaced format. All manuscript pages must be numbered. Manuscript text files must be in MS Word or LaTeX format.

Title page This should include (a) the complete manuscript title; (b) all authors' names and affiliations; (c) the name and address for correspondence, fax number, telephone number, and e-mail address; (d) Conflict of Interest statement; and (e) Funding information. The title page should also include the keywords.

Title Manuscript titles should be no more than 150 characters and spaces. Running titles should be no more than 50 characters and spaces.

Text Articles should consist of the following ordered sections:

Title Page

Abstract

Introduction

Methods (must contain IRB or IACUC approval: see **Informed Consent and Ethics** below)

Results

Discussion

Study Highlights

Acknowledgements

Author Contributions

References

Figure Legends

Originality A submitted manuscript must be an original contribution not previously published (except as an abstract), must not be under consideration for publication elsewhere, and, if accepted, must not be reproduced elsewhere without the consent of the American Society for Clinical Pharmacology and Therapeutics (ASCPT). Although the editors, editorial board, and referees make every effort to ensure the validity of published manuscripts, the final responsibility rests with the authors, not with *Clinical and Translational Science*, its editors, ASCPT, or Wiley.

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Statement of Human and Animal Rights When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008 (5). If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should indicate whether the institutional and national guide for the care and use of laboratory animals was followed.

Clinical Trials Registry Registration in a public trials registry is required for publication in CTS. A clinical trial is defined as any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Studies designed for other purposes, including exploring pharmacokinetics or safety and tolerability (e.g., phase 1 trials) are exempt. Registration must be with a registry that meets the following criteria: (1) accessible to the public at no charge; (2) searchable by electronic methods; (3) open to all prospective registrants free of charge or at minimal cost; (4) validates registered information; (5) identifies trials with a unique number; and (6) includes information on the investigator(s), research question or hypothesis, methodology, intervention and comparisons, eligibility criteria, primary and secondary outcomes measured, date of registration, anticipated or actual start date, anticipated or actual date of last follow-up, target number of subjects, status (anticipated, ongoing or closed), and funding source(s). Examples of registries that meet these criteria include (1) The registry sponsored by the United States National Library of Medicine (<http://www.clinicaltrials.gov>); (2) The International Standard Randomised Controlled Trial Number Registry (<http://www.controlled-trials.com>); (3) The Cochrane Renal Group Registry (<http://www.cochrane-renal.org/trialsubmissionform.php>); (4) The National (United Kingdom) Research Register (<http://www.update-software.com/national/>); and (5) European Clinical Trials Database (<http://eudract.emea.eu.int/>).

Abbreviations Abbreviations should be defined at the first mention in the text and in each table and figure. Write out the full term for each abbreviation at its first use unless it is a standard unit of measure. For a list of standard abbreviations, please consult the CSE Manual for Authors, Editors, and Publishers (available from the Council of Science Editors, 12100 Sunset Hills Road, Suite 130, Reston, VA 20190) or other standard sources.

Style *The American Medical Association Manual of Style* (9th edition), *Stedman's Medical Dictionary* (27th edition) and *Merriam-Webster's Collegiate Dictionary* (10th edition) should be used as standard references.

Refer to drugs and therapeutic agents by their accepted generic or chemical name, and do not abbreviate them (a proprietary name may be given only with the first use of the generic name). Code names should be used only when a generic name is not yet available (the chemical name and a figure giving the chemical structure of the drug is required). Copyright or trade names of drugs should be capitalized and placed in parentheses after the name of the drug. Names and locations (city and state in United States; city and country outside United States) of manufacturers of drugs, supplies, or equipment cited in a manuscript are required to comply with trademark law and should be provided in parentheses.

Language Editing Authors who require editing for language are encouraged to consult language editing services prior to submission.

STUDY HIGHLIGHTS

Original research articles should include a Study Highlights section after the Discussion section in the manuscript text. The highlights section should include and answer each of the questions below. The entire section, not including the questions, should be under 150 words.

- What is the current knowledge on the topic?
- What question did this study address?
- What does this study add to our knowledge?
- How might this change clinical pharmacology or translational science?

AUTHOR RESPONSIBILITY

Upon submission, the corresponding author must confirm full access to all data in the study and final responsibility.

AUTHOR CONTRIBUTIONS

A list of each authors' contributions should be provided in the manuscript text on the title page. The standard contributions include: Wrote Manuscript, Designed Research, Performed Research, Analyzed Data, and Contributed New Reagents/Analytical Tools.

ACKNOWLEDGMENTS

This should include sources of support, including federal and industry support. All authors who have contributed to the manuscript must be acknowledged. Medical writers, proofreaders, and editors should not be designated as full authors, but acknowledged here.

DISCLOSURE

At the time of submission, each author must disclose and describe any involvement, financial or otherwise, that might potentially bias his or her work. Disclosures must be included on the title page and in the online submission form.

REFERENCES

The reference list should contain the references in the order in which they are cited in the text (Vancouver style). Citations included in tables/figures count toward the maximum references allowed for the article type and must be included in the reference list. Tables created solely of references are not permitted. Only published works, as well as manuscripts in press, should be included in the reference list; articles that are submitted or in preparation should be referred to as "unpublished data" in the text. For publications in the reference list, all authors should be included unless there are more than 6, in which case only the first author should be listed followed by 'et al.' Titles of cited articles are required for all article types. For book citations, the publisher and city of publication are required; include the country (and state for US) for lesser-known cities or where any ambiguity is possible. Please note the following examples:

Journal articles:

Kashuba, A.D. *et al.* Effect of fluvoxamine therapy on the activities of CYP1A2, CYP2D6, and CYP3A as determined by phenotyping. *Clin. Pharmacol. Ther.* **64**, 257–268 (1998).

Books:

Eisen, H.N. *Immunology: An Introduction to Molecular and Cellular Principles of the Immune Response* 5th edn. (Harper & Row, New York, 1974).

Articles in books:

Weinstein, L. & Schwartz, M.N. Pathogenic properties of invading microorganisms. In *Pathologic Physiology: Mechanisms of Disease* (eds. Sodeman, W.A., Jr. & Sodeman, W.A.) 457–473 (W.B. Saunders, Philadelphia, 1974).

Website:

Fleischbein, J. Northeast Pacific long-term observation program. US GLOBEC <<http://globec.oce.orst.edu/groups/nep/index.html>> (2003). Accessed 13 April 2006.

GUIDELINES FOR FIGURES AND ARTWORK

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For single images:

Width 500 pixels (authors should select “constrain proportions,” or equivalent instructions, to allow the application to set the correct proportions automatically)

Resolution 125 dpi (dots per inch)

Format TIFF for photographs, EPS for line drawings or charts

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Figures should be numbered consecutively in the order of first citation in the text. If a table, figure or any other previously published material is included, the authors must obtain written permission to reproduce the material from the copyright owner and submit it with the manuscript. The original source should be cited. Figures and tables must be uploaded separately from the manuscript text. Each figure must be provided as an individual file. Composite figures should be submitted preassembled. Authors are encouraged to use color in their figures.

FIGURE LEGENDS

Legends should be brief and specific and should appear after the Reference section in the manuscript text.

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Accepted file types include MS Word. If you submit a LaTeX file, please provide a PDF copy as reference for the editorial staff. This PDF copy can be uploaded as a supplementary information file. Tables should be numbered consecutively in the order of first citation in the text. Supply a brief title for each table but place explanatory matter in the footnotes (not in the heading). Do not use internal horizontal and vertical lines. Tables and figures must be uploaded separately from the manuscript text. Please do not include

multipart tables (such as Table 1a and 1b). Tables should be editable and not embedded images or excel files.

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Papers should be prepared as follows:

1. See the artwork guidelines above
2. Do not make rules thinner than 1 pt (0.36mm)
3. Use a coarse hatching pattern rather than shading for tints in graphs
4. Color should be distinct when used as an identifying tool
5. Commas should be used to separate thousands
6. At first mention of a manufacturer, the town (state if USA) and country should be provided

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Authors are required to submit final, publication-ready files at the revision stage, along with a version tracking all changes to the paper. Use the Track Changes mode in MS Word or indicate the revised text with bold, highlighted, or colored type. Authors should submit a point-by-point response to each referees' set of comments.

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Supplementary information is peer-reviewed material directly relevant to the conclusion of an article that cannot be included in the printed version owing to space or format constraints. It is posted on the journal's website and linked to the article online; it may include data files, graphics, movies, or extensive tables. The printed article must be complete and self-explanatory without the supplementary information.

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SUBMISSION OF PAPERS

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CONTACT INFORMATION

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