EUROPEAN
Pharmaceutical
Executive

Doing it Right

Peer-reviewed journals are a safe way for pharmaceutical companies to get product information to doctors — if the information is accepted for publication. Acceptance requires not only withstanding regulatory scrutiny, but knowing what, where and when to publish.

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For 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 the US Food and Drug Administration's (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 several things: 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 with presenting those data, targeting publications and developing 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Pharma companies must decide where to publish their original research, based on primary, previously unpublished data from preclinical and Phase I, II and III clinical studies as well as pharmacoeconomic and quality-of-life studies.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 such as 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 (see Table I).

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 counselling 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: 8 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 Table II). Of the several thousand manuscripts *JAMA* and *The Lancet* receive each year, less than 10% 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.

Table I: How do they compare?

Publication	Very useful	Somewhat useful	Not at all useful	Do not read	No answer
Psychiatric Times	70%	21%	2%	6%	1%
Journal of Clinical Psychiatry	57%	24%	2%	16%	1%
Clinical Psychiatry News	47%	31%	2%	19%	1%
Psychiatric News	48%	27%	4%	20%	1%
Current Psychiatry	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.

Table II: Acceptance rates

Top-tier medical journals	Manuscripts received/year	% accepted
Journal of the American Medical Association	4000	10
The New England Journal of Medicine	3500	10
The Lancet	20000	5–10
Other journals	**Manuscripts received/year**	**% accepted**
Diabetes Care	1200	40–45
Cancer Detection and Prevention	varies	25*
American Family Physician	181 unsolicited (2001)	more than 50**
Journal of American College of Cardiology	3000	about 15

**Cancer Detection and Prevention:* Approximately 75 per cent 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.

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 turnaround 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 and therefore does not regulate their content.

But that protection may not hold when an article leaves the safety of a journal's bound 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 time line of a publication — no easy task when there are so many potential delays.

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.

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, 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 3–5 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 time line also gives companies the ability to co-ordinate 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, 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 execution of the plan in medical and marketing groups need to see every detail, whereas public relations groups may only need to know what data are being released so they can plan a complementary 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 market place, it's more important than ever for pharma companies to ensure they have well co-ordinated 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. ■

ELEMENTS OF A PUBLICATION PLAN

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

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.**

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PHASE V