

Information for Authors

Appplied Clinical Trials welcomes manuscripts that provide sound, practical ideas and advice about the day-to-day activities of readers involved in the clinical trials process. Appropriate topics include: recruiting and working with human subjects; managing data; dealing with IRBs and ethical issues; training, educating employees; FDA and International compliance, GCP guidelines, and partnerships strategies between sponsors, CROs, labs, and IT. Articles should engage and inform readers involved in all phases of trials and with diverse levels of professional knowledge and expertise. We do not accept advertorial articles or articles that are overly promotional toward a company or its product.

Who reads *Applied Clinical Trials*?

Each month, more than 18,000 clinical trials professionals in about 40 countries receive *Applied Clinical Trials*, and approximately 15,575 people per month in 2009 accessed articles at our Web site www.appliedclinicaltrialsonline.com. Readers are involved in all phases of clinical research. They are professionals, executives, and managers with pharmaceutical, biologics, and biopharmaceutical companies; contract research organizations; academic, medical, and research institutions; clinical study sites; clinical laboratories; and state, provincial, and national regulatory agencies. *Applied Clinical Trials* readers design and develop clinical study plans; they manage, coordinate, and monitor trials. They are involved in every aspect of clinical research, including QA/QC, data management, project management, academic research and teaching, and corporate management.

Who writes for *Applied Clinical Trials*?

Clinical trials professionals write for *Applied Clinical Trials* to share their experience and expertise with their colleagues and to explain innovative approaches to common problems. Industry observers describe research trends and developments. Regulators and regulatory affairs professionals outline regulations in individual countries and the harmonized regulatory guidelines developed by ICH. Suppliers of clinical trials products and services who submit manuscripts need to take particular care to avoid any appearance that their article is an attempt to sell products or services.

What types of articles does *Applied Clinical Trials* publish?

Peer-Review feature articles are fact-based, how-to articles about some specific aspect of conducting a clinical trial—for example, preparing for an audit, negotiating a contract, recruiting subjects, or selecting an investigative site. The best articles on conducting trials in a specific country include information not only on regulations, but also on cultural and logistical issues. Review articles can update readers on the state of the art or on industry trends. Although not necessarily focused on the details of a single project, review articles should still emphasize practical

information: Why are various techniques or approaches successful or unsuccessful in certain situations? What does this trend mean for readers? How can clinical trials professionals use the information in their own work? Feature articles should be about 2000 to 3000 words, with perhaps 3 carefully selected graphic illustrations such as charts, tables, photos, and diagrams that support the topic. These articles should be referenced to previously published articles on the subject.

Letters to the Editor may respond to published articles, comment on issues of significance to clinical trials professionals, or open a debate on a topic of interest to *Applied Clinical Trials* readers. Each letter should address one topic and be limited to 350 words.

A Closing Thought is a thought piece of 500 to 575 words that addresses an important issue in the world of clinical trials. The purpose is to provide fresh views or ideas for the readers.

Appliedclinicaltrialsonline.com

More and more publications are moving to an online, Web-based content delivery model, and we are no exception. While a magazine printed on paper is still the most portable and design-friendly way to read information, there is no denying the power of the Web for information and research gathering. While a magazine is limited in the number of pages it can comfortably print, our Web presence is limitless to the content it can provide.

To that end, this section describes how you can be published on appliedclinicaltrialsonline.com.

Peer-Reviewed Online Exclusives. This is the same process as our peer-reviewed feature article for the magazine, which is detailed later in this guide. However, instead of waiting for the accepted article to be published, the article is posted online with our identifiable peer-review icon. Only articles that go through our peer-review can be identified with this icon.

The benefits of appearing online include timeliness, metrics gathering (to know exactly how many people accessed your article and how long they spend viewing it), and additional reach beyond our print subscribers.

Press releases. We regularly accept press releases, which are posted to our Web site as News on a daily basis.

Articles. We also consider for publishing articles that are written without the benefit of peer-review. These articles are usually shorter, do not discuss a topic as in-depth, with the references or graphics needed to support a peer-reviewed article. These articles still highlight an issue of importance in the clinical trials industry. Authors wishing to submit an article for online publication should take into account that their topic should not be promotional, should not be an opinion, and will require both acceptance by the Editor and a signed license agreement for posting.

Opinion. Opinion pieces considered for online posting are labeled as such, should explore and explain your standpoint, and/or clarify your position.

How quickly can an article be published?

Getting an article from idea to publication takes approximately six months. The typical time between an initial inquiry and a published magazine article is six to eight months. Timely subjects of immediate interest may occasionally be rushed through in less time. Articles may be slated to appear online prior to a scheduled magazine appearance and online articles may not yet be peer-reviewed.

What about payment?

Applied Clinical Trials does not pay for articles, but publication in the magazine or online has other potential payoffs for authors. Having an article appear in *Applied Clinical Trials* or www.appliedclinicaltrials.com may enhance a writer's professional recognition and contribute to career advancement. It indicates that the author's company, agency, site, or institution appreciates the value of information exchange that can advance the pharmaceutical industry in general and clinical trials professionals in particular. Contributing an article to *Applied Clinical Trials* also gives organizations and individuals an opportunity to demonstrate their clinical trials knowledge and expertise. As articles are archived online, they remain as reference and research resource.

License

Applied Clinical Trials generally considers only original unpublished manuscripts. Submissions may, however, be based on material originally developed for another purpose, such as a presentation for a professional conference. Articles are considered for publication with the understanding that they are not under consideration for publication elsewhere, and that they have not been published elsewhere, even online. White Papers are considered promotional and pre-printed material and will not be accepted for publication as an article. When a manuscript is accepted for publication, the license to reproduce the article in other print or on-line media (for example, at our Web site at www.appliedclinicaltrials.com or links to newsletters that we produce) is shared by *Applied Clinical Trials*, its parent company Advanstar Communications and the Author. Authors retain the right to prepare derivative works or to revise, adapt, or orally present their articles elsewhere. Authors must not violate or infringe on any copyrights of others when submitting materials to *Applied Clinical Trials*. Permission to reprint articles must be obtained from *Applied Clinical Trials* through our reprint services at nthome@advanstar.com.

Ideas, queries, outlines

The editors recognize that writing for magazines or the Web is rarely the specialty or first priority of an *Applied Clinical Trials* author. These guidelines and our review and revision process are designed to make your writing project as painless as possible. The best first step is to email the Editor Lisa Henderson or the European Editor Philip Ward about your idea. You can then follow up with a brief outline via email that clearly describes the content and structure of the proposed article. Be sure your outline focuses on what *Applied Clinical Trials* readers will learn and how they can use it more effectively.

These early steps are important to writers. Before you invest time and energy in a finished manuscript, you can find out whether the magazine already has a similar article on hand or whether the Editor has a specific approach in mind for your topic. You may even discover that the Editor-in-Chief has been looking for someone with your special expertise to write an article on a specific topic. When an idea fits into the magazine's editorial plans, a manuscript deadline will be suggested based primarily on the author's schedule and obligations. Assignment of a deadline is no guarantee that an article will be accepted or published. It means only that the Editor sees potential.

Note that *Applied Clinical Trials* does not publish article abstracts.

Writing, preparing, and submitting a manuscript

Authors are responsible for all statements in their work and for obtaining permission to use previously published tables and illustrations.

Consider house style and writing style. *Style*, in the context of writing and editing, has two distinct meanings. *House style* is the set of rules for spelling, punctuation, abbreviations, capitalization, and other details that a publisher has adopted for consistency. *Applied Clinical Trials* house style, for example, forbids the use of certain abbreviations, dictates that spelling conform to *Webster's Third International Dictionary*, and requires that numbers above nine be expressed in numerals. These are all matters that the editorial staff handles during copy editing, but they often elicit questions from authors who are examining proofs.

Writing style refers to the writer's turn of phrase, the tone of the author's "voice"—academic, technical, informal and anecdotal, or straightforward and businesslike.

In general, manuscripts submitted to *Applied Clinical Trials* should be written in a straightforward, businesslike style that presents factual information in a clear and orderly manner. You may, however, introduce anecdotal elements that help illustrate points or convey a fresh and candid impression of the circumstances in which events took place. The paper should be detailed enough to ensure that readers can use the information, but not so technical that only specialists can understand it.

Engage the readers. It is important to remember that the magazine's readers live in more than 40 countries around the world. Write in clear, unambiguous English, using active voice wherever possible. In the first two or three paragraphs, tell readers why and how reading the article can help them to conduct clinical trials more efficiently and effectively. The first two or three paragraphs should answer the question uppermost in each reader's mind: "What's in it for me?"

Be specific. Concrete examples are the key to a useful article. Readers do not find it particularly useful, for example, to read that an approach "made it possible to recruit the necessary number of appropriate subjects in record time." It is far more useful to report that a clearly described "recruitment program resulted in enrolling 40 subjects with insulin-dependent diabetes mellitus in 10 weeks."

Suggest titles and subtitles. Suggest a short and specific title that accurately reflects the article's purpose and content. Although authors may suggest titles and identify the parts of their articles with subheadings, the editorial staff makes all final decisions about titles and subheadings.

Provide keywords and Web sites. As the writer of the article, you may have special knowledge of the Web sites and keywords specific to your topic. Please provide those keywords—common search terms used to search the Web about your topic—at the end of the document after your references.

Provide appropriate graphics. High-quality illustrations, charts, tables, graphs, and other figures increase reader involvement and can reinforce the message in your article.

Submitting Graphics Electronically. We accept graphics via e-mail attachment in the following formats: *JPEG*, *TIFF*, *EPS*, *Photoshop*, and *Adobe Illustrator*. Required image resolution is 300 dpi to ensure high-quality results.

Identify Tables and Illustrations. Refer to tables and figures in order: Table 1, Table 2, Figure 1, Figure 2. Identify figures and captions by number. Also, provide a source of where the chart came from and make sure that you are allowed to use it in the article (copyright issues).

Include byline with additional information. Provide authors' names, titles, and affiliations (company, agency, university)—exactly as each prefers that it appear in the article. Include the corresponding author's mailing address, email, and telephone and fax numbers.

Check facts and spelling. Before submitting a manuscript, review the text for clarity and accuracy. Check the spelling of proper nouns (names of people and products), include the locations of any companies named in the text, and make sure that references are complete and cited in numerical order in the body of the article. Define acronyms and abbreviations, even those that seem obvious.

Submit electronically. A manuscript should be submitted via e-mail as a Word attachment. When submitting reference lists in Word, do not embed them; they should be listed in order of attribution at the end of the manuscript. Also, do not use footnotes or embed properties when preparing a manuscript.

Acknowledgment, review, revisions

Within 10 working days after receiving a manuscript, *Applied Clinical Trials* notifies the author of its receipt and enters the manuscript into the review process. The Editor-in-Chief, with the counsel of the Editorial Advisory Board and other appropriate outside reviewers, determines whether a manuscript is suitable for publication. Reviews typically take 6–8 weeks, but can take 9–12 weeks due to high submission volume. Few articles are accepted without some requests for additional information or clarification. Peer-review is a blinded process. Authors do not know who provided review, and reviewers are not given information about the author. When the reviewers are satisfied with a manuscript but have a few minor suggestions, an article is generally accepted and changes and clarifications worked out with the author during the copy editing stage. When reviewers recommend major revisions or extensive rewriting, the author is provided with their comments and an explanation of the revisions or clarification required.

Copy editing, review of first proofs

All accepted articles are subject to copy editing for clarity and for conformity with *Applied Clinical Trials* house style. As a safe-

guard against publishing any changes in meaning that might inadvertently slip into an article during copy editing, we ask authors to review the first proofs of their articles before publication in the magazine.

Active voice

Applied Clinical Trials calls for the use of active voice whenever possible. Passive statements tend to leave questions in the reader's mind: "Who did that?" "How did that happen?"

Passive: A contract was negotiated.

Active: The manager of the CRO and the project manager for the pharmaceutical company negotiated a contract.

Passive: Inclusion/exclusion criteria were formulated.

Active: The study design team formulated inclusion/exclusion criteria.

Active voice not only leads to greater clarity, but also makes writing livelier and more informative. A number of good books are available to help writers express themselves. For accessible and practical advice, pick up a paperback edition of *The Elements of Style* by William Strunk Jr. and E.B. White.

References

References in *Applied Clinical Trials* appear in numerical order, in the order in which they are cited in the body of the article. Their purpose is to make it possible for interested readers to find your source material or recommended additional reading.

In a magazine

1. T.M. Foody, "Field Research: A Case for Flexibility, Adaptability, and a Sense of Humor," *Applied Clinical Trials*, February 2007, 28–30.

In a journal

2. W.C. Appel, "Postmarketing Surveillance in Canada," *Drug Information Journal* 30 (3) 655–660 (1996).

In a newspaper

3. S. Rubenstein and M. Schoofs, "Canceled Vaccine May Have Boosted Risk," *Wall Street Journal* B1 (21 November 2007).

Online Source

4. M. Angell, "Is Academic Medicine for Sale," *New England Journal of Medicine*, 343 (7) 1516–1518 (2000), <http://www.http://content.nejm.org> (accessed February 12, 2006).

In press

5. E.L. Posvar and A.J. Sedman, "First-in-Human Studies of Synthetic Molecules," *Applied Clinical Trials* (in press).

Book

6. B. Spilker, *Guide to Clinical Trials*, 2nd Edition, (Raven Press, New York, 1994).

Chapter in edited book

7. V.H.L. Lee, "Problems and Solutions in Peptide and Protein Drug Delivery," in *Peptides, Peptoids, and Proteins, Vol. 3*, P. Garzone, W.A. Colburn, and M. Mokotoff, eds. (Harvey Whitney Books, Cincinnati, 1989), pp. 80–92.

Code of Federal Regulations

8. *Code of Federal Regulations*, Title 21, Part 56, Section 109(e) (U.S. Government Printing Office, Washington, DC).

Federal Register

8. Department of Health and Human Services, proposed rule: "Investigational New Drug Applications and New Drug Applications," *Federal Register* 60 (174), 46794 (8 September 1995).

Government publication

APPLIED CLINICAL TRIALS MANUSCRIPT REVIEW FORM

Manuscript title:

As you review the accompanying manuscript, please consider the following questions.

Subject matter: Is the subject of this manuscript significant to Applied Clinical Trials readers?

Does it make a new and innovative contribution to the literature?

Does it put a fresh and enlightening spin on a topic we should remind readers about from time to time?

Credibility: Is the presentation so objective that readers cannot accuse the author of bias or self-promotion?

Are the article's conclusions supported by the data presented?

Is the article sufficiently supported by references?

Does it cite previous ACT articles on the subject?

Structure and presentation: Is the overall structure of the manuscript sound?

Does the title accurately reflect the manuscript's content as briefly as possible?

Does the manuscript mention relevant ethical requirements?

Is the text internally consistent?

Does the narrative flow logically?

Do the figures and tables supplement the text adequately and appropriately?

Could the material be clarified by including additional illustrative material, such as tables or figures?

Are any tables or other illustrative material superfluous or trivial?

Comments:

Overall assessment

- Excellent, exemplary in its class/category
- Very good, on target for most ACT readers
- Good, should appeal to a significant number of ACT readers
- Weak, good topic, but needs work
- Low-priority topic but well-done
- Marginal appeal to only a few readers
- Fails to meet ACT standards for topic or execution

Publication recommendation

- Publish as is, timely and perishable
- Publish as is, no rush
- Acceptable, but better with minor revisions. See comments.
- Acceptable only after important revisions. See comments.
- Major rewrite/revision needed, followed by a new review. See comments.
- Reject

