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EDITORIAL

Peer Review Certifies Quality and Innovation in *Clinical Pharmacology & Therapeutics*

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Abstract

Clinical Pharmacology & Therapeutics (CPT) is an established voice of the discipline, a trusted source of new knowledge showcasing discovery, translation and application of novel therapeutic paradigms to advance the management of patients and populations. Identifying, evaluating, prioritizing and disseminating the best science along the discovery-development-regulatory-utilization continuum are responsibilities shared through peer review. To enhance the uniformity of this essential component of quality assurance and innovation, and maximize the value of the journal and its contents to authors, reviewers, and the readership, we review key concepts concerning peer review as it specifically relates to CPT.

Even if individual researchers are prone to falling in love with their own theories, the broader process of peer review and institutionalized skepticism are designed to ensure that, eventually, the best ideas prevail.

Chris Mooney

Clinical Pharmacology & Therapeutics (CPT) is a recognized, long-standing leader in publishing primary research across the category of "Pharmacy and Pharmacology" defined by International Scientific Indexing Web of Knowledge.[1,2] In part, the journal's ranking reflects the quality of papers selected by peer review for ultimate publication.[3,4] In that regard, the journal reflects the collective wisdom of the discipline's practitioners and their diverse communities of practice, which shape the content through participation in peer review.[5] Given this essential role of peer review as one key element of quality assurance for the content of the journal, this editorial is directed at optimizing the attributes and uniformity of this process, to best position the journal to publish the most impactful papers. In that context, expectations for reviewers are explicitly outlined, to minimize guesswork and maximize the opportunity for learning. In turn, it is anticipated that this will translate into the most informative and constructive reviews, maximizing the value of the process for authors regardless of the disposition of their manuscripts.

Overview of the Peer Review Process for CPT

No one should see how laws or sausages are made. To retain respect for sausages and laws, one must not watch them in the making. The making of laws like the making of sausages, is not a pretty sight.

Otto von Bismarck

In contrast to sausages (but not laws), the process of selecting manuscripts for publication benefits from full and complete transparency. Thus, it is useful here to describe the process of handling submissions to CPT, a procedure which is agnostic to manuscript type. In that context,

beyond the authors and reviewers, there are a number of individuals that comprise the Editorial Team that drives decision making at the journal. The Editor and Deputy Editor in Chief collaborate to create the vision and strategy for overall journal content. They are responsible for leading deliberations and discussions of the Editorial Team and for all final decisions on content. The thirteen Associate Editors are appointed by the Editors in Chief and are selected for their broad and complementary expertise covering the knowledge domains of clinical pharmacology and related disciplines. They are responsible for deliberations and disposition of manuscripts in their area of expertise, including initial evaluations of manuscripts for suitability for review, the selection of reviewers, discussions of manuscripts for publication by the Editorial Team, and recommendations for disposition of papers to the Editors in Chief. Associate Editors also conceive, develop, and implement each of the themes that form the core of each monthly issue of the journal reflecting advances in the field. Finally, the Editorial Team is completed by the Managing Editor and Senior Editorial Coordinator, who coordinate the review process, oversee communications between authors, editors and reviewers, and manage the publication process once final disposition of a manuscript has been determined.

Electronic submission of manuscripts through the journal home page (https://cpt.msubmit.net/cgi-bin/main.plex) triggers an initial series of quality control steps that precede peer review. The Managing Editor and Senior Editorial Coordinator reviews each submission to ensure that it is compliant with the Journal's ***Guide to Authors*** (http://ascpt.onlinelibrary.wiley.com/hub/journal/10.1002(issn)1532-6535/Combined_CPT_Guide_to_Authors.pdf), confirming that it conforms structurally and conceptually to those broad instructions. Deviations from those instructions result in administrative triage of the manuscript back to the authors. Confirmation of suitability for consideration results in the manuscript advancing to the Associate Editor with subject matter expertise in the field aligned with the work under consideration. The Associate Editor reviews the manuscript to determine if it is within the aims and scope of the journal and whether it appears of sufficient potential

impact to warrant external review. This decision tree is designed to provide expedited feedback, within about 48 hours, to permit authors to advance their work to other journals. In that context, the journal recently instituted a new enhanced policy that bypasses this initial triage step, ensuring full review of papers on which a member of the ***American Society for Clinical Pharmacology and Therapeutics*** (ASCPT), the parent Society for the journal, is the senior or communicating author.

Once manuscripts have cleared these initial quality control checkpoints, the Associate Editor identifies multiple (typically 2 to 3) external reviewers to evaluate the paper. Reviewers are selected on the basis of their domain expertise, availability, and previous history of providing timely and high quality reviews. Reviewers are recruited from a number of different sources, including the Journal's dynamic database of reviewers, the paper's bibliography, the Associate Editor's professional network, and searches of the relevant literature (e.g., PubMed). Sometimes, but not always, reviewers suggested by authors are invited to participate. Conversely, identification of reviewers by authors as conflicted, or not preferred, is honored. One key resource for manuscript review includes the extensive journal Editorial Board, comprising more than 70 key thought leaders across communities of practice that encompass the spectrum of clinical pharmacology science and practice. Generally, each manuscript is reviewed by at least one member of the Editorial Board, to provide a level of uniformity across the review process and within the field of study.

Upon receipt of external reviews, generally within 2 weeks, Associate Editors formulate recommendations on manuscript disposition for consideration by Editors in Chief. In some cases, manuscripts are deemed to be of insufficient priority for further considerations and are rejected. Rarely, a manuscript might be deemed suitable for publication, with immediate acceptance. Most manuscripts considered of sufficient interest with appropriate quality and priority require revision. A decision of "minor revision" typically indicates that the Associate Editor is satisfied with major aspects of study design, statistics, analysis, interpretation, and

conclusions and seeks minor additions, points of clarification, positioning the paper in the context of current knowledge in the field, or copy editing. A decision of "major revision" indicates that the Associate Editor has serious concerns about study design, analyses, or interpretation but believes the work could be impactful if those concerns were properly addressed. Commonly, Associate Editors seek the advice of the Editorial Team concerning the disposition of manuscripts, which are discussed in detail with the entire team on semi-monthly editorial teleconferences.

All submissions, regardless of manuscript type, are subjected to the same process outlined above. Revised manuscripts undergo the same initial quality control steps coordinated by the Managing Editor and Senior Editorial Coordinator. Once through this checkpoint, revised manuscripts typically are re-assigned to the Associate Editor who handled the original submission. Generally, papers with an original disposition of "major revision" go back to original reviewers for evaluation and consideration. Papers with an original disposition of "minor revision" may only require review by the Associate Editor to determine a recommendation of acceptability. Editors in Chief make all final decisions on manuscripts.

Expectations of Peer Reviewers

> *If you have no critics you'll likely have no success.*
>
> Malcolm X

CPT seeks to publish original research that represents the highest level of innovation our discipline offers to the scientific enterprise. It strives to highlight work that evolves clinical pharmacology practice or advances the therapeutic management of patients. Peer review is one essential mechanism to achieving those objectives. In that context, it allows subject matter experts to identify the most innovative advances in the field. Also, it validates and certifies that innovation to the readership, and the overarching scientific enterprise. Moreover, the iterative process of review-and-revise maximizes the overall quality of the science, ensuring the integrity

of the data, the appropriateness of the analytics, the value of the presentation, the boundaries of interpretation, and the transparency of limitations.

An informative review of an original research paper provides the Editorial Team with a complete and detailed analysis of the importance and scientific validity of the study. Importance of the study reflects the quality and novelty of the science, and whether the work will highly impact readers. On the review template, ***Quality of Science and Novelty*** is quantified on a scale of 1-5 (highest score=best); ***Will*** (the work) ***Highly Impact Readers*** is assessed through direct comments from Reviewers. It is essential to consider that this Reviewer assessment of impact is one of the elements of greatest value to the Editorial Team in decisions about manuscript disposition. This assessment of impact addresses the key objectives of the journal to publish the most innovative science that will change the practice of clinical pharmacology and/or advance patient care.

An ideal review will provide comprehensive ***Remarks to the Authors*** that are constructive, specific, and focused on improving the science. A very brief introductory paragraph recapitulating the major goals, observations, and conclusions of the study will communicate to authors and editors that the paper was thoroughly assessed and understood. A fair and balanced assessment of strengths and weaknesses builds confidence and validity into the review. Categorization into major and minor issues provides a framework for authors for their revisions, and for editors to assess relative quality, innovation, and impact. Comments are most helpful to authors and editors when they are highly specific and constructive, and least helpful when they are vague and ambiguous. There are a few elements that deserve special attention. Manuscripts are often rejected based on the assessment by editors and reviewers that the impact of the work does not rise to the level of priority sought by the journal. As an example, studies of only limited incremental value, e.g., a routine phase I study of another 'me-too' calcium channel blocker is typically not well-suited for the journal. Also, manuscripts are often rejected because of inadequacies of study design, study population, analytical methodologies,

or statistical approaches, all key areas for reviewer attention and focus. Moreover, manuscripts are often rejected because the study, knowingly or unknowingly, replicates previously published work. In that context, it is helpful for Reviewers to perform a brief search of the literature to confirm the novelty of the work under consideration.

Beyond these open comments to the authors, Reviewers should always provide confidential ***Remarks to the Editor***. These should summarize the major strengths and weaknesses of the paper and present in a succinct fashion the rationale for recommendations concerning the disposition of the manuscript. These confidential comments are extremely useful to the Editorial Team for informed decision-making because they represent the unambiguous analyses of Reviewers which are not encumbered by collegial necessity. However, it is critically important that confidential comments in Remarks to Editor are aligned, directionally, with ***Remarks to the Authors*** so that authors are not receiving mixed and confusing messages about their manuscripts.

All submissions, regardless of manuscript type, are subjected to peer-review, and the principles outlined above for Reviewers apply to State of the Art articles, Reviews, Commentaries, and all other formats in the journal. However, for these other formats, it is important that Reviewers are familiar with the requirements of these articles outlined in the ***Guide to Authors***, to understand their structural constraints and more realistically shape their reviews. For example, requesting authors to add numerous references to a Commentary, which has an absolute limit of 10 citations, only serves to frustrate authors who are unable to comply with the request.

Finally, some general comments are offered here concerning Reviewer etiquette. It is essential for Reviewers to provide feedback to authors that both follow collegial etiquette and offer constructive criticism. In that context, science is a collaborative endeavor, and Reviewers should provide comments to authors like they would prefer to receive for their own manuscripts. Even if comments are negative, it is essential to remain highly professional. Of course, Reviewers always should be unambiguous, honest, and straightforward about

manuscript issues. But, it is never appropriate for a review to contain derogatory statements or ad hominem attacks personally targeting the authors. This is especially important in that the Editorial Team never edits Reviewer ***Remarks to the Authors***, and always provides them unmodified to authors, in their original fashion. We are a tightly knit community of practitioners and our goal at the journal is to promote the success of our colleagues and of the field as a whole. Also, the journal is international in scope, serving a global discipline and readership, and most submissions originate from authors that are outside the United States. In that context, some manuscripts have issues with English as a second language. Reviewers are encouraged to focus on the major concepts of manuscripts, in order to be able to identify highly promising work unencumbered by any linguistic deficits. Indeed, the Managing Editor has resources to which authors can be directed to resolve issues of language in an otherwise important paper. Finally, Reviewers are strongly encouraged to submit reviews on time, or even early. Again, we have all suffered through review delays for our own work and know too well the frustrations these delays represent.

Conclusions

The position of CPT as one of the leading journals publishing original research in clinical pharmacology and human therapeutics in large part reflects the role of Reviewers in identifying the most innovative, cutting-edge work on the leading front of the discipline. It is their ability to identify work that will change the practice of clinical pharmacology, or advance the therapeutic management of patients, that sets the journal apart from other periodicals in the field. In that context, their efforts elevate the journal to the vaunted position as the authoritative voice of the discipline of clinical pharmacology and therapeutics. We look forward to continuing our work with this highly talented group of practitioners at the vanguard of science-driven practice advancement.

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