

**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.

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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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**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:** 4,000-8,000 words excluding introduction, references, tables, and figures

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

**References:** 75-100 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**

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**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:** 4,000-8,000 excluding introduction, references, tables, and figures

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**References:** 75-100 maximum

**Figures/Tables:** 8 maximum

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

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

**Abstract:** 150 words maximum

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*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; and (c) the name and address for correspondence, fax number, telephone number, and e-mail address. The title page should also include the number of figures and tables and the key words.

**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

Conflict of Interest/Disclosure

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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on human experimentation or with the Helsinki Declaration of 1975 (as revised in 1983). IRB or IACUC approval must be cited in the Methods section of the text. If there has been no IRB review of the study, please indicate so in the cover letter. In such situations, the manuscript will be reviewed to determine if IRB review should have been conducted. The result of this review may determine whether or not the manuscript will be considered for publication.

**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/trials/submitform.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.

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**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 this study adds to our knowledge
- How this might 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. 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 in the text of the manuscript and the online submission form.

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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:

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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).

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

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**Format** TIFF for photographs, EPS for line drawings or charts

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Papers should be prepared as follows:

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4. Color should be distinct when used as an identifying tool
5. Commas should be used to separate thousands
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**SUPPLEMENTARY INFORMATION**

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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USA

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USA

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