

Instructions to the Authors

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About the Journal



Drug Development and Therapeutics, a publication of Organization of Pharmaceutical Unity with BioAllied Sciences (OPUBS), is a peer-reviewed online journal with Semiannual print on demand compilation of issues published. The journal's full text is available online at <http://www.ddtjournal.org>. The journal allows free access (Open Access) to its contents and permits authors to self-archive final accepted version of the articles on any OAI-compliant institutional / subject-based repository. The journal does not charge for submission but there are charges for processing or publication of accepted manuscripts.

Scope of the journal



The Drug Development and Therapeutics journal publishes original research work, review articles and commentary on contemporary pharmaceutical and clinical research issues. The scope of the journal covers various aspects of drug development and therapeutics including natural products, target validation, targeted drug discovery, High-throughput screening, Combinatorial chemistry, and library design, Drug delivery, ADME/Tox, PK/PD, pharmacology, Pharmaceutical formulation, Genomics and proteomics, molecular modeling, Bioinformatics, vaccines, clinical trial evaluations. Along with quantitative research work, this journal also invites case studies encompassing the area of drug development and therapeutics from industry, clinicians and academia. The journal will cover technical and clinical studies related to health, ethical and social issues in field of Pharmaceutical sciences, medicinal/analytical sciences, Biotechnology, Bioallied sciences. Articles with clinical interest, drug synthesis and development and implications will be given preference.

The Editorial Process



A manuscript will be reviewed for possible publication with the understanding that it is being submitted to Drug Development and Therapeutics alone at that point in time and has not been published anywhere, simultaneously submitted, or already accepted for publication elsewhere. The journal expects that authors would authorize one of them to correspond with the Journal for all matters related to the manuscript. All manuscripts received are duly acknowledged. On submission, editors review all submitted manuscripts initially for suitability for formal review. Manuscripts with insufficient originality, serious scientific or technical flaws, or lack of a significant message are rejected before proceeding for formal peer-review. Manuscripts that are unlikely to be of interest to the Drug Development and Therapeutics readers are also liable to be rejected at this stage itself.

Manuscripts that are found suitable for publication in Drug Development and Therapeutics are sent to two or more expert reviewers. During submission, the contributor is requested to provide names of two or three qualified reviewers who have had experience in the subject of the submitted manuscript, but this is not mandatory. The reviewers should not be affiliated with the same institutes as the contributor/s. However, the selection of these reviewers is at the sole discretion of the editor. The journal follows a double-blind review process, wherein the reviewers and authors are unaware of each other's identity. Every manuscript is also assigned to a member of the editorial team, who based on the comments from the reviewers takes a final decision on the manuscript. The comments and suggestions (acceptance/ rejection/ amendments in manuscript) received from reviewers are conveyed to the corresponding author. If required, the author is requested to provide a point by point response to reviewers' comments and submit a revised version of the manuscript. This process is repeated till reviewers and editors are satisfied with the manuscript.

Manuscripts accepted for publication are copy edited for grammar, punctuation, print style, and format. Page proofs are sent to the corresponding author. The corresponding author is expected to return the corrected proofs within three days. It may not be possible to incorporate corrections received after that period. The whole process of submission of the manuscript to final decision and sending and receiving proofs is completed online. To achieve faster and greater dissemination of knowledge and information, the journal publishes articles online as 'Ahead of Print' immediately on acceptance.

Clinical trial registry



Drug Development and Therapeutics favors registration of clinical trials and is a signatory to the Statement on publishing clinical trials in Indian biomedical journals. Drug Development and Therapeutics would publish clinical trials that have been registered with a clinical trial registry that allows free online access to public. Registration in the following trial registers is

acceptable: <http://www.ctri.in/>; <http://www.actr.org.au/>; <http://www.clinicaltrials.gov/>; <http://isrctn.org/>; <http://www.trialregister.nl/trialreg/index.asp>; and <http://www.umin.ac.jp/ctr>. This is applicable to clinical trials that have begun enrollment of subjects in or after June 2008. Clinical trials that have commenced enrollment of subjects prior to June 2008 would be considered for publication in Drug Development and Therapeutics only if they have been registered retrospectively with clinical trial registry that allows unhindered online access to public without charging any fees.

Authorship Criteria

Authorship credit should be based only on substantial contributions to each of the three components mentioned below:

1. Concept and design of study or acquisition of data or analysis and interpretation of data;
2. Drafting the article or revising it critically for important intellectual content; and
3. Final approval of the version to be published.

Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Each contributor should have participated sufficiently in the work to take public responsibility for appropriate portions of the content of the manuscript. The order of naming the contributors should be based on the relative contribution of the contributor towards the study and writing the manuscript. Once submitted the order cannot be changed without written consent of all the contributors. The journal prescribes a maximum number of authors for manuscripts depending upon the type of manuscript, its scope and number of institutions involved (vide infra). The authors should provide a justification, if the number of authors exceeds these limits.

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Contributors should provide a description of contributions made by each of them towards the manuscript. Description should be divided in following categories, as applicable: concept, design, definition of intellectual content, literature search, clinical studies, experimental studies, data acquisition, data analysis, statistical analysis, manuscript preparation, manuscript editing and manuscript review. One or more author should take responsibility for the integrity of the work as a whole from inception to published article and should be designated as 'guarantor'.

Conflicts of Interest/ Competing Interests

All authors must disclose any and all conflicts of interest they may have with publication of the manuscript or an institution or product that is mentioned in the manuscript and/or is important to the outcome of the study presented. Authors should also disclose conflict of interest with products that compete with those mentioned in their manuscript.

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[1] **Title Page/First Page File/covering letter:**

This file should provide

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Preparation of Manuscripts



Manuscripts must be prepared in accordance with "Uniform requirements for Manuscripts submitted to Biomedical Journals" developed by the International Committee of Medical Journal Editors (October 2008). The uniform requirements and specific requirement of Drug Development and Therapeutics are summarized below. Before submitting a manuscript, contributors are requested to check for the latest instructions available. Instructions are also available from the website of the journal (<http://www.ddtjournal.org>) and from the manuscript submission site <http://www.journalonweb.com/ddt>.

Drug Development and Therapeutics accepts manuscripts written in American English.

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Types of Manuscripts



Original articles:

These include randomized controlled trials, intervention studies, studies of screening and diagnostic test, outcome studies, cost effectiveness analyses, case-control series, and surveys with high response rate. The text of original articles amounting to up to 3000 words (excluding Abstract, references and Tables) should be divided into sections with the headings Abstract, Key-words, Introduction, Material and Methods, Results, Discussion, References, Tables and Figure legends.

Introduction: State the purpose and summarize the rationale for the study or observation.

Materials and Methods: It should include and describe the following aspects:

Ethics: When reporting studies on human beings, indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 2000 (available at http://www.wma.net/e/policy/17-c_e.html). For prospective studies involving human participants, authors are expected to mention about approval of (regional/ national/ institutional or independent Ethics Committee or Review Board, obtaining informed consent from adult research participants and obtaining assent for children aged over 7 years participating in the trial. The age beyond which assent would be required could vary as per regional and/ or national guidelines. Ensure confidentiality of subjects by desisting from mentioning participants' names, initials or hospital numbers, especially in illustrative material. When reporting experiments on animals, indicate whether the institution's or a national research council's guide for, or any national law on the care and use of laboratory animals was followed. Evidence for approval by a local Ethics Committee (for both human as well as animal studies) must be supplied by the authors on demand. Animal experimental procedures should be as humane as possible and the details of anesthetics and analgesics used should be clearly stated. The ethical standards of experiments must be in accordance with the guidelines provided by the CPCSEA and World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Humans for studies involving experimental animals and human beings, respectively). The journal will not consider any paper which is ethically unacceptable. A statement on ethics committee permission and ethical practices must be included in all research articles under the 'Materials and Methods' section.

Study design:

Selection and Description of Participants: Describe your selection of the observational or experimental participants (patients or laboratory animals, including controls) clearly, including eligibility and exclusion criteria and a description of the source population. *Technical information:* Identify the methods, apparatus (give the manufacturer's name and address in parentheses), and procedures in sufficient detail to allow other workers to reproduce the results. Give references to established methods, including statistical methods (see below); provide references and brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

Reports of randomized clinical trials should present information on all major study elements, including the protocol, assignment of interventions (methods of randomization, concealment of allocation to treatment groups), and the method of masking (blinding), based on the CONSORT Statement (<http://www.consort-statement.org>).

Reporting Guidelines for Specific Study Designs

Initiative	Type of Study	Source
CONSORT	Randomized controlled trials	http://www.consort-statement.org
STARD	Studies of diagnostic accuracy	http://www.consort-statement.org/stardstatement.htm
QUOROM	Systematic reviews and meta-analyses	http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf
STROBE	Observational studies in epidemiology	http://www.strobe-statement.org
MOOSE	Meta-analyses of observational studies in epidemiology	http://www.consort-statement.org/Initiatives/MOOSE/moose.pdf

Statistics: Whenever possible quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Authors should report losses to observation (such as, dropouts from a clinical trial). When data are summarized in the Results section, specify the statistical methods used to analyze them. Avoid non-technical uses of technical terms in statistics, such as 'random' (which implies a randomizing device), 'normal', 'significant', 'correlations', and 'sample'. Define statistical terms, abbreviations, and most symbols. Specify the computer software used. Use upper italics (P 0.048). For all P values include the exact value and not less than 0.05 or 0.001. Mean differences in continuous

variables, proportions in categorical variables and relative risks including odds ratios and hazard ratios should be accompanied by their confidence intervals.

Results: Present your results in a logical sequence in the text, tables, and illustrations, giving the main or most important findings first. Do not repeat in the text all the data in the tables or illustrations; emphasize or summarize only important observations. Extra- or supplementary materials and technical detail can be placed in an appendix where it will be accessible but will not interrupt the flow of the text; alternatively, it can be published only in the electronic version of the journal.

When data are summarized in the Results section, give numeric results not only as derivatives (for example, percentages) but also as the absolute numbers from which the derivatives were calculated, and specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Where scientifically appropriate, analyses of the data by variables such as age and sex should be included.

Discussion: Include summary of *key findings* (primary outcome measures, secondary outcome measures, results as they relate to a prior hypothesis); *Strengths and limitations* of the study (study question, study design, data collection, analysis and interpretation); *Interpretation and implications* in the context of the totality of evidence (is there a systematic review to refer to, if not, could one be reasonably done here and now?, what this study adds to the available evidence, effects on patient care and health policy, possible mechanisms); *Controversies* raised by this study; and *Future research directions* (for this particular research collaboration, underlying mechanisms, clinical research).

Do not repeat in detail data or other material given in the Introduction or the Results section. In particular, contributors should avoid making statements on economic benefits and costs unless their manuscript includes economic data and analyses. Avoid claiming priority and alluding to work that has not been completed. New hypotheses may be stated if needed, however they should be clearly labeled as such. About 30 references can be included. These articles generally should not have more than six authors.

Review Articles:

It is expected that these articles would be written by individuals who have done substantial work on the subject or are considered experts in the field. A short summary of the work done by the contributor(s) in the field of review should accompany the manuscript.

The prescribed word count is up to 3000 words excluding tables, references and abstract. The manuscript may have about 90 references. The manuscript should have an unstructured Abstract (250 words) representing an accurate summary of the article. The section titles would depend upon the topic reviewed. Authors submitting review article should include a section describing the methods used for locating, selecting, extracting, and synthesizing data. These methods should also be summarized in the abstract.

The journal expects the contributors to give post-publication updates on the subject of review. The update should be brief, covering the advances in the field after the publication of the article and should be sent as a letter to editor, as and when major development occurs in the field.

Case reports:

New, interesting and rare cases can be reported. They should be unique, describing a great diagnostic or therapeutic challenge and providing a learning point for the readers. Cases with clinical significance or implications will be given priority. These communications could be of up to 1000 words (excluding Abstract and references) and should have the following headings: Abstract (unstructured), Key-words, Introduction, Case report, Discussion, Reference, Tables and Legends in that order.

The manuscript could be of up to 1000 words (excluding references and abstract) and could be supported with up to 10 references. Case Reports could be authored by up to four authors.

Letter to the Editor:

These should be short and decisive observations. They should preferably be related to articles previously published in the Journal or views expressed in the journal. They should not be preliminary observations that need a later paper for validation. The letter could have up to 500 words and 5 references. It could be generally authored by not more than four authors.

Other:

Editorial, Guest Editorial, Commentary and Opinion are solicited by the editorial board.

References

References should be *numbered* consecutively in the order in which they are first mentioned in the text (not in alphabetic order). *Identify references in text*, tables, and legends by Arabic numerals in superscript with square bracket after the *punctuation marks*. *References cited only* in tables or figure legends should be numbered in accordance with the sequence established by the first identification in the text of the particular table or figure. Use the style of the examples below, which are based on the formats used by the NLM *in Index Medicus*. The titles of journals *should be abbreviated* according to the style used in Index Medicus. Use complete name of the journal for non-indexed journals. Avoid using abstracts as references. Information from manuscripts submitted but not accepted should be cited in the text as "unpublished observations" with written permission from the source. Avoid citing a "personal communication" unless it provides essential information not available from a public source, in which case the name of the person and date of communication should be cited in parentheses in the text. The commonly cited types of references are shown here, for other types of references such as newspaper items please refer to ICMJE Guidelines (<http://www.icmje.org> or

http://www.nlm.nih.gov/bsd/uniform_requirements.html).

Articles in Journals

1. Standard journal article (for up to six authors): Parija S C, Ravinder PT, Shariff M. Detection of hydatid antigen in the fluid samples from hydatid cysts by co-agglutination. *Trans. R.Soc. Trop. Med. Hyg.*1996; 90:255–256.
2. Standard journal article (for more than six authors): List the first six contributors followed by *et al.*

Roddy P, Goiri J, Flevaud L, Palma PP, Morote S, Lima N. *et al.*, Field Evaluation of a Rapid Immunochromatographic Assay for Detection of *Trypanosoma cruzi* Infection by Use of Whole Blood. *J. Clin. Microbiol.* 2008; 46: 2022-2027.

1. Volume with supplement: Otranto D, Capelli G, Genchi C: Changing distribution patterns of canine vector borne diseases in Italy: leishmaniosis vs. dirofilariosis. *Parasites & Vectors* 2009; Suppl 1:S2.

Books and Other Monographs

1. Personal author(s): Parija SC. Textbook of Medical Parasitology. 3rd ed. All India Publishers and Distributors. 2008.
2. Editor(s), compiler(s) as author: Garcia LS, Filarial Nematodes In: Garcia LS (editor) Diagnostic Medical Parasitology ASM press Washington DC 2007: pp 319-356.
3. Chapter in a book: Nesheim M C. Ascariasis and human nutrition. In Ascariasis and its prevention and control, D. W. T. Crompton, M. C. Nesbemi, and Z. S. Pawlowski (eds.). Taylor and Francis, London, U.K.1989, pp. 87–100.

Electronic Sources as reference

Journal article on the Internet: Parija SC, Khairnar K. Detection of excretory *Entamoeba histolytica* DNA in the urine, and detection of *E. histolytica* DNA and lectin antigen in the liver abscess pus for the diagnosis of amoebic liver abscess. *BMC Microbiology* 2007, 7:41. doi:10.1186/1471-2180-7-41. <http://www.biomedcentral.com/1471-2180/7/41>

Tables

- Tables should be self-explanatory and should not duplicate textual material.
- Tables with more than 10 columns and 25 rows are not acceptable.
- Number tables, in Arabic numerals, consecutively in the order of their first citation in the text and supply a brief title for each.
- Place explanatory matter in footnotes, not in the heading.
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- Upload the images in JPEG format. The file size should be within 1024 kb in size while uploading.
- Figures should be numbered consecutively according to the order in which they have been first cited in the text.
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Identifying information should not be published in written descriptions, photographs, sonograms, CT scans, etc., and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian, wherever applicable) gives informed consent for publication. Authors should remove patients' names from figures unless they have obtained informed consent from the patients. The journal abides by ICMJE guidelines:

1. Authors, not the journals nor the publisher, need to obtain the patient consent form before the publication and have the form properly archived. The consent forms are not to be uploaded with the cover letter or sent through email to editorial or publisher offices.
2. If the manuscript contains patient images that preclude anonymity, or a description that has obvious indication to the identity of the patient, a statement about obtaining informed patient consent should be indicated in the manuscript.

Sending a revised manuscript



The revised version of the manuscript should be submitted online in a manner similar to that used for submission of the manuscript for the first time. However, there is no need to submit the "First Page" or "Covering Letter" file while submitting a revised version. When submitting a revised manuscript, contributors are requested to include, the 'referees' remarks along with point to point clarification at the beginning in the revised file itself. In addition, they are expected to mark the changes as underlined or colored text in the article.

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- No repetition of data in tables and graphs and in text
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- Figures necessary and of good quality (colour)
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