

The **P**'S  
and **Q**'S  
of Publication Planning

**Peer-reviewed journals are a safe way for pharma to get product information to MDs. But companies can build better brands if they coordinate their efforts.**

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**F**or a pharma company, getting research published in a peer-reviewed medical journal is like winning a stamp of approval from its most influential audience. It's an automatic validation unmatched by any other medium.

And, given FDA's recent scrutiny of journal and consumer ads, among other pharma marketing materials, peer-

reviewed medical publications have become one of the safest ways to communicate information about new medicines and indications to physicians. Readers are reassured by the publications' peer-review process and conflict-of-interest standards that ensure that the data presented are fair, balanced, and impartial. And that, in turn, reassures FDA regulators.

However, publication planning—data mining, ensuring the findings can withstand regulatory scrutiny, and deciding what, where, and when to publish—is a strategic and time-intensive process. Before submitting a clinical study or data to any journal, pharma companies must be aware of publications that are appropriate for their data, how the publication of the data fits into the company's overall marketing strategy, and how specialized agencies can help present those data, target publications, and develop time lines for submission.

The cornerstone of publication planning is making sure that key findings reach the right audience at the right time. Agencies specializing in publication planning can help pharma companies develop a strategy for submitting data, from preclinical to Phase III trials. That plan helps pharma companies' data reach the widest possible audience—even beyond the readership of the publishing journal—through media pick-up and subsequent citation of the articles in other written pieces.

### The Right Journals

Pharma companies must decide where to publish their original research, based on primary, previously unpublished data from preclinical and Phase I, II, and III clinical studies as well as pharmacoeconomic and quality-of-life studies. Those data can appear in specialist research and clinical publications, such as the *Journal of Clinical Oncology* and the *Journal of Investigative Dermatology*, or, depending on the clinical significance of the data, in top-tier general medical journals like the *New England Journal of Medicine (NEJM)*, the *Journal of the American Medical Association (JAMA)*, and the *Lancet*.

Abstracts presented at medical

congresses are another source of original data. Specialist journals associated with a specific congress often publish presented research. As a result, data enter the public domain as original, citable material.

Many journals often publish a “Reader’s Digest” version of original data. Authors summarize many studies already in the public domain and place them in perspective relative to each other in review articles. Journals may also include previously published data in discussion forums such as editorials, letters to the editor, case studies, or clinical update features.

Agencies counseling companies on their publication strategies must consider the desired time frame of publication and the quality or clinical relevance of the data when deciding which journal is the most appropriate for the submission.

The publication process at a top-tier journal takes time. Eight months to a year or more can pass between submission and publication. However, in response to the competition of new online rapid publication vehicles, many of the top-tier journals are working to reduce lead times with “rapid review” of unique or compelling data. *JAMA* now offers *JAMA-Express*, a faster system of reviewing and publishing original research it deems to be of major clinical or public health importance. *JAMA-Express* can publish data in days or weeks rather than months, but standards for that review are often even higher than data submitted through the normal process.

The rejection rate at top-tier journals is very high. (See “Acceptance Rates.”) Of the several thousand manuscripts *JAMA* and the *Lancet* receive each year, less than ten percent are published. Those journals are only

interested in information that significantly affects an important clinical or scientific issue for a large proportion of their readers. Companies should consider their odds when submitting to those journals, knowing that they may need to resubmit an article somewhere else following rejection, which can result in significant delays in a study’s publication.

The time it takes secondary journals to peer review, produce, and distribute the journal varies from one publication to the next, although some also offer accelerated review times. But in general, secondary journals tend to have faster turn-around times and higher acceptance rates. Companies that wish to arm product spokespeople with article reprints to hand out at a targeted medical conference or other events may submit studies to secondary journals or journals with accelerated review times to ensure timely publication.

### Regulatory Issues

Peer-reviewed publications offer pharma companies shelter from often-stormy regulatory waters. FDA views published articles as protected commercial speech so doesn’t regulate their content.

But that protection may not hold when an article leaves the safety of a journal’s bound

### Elements of a Publication Plan

- ▶ Abstract title
- ▶ Meeting for abstract
- ▶ Meeting date and location
- ▶ Abstract deadline
- ▶ Abstract author
- ▶ Manuscript title
- ▶ Key messages
- ▶ Manuscript author
- ▶ Target audience
- ▶ Target journal
- ▶ Target start development date
- ▶ Target submission date
- ▶ Target publication date

pages. FDA considers reprints of articles that discuss off-label indications or refer to unapproved dosing regimens as off-label promotion if companies distribute that information to anyone other than physicians who request it.

Agencies can help companies make the most impact on their audience by ensuring that a selection of articles discussing on-label usage will be published by the time FDA grants product approval and that the sales force has those reprints in hand when promotional activities begin. They do this by carefully monitoring and controlling the development timeline of a publication—no easy task when there are so many potential delays.

### How Do They Rate?

Publication	Very Useful	Somewhat Useful	Not at all Useful	Do not read	No answer
<i>Psychiatric Times</i>	70%	21%	2%	6%	1%
<i>Journal of Clinical Psychiatry</i>	57%	24%	2%	16%	1%
<i>Clinical Psychiatry News</i>	47%	31%	2%	19%	1%
<i>Psychiatric News</i>	48%	27%	4%	20%	1%
<i>Current Psychiatry</i>	40%	28%	2%	29%	1%

Source: CMP Healthcare Media/Readex, 2003



**Readex, a third-party auditor commissioned by CMP Healthcare Media, conducted a survey of 200 psychiatrists, psychologists, and other clinicians in the mental health field to find out how useful practitioners felt various publications were to their work. Agencies may commission similar surveys to help their clients decide where to submit articles.**

## Acceptance Rates

### Top-Tier Medical Journals

Journal	Manuscripts received/year	% accepted
<i>Journal of the American Medical Association</i>	4,000	10
<i>The New England Journal of Medicine</i>	3,500	10
<i>The Lancet</i>	20,000	5–10

### Other Journals

Journal	Manuscripts received/year	% accepted
<i>Diabetes Care</i>	1,200	40–45
<i>Cancer Detection and Prevention</i>	varies	about 25*
<i>American Family Physician</i>	181 unsolicited (2001)	more than 50**
<i>Journal of American College of Cardiology</i>	3,000	about 15

\**Cancer Detection and Prevention*: 75 percent of manuscripts are rejected with a request for authors to resubmit after making changes to address the reviewers' comments.

\*\**American Family Physician*: Of 181 unsolicited manuscripts received in 2001, 117 manuscripts were accepted for publication. Family physicians wrote half of those accepted; "non-family physicians" bylined the others.



### Timing is Critical

Researchers and authors need time to collect data, write an article, and pass it through the review of all stakeholders such as a pharma company's medical and legal review board, before submitting it to the most appropriate journal. Smaller companies must often submit data to an investor relations review board as well. Agencies can help ease the pressure on already

overburdened medical teams by helping companies set up a sign-off procedure that determines who will see data in what order and who will police and adjudicate conflicting comments.

New product managers are often unaware that internal review processes can be laborious. They think that, because abstracts are short, they will fly through the review. However, because abstracts usually contain the first data published from a particular study, internal review boards usually spend considerable time deciding how best to present the results.

Publication agencies can help pharma companies develop those first messages, which will affect how the rest of the studies are presented. In that way, agencies should be an extension of their client's medical group. Scientific staff members with MD and PhD credentials examine the data the way journal reviewers do to make sure they are clinically rigorous. Agencies help ensure that companies' conclusions are based on clinical studies conducted with accepted medical and ethical protocols and that the study's researchers are free of

conflicts of interest. (See "Disclosure Policies".)

Once the article is submitted, the journal's staff needs time to review it, make changes, correspond with the authors, and fit the piece into the journal's editorial and production schedule. Therefore, companies must plan ahead if they want the eventual publication date to coincide with the optimal time for the data to reach the market.

Companies should start the publication planning process by bringing a third-party publication agency on board as soon as they have preclinical data. Many agencies use data mapping, a system that shows when and to whom to release data, in order to build the story of a company's research. For practical purposes, readers should be exposed to a gradual ground swell of published information—starting with preclinical data and moving through Phases I, II, III, and pivotal trials—to build the brand.

A publishing time line is imperative. If a company's plan doesn't look three to five years ahead it is easy for data to be published in the wrong order, presenting clinical data without the essential underpinnings of the toxicology or drug interactions studies, for example. A timeline also gives companies the ability to coordinate the release of information with the editorial calendars of targeted journals.

Additionally, companies should use agencies to discover when and where the competition's research has been published. Companies can then piggyback their messages on the awareness that other research created. Or, companies can publish research that fills the gaps in data left by the competition. For instance, after carefully studying publications that carried research about a new class of products' mechanism of action,

## The Right Agency

An effective publication-planning partner must have

- ▶ a group dedicated to publication planning, not just medical education
- ▶ staff members with publication experience who maintain strong journal and medical association contacts
- ▶ best practices for publication planning and execution
- ▶ examples of past successes
- ▶ the ability and staff structure to build resources and databases that support publication planning and fact checking
- ▶ a delivery system that allows all key players to track the publication plan
- ▶ a command of relevant regulatory guidelines and ready access to regulatory counsel.

## Disclosure Policies

### ***Journal of the American Medical Association***

Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Authors should indicate relevant conflicts of interest, including specific interests relevant to the subject of their manuscript, in their cover letter, on the journal's financial disclosure form, or in an attachment to the form. Authors without relevant financial interest in the manuscript should indicate they have no such interest.

### ***The New England Journal of Medicine***

Authors of research articles should disclose at the time of submission any financial arrangement they may have with a company whose product is pertinent to the submitted manuscript or with a company making a competing product. Such information will be held in confidence while the paper is under review and will not influence the editorial decision, but if the article is accepted for publication a disclosure will appear with the article. Because the essence of review and editorials is selection and interpretation of the literature, the journal expects that authors of such articles will not have any significant financial interest in a company (or its competitor) that makes a product discussed in the article.

The source of funding for the study and a statement of financial disclosure (or a statement that none is necessary) must be provided in appropriate places in the manuscript. During the editorial process, authors will be asked for details of their financial relationships with biomedical companies, such as consulting fees, service on advisory boards, ownership of equity, patent royalties, honorariums for lectures,

fees for expert testimony, and research grants.

### ***The Lancet***

Conflict of interest and source of funding statements from authors are required. *The Lancet* considers a conflict of interest to exist "when an author or the author's institution has financial or personal relationships with other people or organizations that inappropriately influence (bias) his or her actions." Conflict can be actual or potential, therefore full disclosure to the editor is the safest course. Authors must disclose any employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications, or travel grants received within three years of beginning the work submitted. Finally, all sources of funding should be declared as an acknowledgment at the end of the text.

### ***Circulation***

The acknowledgment section recognizes all sources of support for research, plus substantive individual contributions. The editorial office must receive written signed consent from each person recognized in the acknowledgments to be mentioned in the article because acknowledgment can imply endorsement of data and conclusions.

Authors submitting articles to *Circulation* (or any American Heart Association journal) must sign a statement acknowledging the journal's requirement to scrupulously avoid direct and indirect conflicts of interests and agree to inform editors of any commercial or other proprietary support, relationships, or interest that relate directly or indirectly to the subject of the work.

### ***Journal of the National Cancer Institute***

Journal policy requires that all authors of research papers, reviews, commentaries, editorials, and correspondence sign a statement when they sign the license to publish revealing any financial interest in or arrangement with a co-payer whose product was used in a study or is referred to in a review, opinion piece, or letter; any financial interest in, or arrangement with, a competing company; any other financial connections, direct or indirect, or other opinions stated, including pertinent commercial or other sources of funding for the authors or for the associated departments or organizations, personal relationships, or direct academic competition.

### ***British Medical Journal***

"We are not aiming at eradicating competing interest—they are almost inevitable," says *BMJ's* submission guidelines. "We will not reject opinions simply because you have a competing interest, but we would like to know about it." The editors ask authors and referees about any competing interests, but restrict those to financial ones. They ask authors to answer a series of questions to ascertain their level of financial interest and consider other types of competing interests.

Additionally, the BMJ Publishing Group and Stanford University Press Libraries HighWire Press offer authors a place to post original research on a dedicated website before, during, or after peer review by other agencies. After a pre-screening process, accepted articles are posted within 24–48 hours on [clinmed.netprints.org](http://clinmed.netprints.org). However, BMJ does not automatically accept articles for web posting and a detailed disclaimer prefaces each article on the site.

**The New England Journal of Medicine**



**Description:** *NEJM* is a general medical journal that publishes new medical research findings, review articles, and editorial opinion. Founded in 1812, *NEJM* is the oldest continuously published medical journal in the world and maintains the largest paid circulation of any peer-reviewed journal.

**Circulation:** 231,125

**\*Impact Factor:** 29.065

**Published by:** Massachusetts Medical Society

**The Journal of the American Medical Association**



**Description:** *JAMA* publishes original, well-documented, clinical and laboratory articles on a wide range of medical topics. Its motto is "to promote the science and art of medicine and the betterment of the public health."

**Circulation:** 332,350

**\*Impact Factor:** 17.569

**Published by:** American Medical Association

**The Lancet**



**Description:** *The Lancet*, an international general medical journal, publishes original contributions that advance medical science or educate or entertain the journal's readers. *The Lancet* describes itself as "the world's leading independent general medical journal."

**Circulation:** 45,000

**\*Impact Factor:** 13.251

**Published by:** The Lancet/Elsevier Science London

\*The "Impact Factor," developed by ISI Thompson Scientific, is considered an industry standard in medical peer-reviewed publishing. It measures how often the "average article" in a journal is cited in a particular year. It is calculated by dividing the number of citations to articles published in the previous two years by the total number of journal articles published within the same time period.

one of a product's manufacturers realized its publication efforts needed to focus only on the product's efficacy and safety, as physicians had already accepted and understood the mechanism of action of the class.

**In the Loop**

For the journal planning process to work, companies must keep their internal staff informed about data mining and time lines. Pharma companies need to decide who should have access and how and when to obtain the plan according to their different

functions and needs.

Those responsible for the plan's execution of the plan in medical and marketing groups need to see every detail, while public relations groups may only need to know what data are being released so they can plan a complimentary PR effort. Most of the industry works globally, so companies may also consider distributing their publication plans electronically. Agencies can help clients work more efficiently by creating a website or intranet for that purpose.

In a competitive marketplace,

it's more important than ever for pharma companies to ensure they have well coordinated and executed publication plans. Companies that get the right data published in the right place at the right time will make a long-lasting impression on both the medical community and a brand's potential consumers.

By ensuring that data supporting a product's key messages are placed in the most appropriate journal possible at the best possible time, a savvy agency partner can be the cornerstone to a brand's success. ■

**this is grey**

**Gold. It's the only thing Wendy ever thinks about.** Wendy Balter's team of powerhouse conceptual alchemists transforms scientific base metal into strategic pure gold via exceptional marketing initiatives, medical meetings, and manuscripts.

Connected with the industry's top opinion leaders and marketers, Phase Five's experienced PhDs and MDs understand how to energize your data with precious meaning. The result: powerful marketing programs to drive your brand to unexpected heights.

Let Wendy demonstrate how Phase Five can create outstanding value for you. You're guaranteed a 24-karat response.



**PHASE**  
**V**

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