

# TRANSLATIONAL AND REGULATORY SCIENCES

## Instructions for Authors

### ABOUT THE JOURNAL

#### Aim

The aim of this international open access journal, Translational and Regulatory Sciences (TRS), is to create a new platform for launching new ideas, by not only industry and regulatory authorities but also members of the academe who want to contribute to better use of their research activities within the medical realm. Thereby, the journal aims to render a significant impact on the abilities of those communities to bring new medicines and medical devices to patients in need. An expected effect of TRS is that experts from the industry, academe, and government will harmonize their efforts on equal footing and will promote academic progress and dissemination regarding the regulatory science of pharmaceuticals, medical devices, and related aspects using this journal.

#### Scope

##### Categories

- Translational Science
- Regulatory Science

##### Including but not limited to:

- Analytical Chemistry
- Assay Development for Screening
- Automation of screening (high throughput screening)
- Clinical Research Efficiency
- Collaboration and Partnerships
- Compound/Library Management
- Data Transparency and Sharing
- De-risking Therapeutics Development
- Early-Stage Drug Repurposing
- Flexible Study Designs
- Groundbreaking Efforts to Transform the Way Drugs and Medical Devices are Developed, Evaluated, and Manufactured
- Informatics
- involvement and Ethical Aspects
- Late-Stage Drug Repurposing
- New Animal Models of Human Diseases
- New Approaches to Assess the Safety, Efficacy, Quality, and Performance of Medical Products
- New Biomarkers and Clinical Application
- New Concepts of Benefit/Risk Assessment, Submission, and Approval Strategies, Patient's Involvement and Ethical Aspects
- New Human Health and Ecological Risk Assessment Procedures and Post-marketing Evaluation Method and Processes for Drugs and Medical Devices
- New Methods/Approaches to Improve Patient Recruitment and Retention in Clinical Research Studies
- New Methods/Approaches to Reduce Research Costs and Complexity

- New Predictive Methods/Models for Efficacy Evaluation
- New Predictive Methods/Models for Toxicity Evaluation
- New Standards and Approaches to Facilitate Sound and Transparent Regulatory Decision-making Regarding Drugs and Medical Devices
- New Standards, Concepts, Proposals, and/or Regulations for Gene Therapy, Cell Therapy, and Regenerative Medicine
- Patient and Contact Registries
- Probe Development and Lead Optimization
- Translational Clinical Sciences from Animals to Humans
- Target Identification and Validation

##### Sub-categories

One of the following sub-categories should be noted as the field of the paper:

Biochemistry, Organic Chemistry, Natural Product Chemistry, Herbal Medicine, Metabolism, Neuroscience, Immunology/Allergy, Experimental Animal, Cell Signaling, Stem Cell/iPS, Oncology, Genome/Epigenome, Drug Delivery System, Drug Metabolomics, Toxicology, Evaluation Study, Public Health, Risk Assessment Study, and Epidemiology

##### Frequency of publication

TRS is issued quarterly, and the inaugural issue of TRS will be published in August 2019.

#### **Ethical Treatment of Subjects**

Submission of a manuscript implies that the authors warrant compliance with institutional policies governing the ethical treatment of human subjects and animals, and are ready to share the original approval documents if so requested.

##### Human and animal rights

If the work involves the use of human subjects, the authors should ensure that the work has been carried out in accordance with the International Code of Medical Ethics of the World Medical Association, Inc. (Declaration of Helsinki) for experiments involving humans and Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Authors should include a statement in the manuscript that informed consent was obtained for experimentation with human subjects. The privacy rights of human subjects must always be observed.

All animal experiments should comply with the Law (or guidelines) for the Humane Treatment and Management of Animals as well as Standards Relating to the Care and Management of Laboratory Animals and Relief of Pain. Such studies should be carried out in accordance with the official guidelines for experimental animal treatment and

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### Types of Manuscript

Original articles (Full papers, Short communication), Letters, News, Platform, and Review articles that are principally related to translational and regulatory sciences and are unpublished and not being considered for publication elsewhere can be accepted. Submitted manuscripts not rejected at the first screening will undergo a peer-review process that occasionally could require substantial revision and may last several months, depending on the timeliness of author response. All manuscripts must be written in good English (American or British usage is accepted, but not a mixture of these). Manuscripts are selected for publication according to an editorial assessment of their suitability and reports from referees. Papers are rejected if the ethical treatment of subjects has not been appropriate.

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All manuscripts must be submitted through e-mail: [submission@cutrs.jp](mailto:submission@cutrs.jp)

Authors must show related field\* and editors for the submitted manuscript.

Provide up potential reviewers if possible.

\*Field: Biochemistry, Organic Chemistry, Herbal Medicine, Metabolism, Neuroscience, Immunology/Allergy, Experimental Animal, Cell Signaling, Stem Cell/iPS, Oncology, Genome/Epigenome, Drug Delivery System (DDS), Drug Metabolomics, Toxicology, Regulatory Science (Evaluation/Policy). If none of the above applicable, please choose TS, RS or TRS.

### Submission Format

The following files should be prepared.

- Text of the manuscript: The file should contain all text from the cover page to the references.
- Manuscripts in Microsoft Word are preferred; standard fonts (Times New Roman, Century, Helvetica, Arial, and others) should be used.
- Figures: Colored figures are welcome.
  - Files should be submitted in PowerPoint, Word,

Excel, Photoshop, (JPEG, TIFF) formats. Note that SHS, EXE, COM, VBS, and ZIP formats will not be accepted.

- Resolutions: 900–1200 dpi for black and white line art, 600 dpi for color and gray scale, and 300 dpi for photographs that contain no text.
- Please follow the PMC guideline: <https://www.ncbi.nlm.nih.gov/pmc/pub/filespec-images/>
- Tables: The use of Excel is recommended. Files in PowerPoint are not accepted. The titles of tables should clearly reflect the contents.
- Files should be named as follows.
  - Text Author.doc
  - Figure Author\_Fig1.tif (the extension is only an example)
  - Table Author\_Table1.xls
  - Cover Letter Author\_cov.doc
- Figure or table numbers should be contained in the file names.
- All correspondence, including notification of the editor's decision and requests for revision, is sent by e-mail.

#### Contact (e-mail only)

Editorial office: [submission@cutrs.jp](mailto:submission@cutrs.jp)

Other than the manuscript: [inquiry@cutrs.jp](mailto:inquiry@cutrs.jp)

#### Formatting requirements

All manuscripts must contain the essential elements needed to convey your manuscript: Abstract, Highlight, Keywords, Introduction, Materials and Methods, Results, Conclusions, Artwork, and Tables with Captions. If your article includes any videos and/or other supplementary material, please include such material in your initial submission for peer review purposes. Divide the article into clearly defined sections. Please ensure that the text of your manuscript is double-spaced.

#### Figures and tables embedded in text

Please ensure that the figures and tables included in the single file are placed next to the relevant text in the manuscript, rather than at the bottom or the top of the file. The corresponding caption should be placed directly below the figure or table.

#### Peer review

All contributions will be initially assessed by the editor for suitability for the journal. Papers deemed suitable are then typically sent to a minimum of two independent expert reviewers to assess the scientific quality of the paper. The editor is responsible for the final decision regarding acceptance or rejection of articles. The editor's decision is final.

## Article Structure

#### Manuscript preparation

Authors of scientific reports should make a point to validate whether the data measure what they claim to

have measured or whether they could be distorted by adventitious interferences. Authors should also provide evidence that test and control conditions differ only on account of the experimental variables tested, or are not affected by spurious confounding conditions. Conclusions should focus on the most probable explanation of results, but should also endeavor to point out other less apparent but plausible inferences. Submissions that are not scientific experimental reports, such as policy positions and reviews, should strive for range, logical sequence, clarity, and well-articulated conclusions.

The popularity of Translational and Regulatory Sciences makes it necessary to severely limit authors' discussions and data presentations in their manuscripts. Use generic names of chemicals whenever possible. Proprietary names and trademarks should appear only to identify the source of the chemical, and subsequently, only the generic name should be used. All abbreviations, other than those for standard units, should be defined in text or in a footnote. Abbreviations should be unpunctuated. Manuscripts should be double-spaced throughout the body of your manuscript only. Pages should be numbered consecutively and organized as follows: The title page (p. 1) should contain the article title, authors' names and complete affiliations, footnotes to the title, type of paper, category, and the address for manuscript correspondence (including e-mail address and telephone and fax numbers). Separate word counts should be provided for the abstract, highlight, text, and references. The abstract (p. 2) must be a single paragraph that summarizes the main findings of the paper in less than 250 words. After the abstract, a list of three to five keywords that will be useful for indexing or searching should be included. Additionally, please include a 100-word highlight that explains the significance of the research purpose and its result. Flexibility of format is allowed, given the mix of multidisciplinary scientific reports and of policy and review articles of interest to the journal. Clarity and brevity will be preferred. The length of papers, including tables, figures, and any other appendices, should not exceed eight PDF pages for a Full paper or Review article, and five for a Letter. One PDF page with no title, tables, or figures, will have about 850 words.

#### Subdivision: numbered sections

Divide your article into clearly defined and numbered sections. Subsections should be numbered 1.1 (then 1.1.1, 1.1.2, ...), 1.2, etc. (the abstract is not included in section numbering). Use this numbering also for internal cross-referencing: do not just refer to "the text." Any subsection may be given a brief heading. Each heading should appear on its own separate line.

#### Introduction

State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

#### Material and methods

Provide sufficient details to allow the work to be

reproduced by an independent researcher. Methods that are already published should be summarized, with the reference indicated. If quoting directly from a previously published method, use quotation marks and also cite the source. Any modifications to existing methods should also be described.

### Theory/calculation

A Theory section should extend, not repeat, the background to the article already dealt with in the Introduction and lay the foundation for further work. In contrast, a Calculation section represents a practical development from a theoretical basis.

### Results

Results should be clear and concise.

### Discussion

This section should explore the significance of the results of the work, not repeat them. A combined Results and Discussion section is often appropriate. Avoid extensive citations and discussion of published literature.

### Conclusions

The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

### Appendices

If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A. 1), Eq. (A. 2), etc.; in a subsequent appendix, Eq. (B. 1) and so on. Similarly, for tables and figures: Table A. 1; Fig. A. 1, etc.

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### Abstract

A concise and factual abstract is required. The abstract should state briefly the purpose of the research, the principal results, and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, References should be avoided, but if essential, then cite the author(s) and year(s). Non-standard or uncommon abbreviations should be avoided, but if essential, they must be defined at their first mention in the abstract itself. The abstract should be fewer than 250 words.

### Highlight

Highlight is mandatory for this journal. It consists of the significance and core findings of the manuscript (maximum 100 words.) the highlight provides readers with an at-a-glance overview of the main findings of your manuscript and lets them quickly identify what they want to read.

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Provide up to five keywords.

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Define abbreviations that are not standard in this field in a footnote to be placed on the first page of the article. Such abbreviations that are unavoidable in the abstract must be defined at their first mention there, as well as in footnotes. Ensure consistency in abbreviations throughout the article.

### Acknowledgements

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 proofreading the article).

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You are requested to identify who provided financial support for the conduct of the research and/or preparation of the article and to briefly describe the role of the sponsor(s), if any, in the study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the article for publication. If the funding source(s) had no such involvement, then this should be stated.

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List funding sources in this standard way to facilitate compliance to funder's requirements:

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### The following are examples of References:

1. Beiser, J. A., Gustin, K. M., Pearce, M. B., Maines, T. R., Zeng, H., Pappas, C., Sun, X. S., Camey P. J., Villanueva, J. M., Stevens, J., Katz, J. M. and Tumpey, T. M. 2013. Pathogenesis and transmission of avian influenza A (H7N9) virus in ferrets and mice. *Nature* 501: 556–559.
2. Hamm, L. L., Alpern, R. J. and Preisig, P. A. 2013. Cellular mechanisms of renal tubular acidification. pp. 1917–1978. In: Seidin and Giebisch's *The Kidney*, 5th ed. (Alpern, R. J., Caplan, M. J. and Moe, O. W. eds.), Elsevier, Amsterdam.
3. Sasaki, H., Sasaki, N., Nishino, T., Nagasaki, K., Kitamura, H., Torigoe, D. and Agui, T. 2014. Quantitative trait loci for resistance to the congenital nephropathy in tensin 2-deficient mice. *PLOS ONE* 9: e99602.
4. Wild, D. G. 2013. *The Immunoassay Handbook*, 4th ed., Elsevier Science & Technology, Oxford.

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