

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 globally and are non advertorial. 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.

Who reads *Applied Clinical Trials*?

Each month, more than 18,000 clinical trials professionals in about 40 countries receive *Applied Clinical Trials*. 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. *ACT* 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?

Feature articles (about 2200 words, with perhaps 3 carefully selected graphic illustrations such as charts, tables, photos, and diagrams) that 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? Reference lists must be included on a separate page, and figures/tables must also be on separate pages.

ACT 101 articles should meet the needs of newcomers to clinical trials by explaining fundamental concepts and practices. They may be full-length articles (2000–2500 words) or short, focused items (650–1200 words). The ACT 101 section includes reading lists and glossaries of regulatory, pharmaceutical, and clinical terms.

Guest Commentary contributors offer opinions or ideas, or take a controversial stand, in 650- to-1400-word essays on topics significant to *ACT* readers.

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 *ACT* readers. Each letter should address one topic and be limited to 500 words.

Notes from the Field are short (about 1400 words), useful suggestions based on experience that can help to make life easier for readers engaged in any phase of clinical research. We expect an article about a case study or a challenge that your company and another company dealt with. You must identify all parties.

A Closing Thought page is a brief thought piece (600–650 words) addressing an important issue in the world of clinical trials. We want to leave the reader with something to think about as they close the last page of the book.

How quickly can an article be published?

Getting an article from idea to publication takes approximately three to six months. The typical time between an initial inquiry and a published magazine article is four to six months. Timely subjects of immediate interest may occasionally be rushed through in less time. Lengthy articles and those addressing complex subjects may take longer (see Sample Timeline on next page).

What about payment?

Applied Clinical Trials does not pay for articles, but publication in the magazine has other potential payoffs for authors. Having an article published in *ACT* 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 exchanging information that can advance the pharmaceutical industry in general and clinical trials professionals in particular. Contributing an article to *ACT* also gives organizations and individuals an opportunity to demonstrate their clinical trials knowledge and expertise.

License

Applied Clinical Trials generally considers only original unpub-

lished 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. When a manuscript is accepted for publication, the license to reproduce the article in other print or on-line media (for example, the Internet) is shared by *Applied Clinical Trials* 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* (email joseph.porter@advanstar.com).

Ideas, queries, outlines

The editors recognize that magazine writing is rarely the specialty or first priority of an *Applied Clinical Trials* author, and 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 Managing Editor Rob Davidson, Editor-in-Chief Toby Jane Hindin or the European Editor Philip Ward about your idea. You can then follow up with a brief outline (email is also a good medium) that clearly describes the content and structure of the proposed article. Be sure your outline focuses on what *ACT* 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 negotiated 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 galley proofs (see also More About House Style).

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 to be 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 appropriate illustrations. High-quality illustrations, charts, graphs, and other figures increase reader involvement and can reinforce the message in your article. Figures, tables, and illustrations must be submitted in separate computer files and at the end narrative text of the manuscript.

Submitting Electronic Art. When sending digital art, please send hard copy art along so our artist can make sure nothing was lost or distorted in transmission. If you have only digital art, please note that *ACT's* art director works with the following software on a Macintosh computer system: *Quark Xpress*, *Adobe Illustrator*, *Adobe Photoshop*. If you submit electronic artwork, it is very important to specify the program used to create the image, the file format, file size, and resolution. Because our artist must create 4-color separations for the printer, **we cannot use Power Point files**. We can accept artwork that is in one of the following programs: *JPEG*, *TIFF*, *EPS*, *Native Photoshop*, *Adobe Illustrator*. If file compression is necessary, files must be compressed using Stuffit. Also, **do not send fonts**; this is a violation of copyright law. **Required image resolution is 300 dpi to ensure high-quality results.** In addition, use the following line resolution depending on format: Mac files—133 lpi (266 pixels/inch); PC files—640X480 lpi. All photos must be high resolution, 300 dpi.

Submitting Hard Copy Photos. Original transparency film yields sharp, clean, vivid color images. Our first choice is 4×5 transparencies, but original 2¼ × 2¼ transparencies, 35-millimeter slides, color prints, or suitable digital images with high resolution are acceptable. If originals are not available, send the best duplicates you have. Please do not write on the back of photographs—it may render them unsuitable for processing.

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. Give tables and each of their component parts appropriate headings, and indicate the software program used to create the tables. Also, explain any symbols used in the illustrations. *ACT*'s artist often rebuilds illustrations from computer files, so be sure to provide the numerical data on which graphs and charts are based. Always send printouts of figures along with computer files.

Include byline and biographical information. Provide authors' names, titles, and affiliations (company, agency, university)—exactly as each prefers that it appear in print. Put them on a separate page for easy blinding of manuscripts for the reviewers. Include the corresponding author's mailing address, email address, and telephone and fax numbers. The submission checklist ensures that we receive a complete package.

Check facts and spelling. Before submitting a manuscript, review the text for clarity and typographical accuracy. Check the spelling of every proper noun (names of people and products), include the locations of any companies named in the text, and make sure that every reference is complete and is cited in numerical order in the body of the article. *Define every acronym and abbreviation, even those that seem obvious.*

Submit electronically. To be considered for publication, a manuscript must be submitted in computer form (e-mailed or on a CD) accompanied by at least one paper copy complete with illustrations, tables, and other auxiliary materials. Manuscript text—in MS Word, text-only or ASCII format—should be in a computer file separate from that of tables, figures, and any other illustrative material. The printout of the manuscript should appear on one side of the paper, double-spaced, with pages numbered consecutively. **When submitting reference lists in Word, do not embed them in End Notes Program; they should be on a separate Reference page. Also, do not use footnotes when preparing a manuscript.**

Acknowledgment, review, revisions

Within 5–10 working days after receiving a manuscript, *Applied Clinical Trials* notifies the author of its receipt and enters the manuscript into a 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. The review process can begin only after the complete manuscript—including **hard copy of text, signed license, computer file, figures, tables, and illustrations**—is in the Iselin editorial offices. 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. When the reviewers are basically 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 editorial 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 articles accepted for publication are subject to copy editing for clarity and for conformity with *Applied Clinical Trials* house style. As a safeguard 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. We look forward to working with you.

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Typical timeline for article publication*

- 1 Feb: 1st draft received in Iselin editorial offices, with computer file, hard copy of text and illustrations, and signed license
- 8 Feb: Acknowledgement sent to author
- 15 Feb: Manuscript sent to reviewers
- 15 Apr: Reviews received by Editor-in-Chief
- 25 Apr: Reviews sent to author
- 5 May: Author and Editor agree on deadline for final revised draft
- 26 May: Editor receives final draft
- 10 Jun: Author receives first proof of copy edited and typeset article
- 12 Jun: Author calls or faxes comments and suggestions to editorial offices
- 20 Jun: Managing Editor sends magazine to printer
- 6 July: Magazine with author's article is mailed to *Applied Clinical Trials* subscribers

*Occasionally, a project is completed in as little as three months; some can take as much as a year.

More about House Style

House Style seems to cause some confusion among authors. *Applied Clinical Trials*, like other high-quality magazines, strives for consistency not only within each issue, but also between issues. A publication that is part of a large group—as *ACT* is—also faces purely practical issues. Proofreaders who work for several magazines should be able to consult only one spelling authority, for example. Consequently, periodical publishers typically have fairly rigid style guidelines. *Applied Clinical Trials* is no exception.

House Style standards are applied to dozens of issues, from when and how to use the words *which* and *that* to institutionally acceptable ways to avoid sexist language. Here is a small sample of the issues that most often elicit questions from authors.

Spelling, punctuation

ACT uses American spelling throughout (except in direct quotations of published material), generally the spelling preferred by *Webster's Third New International Dictionary*. For punctuation guidance *ACT* uses, primarily, *The Chicago Manual of Style*.

Numbers and numerals

ACT uses numerals for all numbers of two digits or more, and for one-digit numbers that indicate feet, inches, liters, milliliters, milligrams, dollars, percentages—anything that can be weighed or measured. For example, “Six venture capitalists, investing \$450,000 each, distributed funds among nine companies; 16.67% of the \$4.05 million (\$675,000) went to each company.”

ACT uses commas for thousands from 10,000 up in text. In tables, commas may be used in lower numbers to make decimals align properly.

For values less than one *ACT* uses a zero before the decimal, that is, 0.03(not .03). An exception is probabilities, such as $p < .005$.

Active voice

For clarity, *ACT* House Style 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 at a bargain price, pick up a paperback edition of *The Elements of Style* by William Strunk Jr. and E.B. White (3rd edition, Macmillan Publishing Company, New York, 1979).

Commonly used terms

ACT House Style has rules governing the use of dozens of commonly used terms. For example, because the magazine's focus is on research, not regular medical practice, using the term *subjects* (which includes both healthy volunteers and sick people) is generally preferred to *patients*.

ACT uses *male* and *female* only as adjectives; nouns are *man*, *woman*, *boy*, and *girl*. Examples include:

The investigator enrolled 12 men and 13 women in the study.

The study coordinator interviewed male subjects on Mondays and female subjects on Wednesdays.

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.

Article in a magazine

1. T.M. Foody, “Field Research: A Case for Flexibility, Adaptability, and a Sense of Humor,” *Applied Clinical Trials*, February 1996, 28–30.

Article in a journal

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

Article in a newspaper

3. N. Templin, “More Retirees Are Booting Up Their Own PCs,” *Wall Street Journal* B1 (21 November 1995).

Article from 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).

Article 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, *Multinational Pharmaceutical Companies: Principles and Practices*, 2nd Ed. (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

9. Food and Drug Administration, *Guidelines for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, Part VI* (FDA, Rockville, MD, 1993).
10. Food and Drug Administration, information sheet: *Continuing Review after Study Approval* (FDA, Rockville, MD, 1 October 1995).

Privately published booklet or report

11. *1992: Leadership in Biotechnology* (J. Robert Scott, 27 State Street, Boston, MA 02109).

When preparing references, if in doubt, provide more information rather than less. Spell out in full every title of every book and every journal or magazine. Provide the full names of authors rather than their initials. Include the name of a book's publisher, the publisher's location, and the year of publication or copyright. If a report or booklet is not readily available in bookstores, provide the address where it can be obtained. □

Manuscript Review Form

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 (Use additional pages as needed):

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

This is the form that editorial reviewers get with each manuscript the Editor asks them to review and evaluate.

Submission Checklist

This package includes:

- signed license, which will be destroyed if manuscript is not accepted for publication.
- Hard copy of manuscript, double-spaced
- Hard copy of tables, charts, graphs, illustrations, on separate sheets, not embedded in manuscript
- Byline and biographical information
- computer file sent by e-mail, or enclosed in this package on Zip disk or CD, includes
 - manuscript text, file name: _____
 - table(s), file name(s): _____
 - graphs, illustrations, file names: _____
 - _____
 - _____
 - _____

Manuscript submitted as:

- Feature Guest Commentary
- ACT 101 Notes from the Field
- A Closing Thought Media Review

Manuscript checked and

- all references complete, all journal titles spelled out in full
- all abbreviations and acronyms defined
- all tables and figures numbered and captioned
- spelling of proper nouns verified need verification
- locations of companies verified need verification
- permission obtained for use of illustrative materials
- permission sought to use illustrative materials, awaiting response
- reference list is on a separate page with all references numbered in order in the text

Submission date _____

Byline (authors names in the order in which you wish them to appear): _____

Corresponding author: _____

Title _____

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Address _____

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Co-author _____

Title _____

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Address _____

Co-author _____

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Company/Organization _____

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(List additional co-authors on separate sheet)

5 Keywords to help us categorize your manuscript _____

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