

Project House Newsletter

STRATEGIES - VOLUME 6 NO 2 SPRING 1996

Is Publication Part of Your Launch Strategy?

Looking ahead to your product launch, you consider all the traditional launch activities: press releases at appropriate stages, presubmission of introductory promotional materials to the FDA, investigator symposia, rep training modules, motivational meetings for the sales force, and the all-important product launch meeting. Long before your product reaches the marketplace, however, you can set the stage for a successful launch with a strategic and comprehensive publication plan.

Countdown to launch

A publication plan should be under way even before pivotal clinical trials or the submission package is completed. This usually means that publication strategies are considered at least 2 years before the anticipated launch date. The reason for the long lead time is that an article commonly takes more than a year from start of writing to publication in a peer-reviewed journal.

Step by step planning

A publication plan is most effective when it follows a series of specific steps that build on one another in a logical order. No one publication can accomplish all your goals, so you'll be generating a series of publications of different types. Yet you want the major messages to remain consistent throughout each phase of the plan. Even before you know exactly how the clinical trials will turn out, you have many important messages to communicate. Appropriate publications can create anticipation, interest, and excitement about your product long before it comes to market.

Although each publication plan is unique and tailored to the characteristics of the product and the market environment, most plans can be rolled out in three fundamental phases.

PHASE I - Create a need for your product

Promoting awareness of the disease for which your product will be indicated can heighten demand for therapeutic solutions. If your drug will be the first in its class, focus your articles on the untoward effects of the disease and its consequences for sufferers and the health-care system. If therapies for the disease already exist, your strategy may be to create dissatisfaction with their effectiveness, convenience, or adverse effects. Articles of this nature, which are most likely to be reviews, need not mention your product or your clinical trial data. Possible topics include, but are not limited to, the following:

- Epidemiology of the disease and its possible risk factors
- Pathophysiology, causes, and sequelae of the disease
- Cost-effectiveness of treating the disease
- Deficiencies of currently available therapies and the need for better ones

PHASE II - Build anticipation

As launch nears, your focus may shift to publishing articles that define criteria for an ideal treatment for the disease and intimate that your product is on the horizon. You may want to defer the release of Phase 1 and 2 data until this point to build more concentrated excitement close to launch. Subject matter suitable for original research reports at this phase include the following:

- Preclinical research synthesis and screening of candidate compounds, mechanism of action of your drug, theoretical basis of human studies, toxicology, and animal studies
- Phase 1 and 2--pharmacology, pharmacokinetics, pharmacodynamics--dose-finding studies, formulation comparisons, and safety studies in humans

PHASE III - Establish superiority

At the time of product launch, making your audience keenly aware of your product's excellent efficacy and safety is a key objective. This is the time to release data from major clinical trials. The data should appear in credible original research journals and may include various types of studies:

- Multicenter, placebo-controlled studies
- Comparative, large-scale studies
- Single-center, small-scale studies (which may be part of larger studies)
- Pharmacoeconomic studies
- Case reports
- Studies of uses for which your product may not receive an indication
- Independent research studies (possibly company funded) that are not part of the submission package

If the content of a publication falls outside of the product labeling you eventually obtain, your professional sales representatives may not be able to use reprints of the article for detailing. However, the article may be made available to physicians upon request or may be distributed by a third party, such as a CME provider.

To establish superiority, review articles can also compare your product to others available. In addition, explaining to doctors, nurses, and pharmacists how to use your product--and helping them to understand which patients will benefit from it--is advantageous. Review articles may highlight a variety of concepts:

- New intervention strategies for better outcomes
- Comparison of available products for the relevant indication
- Overview of your product for clinical use

- Decision analyses and protocol algorithms
- New ideas in clinical management of the indication
- Methods of identifying patients at risk and those likely to benefit from therapy

Choosing media for your publication plan

The publications chosen should reach all audiences important to the success of your product. Oncologists, for example, read different journals and attend different meetings than do internists, pharmacists, or nurses.

The Journals Oncologists Read Most*

Journal	No. subscribers	% articles accepted	Accepts unsolicited reviews?	Typical time to publication Submission to acceptance / Acceptance to print
<i>New England Journal of Medicine</i>	234,000	8% - 10%	Yes	3 - 6 months / 5 - 12 months
<i>Journal of Clinical Oncology</i>	16,300	39%	Yes	2 - 12 months / 3 - 5 months
<i>Annals of Internal Medicine</i>	95,000	12%	Yes	1 - 4 months / 3 - 9 months
<i>Cancer</i>	16,700	31%	Yes	1 - 7 months / 4 - 5 months
<i>Journal of the National Cancer Institute</i>	10,000	15%	Yes	4 - 12 months / 2 - 3 months

*Survey results, 1995 Chemotherapy Foundation Meeting

A creative marketing challenge

From beginning to end of the countdown to launch there's always something to write about, even when your researchers tell you there's no new information to publish. The publications that can be generated in support of a new product are many and varied indeed. And the more you publish, the more excitement and interest you create.

Will your publication plan generate this many peer-reviewed publications in its launch year?

The Index Medicus database can provide a rough measure of publication intensity. A list of the number of indexed publications appearing during the launch year of several successful products follows. Publications that are not indexed, such as post-meeting newsletters, single-sponsor publications, textbook chapters, and publications in many "throwaway" journals, are not included.

Product	Company	Launch Year	No. indexed publications in launch year
Claritin (loratadine)	Schering-Plough	1993	28
Lescol (fluvastatin)	Sandoz	1994	43
Kytril (granisetron)	SmithKline Beecham	1994	85
Serevent (salmeterol)	Glaxo Wellcome	1994	62
Fosamax (alendronate)	Merck	1995	17
Cozaar (losartan)	Merck	1995	202
Glucophage (metformin)	Bristol-Myers Squibb	1994	63
Propulsid (cisapride)	Janssen	1995	73
Prevacid (lansoprazole)	TAP	1995	97
Coreg (carvedilol)	SmithKline Beecham	1995	19
Taxotere (docetaxel)	Rhone Poulenc Rorer	1995	53

Project House Inc., 432 Maitland Ave., Teaneck, NJ 07666, (201) 837-5216, sphillips@projhouse.com

Copyright © Project House Inc., 1996 All Rights Reserved