

# 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, Epidemiology, and Infectious Disease.

##### 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

reporting, as current in the countries where the reporting manuscript originated. Examples of these guidelines are the Guidelines for Proper Conduct of Animal Experiments stipulated by the Science Council of Japan, Animals (Scientific Procedures) Act 1986 and associated guidelines in the U.K., European Communities Council Directive of 24 November 1986 (86/609/EEC), and National Institutes of Health Guide for the Care and Use of Laboratory Animals (NIH Publications No. 8023, revised 1978). The authors should conform to the internationally accepted "3R" (Replacement, Reduction, and Refinement) principle in accordance with the Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities compiled by the related ministries, and should clearly indicate in the manuscript that such guidelines have been followed.

### 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.

### Submission Declaration, Verification, and Fee

Submission of an article implies that the work described has not been published previously (except in the form of an abstract or as part of a published lecture or academic thesis or as an electronic preprint), that it is not under consideration for publication elsewhere, that its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and that, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder. Written authorization by personal sources may be required at the editor's discretion.

The submission charge and publication fee are free as a temporary arrangement.

### Changes to authorship

Authors are expected to consider carefully the list and order of authors before submitting their manuscript and then provide the definitive list of authors at the time of the original submission. Any addition, deletion, or rearrangement of author names in the authorship list should be made only before the manuscript has been accepted and only if approved by the journal editor. To request such a change, the editor must receive the following from the corresponding author: (a) the reason for the change in author list and (b) written confirmation (e-mail, letter) from

all authors that they agree with the addition, removal, or rearrangement. In the case of addition or removal of authors, this includes confirmation from the author being added or removed. Only in exceptional circumstances will the editor consider the addition, deletion, or rearrangement of authors after the manuscript has been accepted. While the editor considers the request, publication of the manuscript will be suspended. If the manuscript has already been published in an online issue, any requests approved by the editor will result in a corrigendum.

### Copyright

Upon acceptance of an article, authors will be asked to complete a Copyright Transfer Agreement form. The copyright for any article appearing in this journal will be held by Catalyst Unit, the publisher. An e-mail will be sent to the corresponding author confirming receipt of the manuscript. Authors may reproduce tables of contents or prepare lists of articles including abstracts for internal circulation within their institutions. Permission of the Publisher is required for resale or distribution outside the institution and for all other derivative works, including compilations and translations. If excerpts from other copyrighted works are included, the author(s) must obtain written permission from the copyright owners and credit the source(s) in the article.

### Publication license

The copyrights for all papers published in TRS belong to the Catalyst Unit. Authors are required to sign a license form to grant permission for publishing their works in Catalyst Unit conforming to the Creative Commons Attribution-Non Commercial-No Derivatives 4.0 International Public License.

### Author rights

As an author you (or your employer or institution) have certain rights to reuse your work.

### Open access

Authors can share their research in a variety of different ways. Authors can also self-archive their manuscripts immediately and enable public access from their institution's repository with the final version of the accepted manuscript.

### Submission

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.

## Essential title page information

- Title. Concise and informative. Titles are often used in information-retrieval systems. Avoid abbreviations and formulae where possible.
- Author names and affiliations. Please clearly indicate the given name(s) and family name(s) of each author and check that all names are accurately spelled. You can add your name between parentheses in your own script after the English transliteration. Present the authors' affiliation addresses (where the actual work was done) below the names. Indicate all affiliations with a lowercase superscript letter immediately after the author's name and in front of the appropriate address. Provide the full postal address of each affiliation, including the country name and, if available,

the e-mail address of each author.

- Type of papers. Please identify as Full paper, Letter, or Review article.
- Category. Please choose the appropriate category.
- Corresponding author. Clearly indicate who will handle correspondence at all stages of refereeing and publication, as well as post-publication. This responsibility includes answering any future queries about Methodology and Materials. Ensure that the e-mail address is given and that contact details are kept up to date by the corresponding author.
- Present/permanent address. If an author has moved since the work described in the article was done, or was visiting at the time, a "Present address" (or "Permanent address") may be indicated as a footnote to that author's name. The address at which the author actually did the work must be retained as the main affiliation address. Superscript Arabic numerals are used for such footnotes.

## 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.

## Keywords

Provide up to five keywords.

## Abbreviations

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).

## Role of the funding source

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.

## Formatting of funding sources

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

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions of the program or type of grants and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding. If no funding has been provided for the research, please include the following sentence: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

## Footnotes

Footnotes should be used sparingly. Number them consecutively throughout the article. Many word processors build footnotes into the text, and this feature may be used. Should this not be the case, indicate the position of footnotes in the text and present the footnotes themselves separately at the end of the article.

## Artwork

### Electronic artwork

- Make sure you use uniform lettering and sizing of your original artwork.
- Preferred fonts: Arial (or Helvetica), Times New Roman (or Times), Symbol, Courier
- Number the illustrations according to their sequence in the text.
- Use a logical naming convention for your artwork files.
- Indicate per figure if it is a single-, 1.5-, or 2-column fitting image.
- For Word submissions only, you may still provide figures and their captions, and tables within a single file at the revision stage.

## Color artwork

Please make sure that artwork files are in an acceptable format (TIFF (or JPEG), EPS (or PDF), or MS Office files) and with the correct resolution.

## Figure captions

Ensure that each illustration has a caption. A caption should comprise a brief title (not on the figure itself) and a description

of the illustration. Keep text in the illustrations themselves to a minimum but explain all symbols and abbreviations used.

## Tables

Please submit tables as editable text and not as images. Each term or phrase should begin with a capital letter. Tables can be placed either next to the relevant text in the article or on separate page(s) at the end. Number tables consecutively in accordance with their appearance in the text and place any table notes below the table body. Reference to footnotes should be designated by symbols in the order a), b), c). Be sparing in the use of tables and ensure that the data presented in them do not duplicate results described elsewhere in the article. Please avoid using vertical rules and shading in table cells.

## Abbreviations, Units, and Nomenclature

Scientific terms for animals, plants, and microorganisms must be italicized. Abbreviations should be written in parentheses after spelling out the term in full at the first appearance in the manuscript. Arabic numerals should be used for quantities. Units and abbreviations should conform to the following examples: M, mM,  $\mu$ M, N, %, m, cm, mm,  $\mu$ m, nm, pm,  $\text{cm}^2$ , l, ml, kg, g, mg,  $\mu$ g, ng, pg, hr, min, sec, msec, rpm, Hz, Bq, mBq,  $\mu$ Bq, kBq, cpm, dpm, ppm, °C, J, KJ, lux, CPE, LD. Nomenclature used in the manuscript should be appropriately given in accordance with the rules and guidelines of international nomenclature. Nomenclature used for chemical compounds shall be in accordance with the nomenclature rules formulated by International Union of Pure and Applied Chemistry (IUPAC). Alternatively, naming may conform to the nomenclature in the index of Chemical Abstracts or the Ring index. The scientific name of animals used in animal experimentations should be given.

## References

References should be cited in the text as numbers in square brackets in the order of appearance (e.g., [1, 3–5, 7]). References should be listed in the reference list by these numbers. Only articles that have been published or are in press should be included in the references. Unpublished results or personal communications should be cited as such in the text.

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.

#### Citation in text

Please ensure that every reference cited in the text is also present in the reference list (and vice versa). Any references cited in the abstract must be given in full. Unpublished results and personal communications are not recommended in the reference list, but may be mentioned in the text. If these references are included in the reference list, they should follow the standard reference style of the journal and should include a substitution of the publication date with either "Unpublished results" or "Personal communication." Citation of a reference as "in press" implies that the item has been accepted for publication.

#### Web references

As a minimum, the full URL should be given and the date when the reference was last accessed.

#### Video

TRS can accept video material and animation sequences to support and enhance your scientific output. Authors who have video or animation files that they wish to submit with their article are strongly encouraged to include links to these within the body of the article.

#### Supplementary material

Supplementary material, such as applications, images, and sound clips, can be published with your article to enhance it. Submitted supplementary items are published exactly as they are received (Excel or PowerPoint files will appear as such online). Please submit your material together with the article and supply a concise, descriptive caption for each supplementary file. If you wish to make changes to supplementary materials during any stage of the review process, please make sure to provide an updated file. Do not annotate any corrections on a previous version. Please switch off the "Track Changes" option in Microsoft Office files as these will appear in the published version.

### AFTER ACCEPTANCE

#### Proof correction

Corresponding authors will receive an e-mail with an attachment file. All instructions for proofing will be given in the e-mail we send to authors. We will do everything possible to get your article published quickly and accurately. Please use this proof only for checking the typesetting, editing, and completeness and correctness of the text, tables, and figures. Significant changes to the article as accepted for publication will only be considered at this stage with permission from the editor. It is important to ensure that all corrections are sent back to us in one communication. Please check carefully before replying, as inclusion of any subsequent corrections cannot be guaranteed. Proofreading is solely the responsibility of the authors.