



Article types and specifications

Therapeutic Innovation & Regulatory Science publishes the following article types:

- Research Article
- Review Article
- Analytical Report
- Editorial
- Commentary
- Letter to the Editor
- Correction

Article Type	Abstract*	Word Count**	Description	References (maximum)
Research Article	Yes, structured.	5,000	The journal publishes original research that strives to advance medical product discovery, development, regulation, and use in order to convert biomedical science into practical solutions to advance human health. For clinical trials, see “Clinical trial registration” and “Other files: Reporting guidelines” sections below.	No limit.
Review Article	Yes, unstructured, unless a systematic review or meta-analysis.	5,000	Comprehensive, significant, critical, and analytical reviews which include essential information on a well-delineated subject will be considered. Reviews must synthesize and critically evaluate available data rather than simply describing the findings.	No limit.
Analytical Report	Yes, unstructured.	3,000	Analytical reports highlight significant technical/methodologic advances that are of value and interest to the broad readership of the journal. These may,	No limit.

			for example, include outcomes of working groups exploring new methodologies across the spectrum of drug development, evaluation, regulation, and communication. These are definitive reports of findings of high impact, significance, and timeliness and import to not only the TIRS readership but all those involved in the medical product development process. Analytical reports follow similar author instructions to TIRS Research Articles.	
Editorial	Yes, unstructured.	1,500	Commentaries from the TIRS Editor-in-Chief and Associate Editors	No limit.
Commentary	Yes, unstructured.	1,500	Commentaries will be written by acknowledged authorities in their fields (often by invitation, although all such experts are encouraged to submit manuscripts in this category). The goal of this article type is to allow the author more freedom than is usually available to express personal insights, views on the likely development of his/her field of study, and perspectives that may influence this development to the benefit of patients.	No limit.
Letter to the Editor	No abstract necessary.	500-1,000	Letters may address articles published in the journal, or provide thoughts and insights on a specific topic not directly related to a specific publication in the journal. In the first case, they should be no longer than 500 words of text. The author(s) of the original article will be given the opportunity to reply to letters in a response of similar length. To keep discussion timely, letters should be received relatively soon after the publication of the original article. In the second case, letters should address a topic of timely interest and be no longer than 1000 words.	Maximum five references.
Correction	Correction requests should be sent to the editorial office with proposed correction text. See below for our correction policies.			

*Abstract should not exceed 250 words.

**Word count includes the abstract and full text, but not references, figures, or tables.

Contact for help with submissions: *Therapeutic Innovation & Regulatory Science* Managing Editor contact: [Sandra Blumenrath](#), PhD, Managing Editor for *TIRS*, Scientific Communications, Drug Information Association (DIA).

Submission order and checklist

Authors can use the below for a Submission Checklist. All submissions should be formatted in the following order. For further information on each section, see the descriptions of each, immediately below.

1. Article File* (Must contain items a-l.)
 - a. Title page containing

1. Title
2. List of authors and affiliations, including the full postal and email address of the corresponding author. No phone or fax numbers are required.
3. Five to six key words
- b. Abstract (See above Article Type Specifications for directions)
- c. Introduction
- d. Materials and Methods

- e. Results
 - f. Discussion
 - g. Conclusion
 - h. Funding statement
 - i. Conflict of Interest statement
 - j. Author contributions (mandatory) for all authors
 - k. References (listed by number, in order of appearance)
 - l. Figure legends (Figures should be uploaded as separate attachments; permission for any which are not original should be obtained by authors)
2. Tables
 3. Figures (See “Style, Figures, and Supplementary Information” section below)
 4. Supplemental material (Will be published online only. See “Style, Figures, and Supplementary Information” section below.)
 5. Other: Reporting guidelines (See “Other files: Reporting guidelines” section)

A cover letter is not required, but the authors may provide a cover letter if they wish to convey information to the editor or the editorial office.

Description of each section

Title page

The running head for a manuscript will be the shortened manuscript title followed by an ellipsis.

Keywords

The journal will publish 5-6 keywords. However, to ensure that your manuscript is easily searchable in PubMed and other repositories, be sure to include any relevant keywords in the title or abstract of your manuscript.

Introduction

The introduction should assume that the reader is knowledgeable in the field and should therefore be brief; it can include a short historical review where desirable. It should also include the study objective.

Methods

This section should contain sufficient detail, so that all experimental procedures can be reproduced, and include references. Methods, however, that have been published in detail elsewhere should not be described in detail. Authors should provide the name of the manufacturer and their location for any specifically named equipment and instruments, and all drugs should be identified by their pharmaceutical names, with their trade name, if relevant, in parentheses following, at first use. Please carefully read the “Editorial Policies” section for information about animal handling, informed consent, and IRB approval.

Results and Discussion

The Results section should briefly present the experimental data in text, tables or figures. Tables and figures should not be described extensively in the text. The Discussion should focus on the interpretation and the significance of the findings with concise objective comments that describe their relation to other work in the area. It should not repeat information in the results.

Conclusions

The conclusions section should highlight the main conclusion(s), stating the answer to the study objective. The Conclusions section should be a distinct section.

Funding statement

The Funding section is mandatory. Authors must declare sources of study funding including sponsorship (e.g. university, charity, commercial organization) and sources of material (e.g. novel drugs) not available commercially. See the Editorial Policy section for detailed information and requirements on this section. This section should also include, if desired, special thanks or dedications. Work done by a contributor or medical writer that does not qualify him/her for authorship, but which warrants acknowledgement, should be noted here.

Conflict of Interest statement

Authors must disclose here any financial interests in relation to the work described. This information must be included at this stage and will be published as part of the paper. See the Editorial Policy section for detailed information and requirements on this section.

Author Contributions

A statement outlining each author’s contributions is mandatory. In order to meet requirements of authorship, each author must have contributed to at least one of the aspects below. The ICMJE and *Therapeutic Innovation & Regulatory Science* considers authorship to be based on the following four criteria:

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- Final approval of the version to be published; and
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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References

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Include all authors up to three. If there are more than three authors, list the first three followed by “et al.” Periodical abbreviations should follow those used by *Index Medicus*. Number all references cited in the text first; if additional references are cited in figure legends and tables, add them to the end of the reference list.

Examples for references are below:

Journal

Lender D Jr, Arauz-Pacheco C, Breen LM III, et al. A double-blind comparison: the effects of amlodipine and enalapril on insulin sensitivity in hypertensive patients. *Am J Hypertens*. 1999;12:252–298.

Goodman RP, Chung DC. Clinical genetic testing in gastroenterology. *Clin Transl Gastroenterol*. 2016;7:e167. <https://www.nature.com/articles/ctg201623>. Accessed 14 June 2017. **[URL and access date not required.]**

Book

Baron EJ, Chang RS, Howard DH, et al. *Medical microbiology: a short course*. New York: Wiley-Liss; 1994.

Elias M, Elias P. Motivation and activity. In: Birren JE, Schaie KE, editors. *Handbook of the psychology of aging*. 3rd ed. Amsterdam, The Netherlands: Elsevier; 1967. p. 357–359.

Meeting

Mickey J, Speers EC. Results of the PRAISE trial. Paper presented at the 7th European meeting on hypertension, Hoboken, NJ, 16–18 June 1995.

Website

National Institute of Neurological Disorders and Stroke. NINDS Stroke Information Page. <http://www.ninds.nih.gov/disorders/stroke/stroke.htm>. Accessed 13 April 2007. **[Access date not required.]**

Thesis/ Dissertation

Wilson TW. Genetic variation and prostate cancer. Dissertation, Harvard University, 1999.

Patent

23andMe. Gamete donor selection based on genetic calculations. US patent 8,543,339, 24 September 2013. **[Name and date of patent not required]**

Preprint

Babichev, S. A., Ries, J. & Lvovsky, A. I. Quantum scissors: teleportation of single-mode optical states by means of a nonlocal single photon. Preprint at <http://arxiv.org/abs/quant-ph/0208066> (2002).

Note: Personal communications should simply be referred to in the text (“Brown et al., personal communication”); the authors must obtain permission from the individual concerned to quote his/her unpublished work.

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For editors and reviewers to accurately assess the work presented in your manuscript, you need to ensure the English language is of sufficient quality to be understood. If you need help with writing in English, you should consider:

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STYLE, FIGURES, AND SUPPLEMENTARY INFORMATION

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- Text should be double spacing with a wide margin
- Use a common word-processing package (such as Microsoft Word or LaTeX) for the text. Embed tables converted into images at the end of the Word document, or as a separate file in whichever program you used to generate them
- If you submit raw data, this can be done in Excel, or tab/comma delimited format

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For more information about reporting guidelines, contact Managing Editor [Sandra Blumenrath](#), PhD. Please also visit the "Research data policy" and "Clinical trials registration" sections below.

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