On the “Write” Track—From Planning to Publication

Publishing in journals is an integral part of a product manager’s marketing plan. It may be a difficult and competitive task to get an article accepted into a scientific journal, but the rewards will be great. In this article, the authors discuss how a successful publication-planning strategy involves more than putting words to paper.

In the world of pharmaceutical marketing, publishing an article about a product in a peer-reviewed medical journal is like finding gold. It tells the readers, potential prescribers, that the drug they are reading about has passed both the scientific scrutiny of their clinical peers and the ethical eye of the journal’s editorial review board.

Yet, good miners (and good product managers) know that one should not start digging for gold just because something glitters. Before submitting data to any journal, pharmaceutical companies need to know which publications are most appropriate and how the publication of their data fits into the company’s overall commercialization plan.

A well-conceived publication plan details how all communications will roll out over time to all relevant target audiences. The plan will guide data placement in the literature for each audience, maximizing the reach of a product manager’s communications to make the most of each data set. The plan should contain enough information to guide a product manager at each decision point, and be flexible if the market dictates a change of approach from initial tactics. A good plan evolves with the market conditions; a publications partner will help recognize these pivot points during maintenance of the publication plan and work through the options with the product manager to arrive at the optimal strategic approach to data communication. Once the plan is complete, it is time to think about developing manuscripts. What does it take to be successful?

Doctor and Author

It may appear that the right time to pick an author is after the clinical trials are completed and the data are ready for review. In fact, the right time to think about an author for a journal article is before the trials begin. That is because an author is needed who is capable of participating as an investigator in the trials where safety, efficacy, and value are proven, and who is highly regarded by his or her peers.

Why so early? Prestigious medical journals have always imposed tough standards on the articles they will accept for publication, and they are getting tougher still. Editors of medical journals are becoming increasingly sensitive to the source of funding for clinical studies, to the identity of the consultants involved with the research, and to anyone with a vested interest, financial or otherwise, in the product. Knowing this, editors of top-tier journals are tightening their standards with regard to acceptance of articles (Sidebar).

It is therefore important to partner early in the process with a publication-planning agency, since it can help determine the right author for the article. No product manager wants to be in the position of having an article about a product just a keystroke away from acceptance only to have the author disqualified. Indeed, this task is so important that some pharmaceutical companies are starting the process of recruiting investigators for phase 3 trials with an eye toward the ultimate authorship in mind.

Planning is key to communication through publications, but the best-laid plans can stall without well-orchestrated execution. A well-conceived and tightly executed process is key to ensuring successful article placement at the right time for all audiences.

Manuscript preparation should begin immediately after a qualified author is chosen. The time from debut of the clinical data to submission to a journal generally takes six...
months. Once the manuscript is submitted, it may take eight months to one year for the article to be published, with very few exceptions.

The good, accurate timeline provided in a publication plan provides a clear picture of the parts of the process that the product manager controls. It enables the product manager to efficiently plan and coordinate the team to submit a manuscript that has a good chance of publication at the desired time.

Success in Seven
An effective process for preparing a manuscript for submission to a professional journal requires seven steps. As previously noted, this process takes approximately six months from beginning to end. It may be helpful to consider the following mnemonic: To achieve communication goals, keep the team “RIVETED” to the production process:

Rollout. At this point, a master publication plan has been developed. It includes desired authors and the journal to target for each article. Phase 3 clinical studies are finished, the database is locked, and the manuscript is ready to be written.

Invite. All authors are invited to meet with other key members of the product team to ensure everyone understands the process, the timeline, and the goal of the work to be written and published. This is the time to discuss the content details for the article in development.

Verify. Once the data have been rolled out and the key team members bring in on board, it is time to verify that the goals established for the publication align with clinical findings. If additional analyses are required, the statistical team will be involved and, perhaps, the goals adjusted. If the data and goals are sufficiently aligned, a concept sheet will be circulated to the full client review team as well as the external authors.

External Authors. The external authors, who are clinical study investigators, will take ultimate responsibility for the published work and for its accuracy. They will review the first working draft and all subsequent drafts. The first draft is circulated for review and comments that will now be tied together.

Tied Together. This is the stage, between the working and final draft, where additions and revisions by the core review team are integrated. In parallel, the publication-planning agency and statisticians should double-check all facts in the document to ensure numeric accuracy and proper interpretation of the data. The manuscript is then ready for a final edit.

Edit. At this stage, the manuscript receives its final polish, ensuring the article is drafted in the style in which the medical journal has requested. Remaining queries are addressed and the article is checked for consistency. The manuscript goes through a final internal review, gets a final sign-off by the client team, and is complete.

Done! The final step is for the publications partner to prepare a package for submission to the selected journal. Then, with all the good planning, and a little luck, the article will be published in about eight months!

Keeping the People and the Process Going
Whereas a flow chart may outline the process and imply that team members must simply follow it to ensure a smooth process, problems in producing a manuscript can and will arise at any stage.

An important component of successfully moving a manuscript from inception to publication is timing. This is a two-pronged approach, requiring mindfulness of internal timelines (those of the product manager, the team, and the company) and external timelines (those of publication planners, authors, and editorial calendars of journals).

Product managers, especially of new products, are often

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MEDICAL JOURNALS AND THEIR EXPECTATIONS

Medical journals are tightening their standards for acceptance. Here is what the New England Journal of Medicine and the Journal of the American Medical Association expect from their authors:

**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. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article. Authorship credit should be based only on substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; drafting the article or revising it critically for important intellectual content; final approval of the version to be published.”

**New England Journal of Medicine**
“Authors of research articles must disclose at time of revision any financial arrangement they 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 statement will appear with the article.”
sorised to find that their own internal review process can be lengthy and complex. Setting up a clear and well-defined process where everyone knows exactly what to do and by when, is the hallmark of a well-coordinated plan. This will ensure timely submission to journals for publication at targeted times.

How to Get Published, Again and Again
Just as the right people should be brought into the manuscript-to-print process at the right time, agencies that specialize in publication planning can ensure that key product data reach the most appropriate audience at the right time.

Publication planning works best when the publication-planning partner is brought on as early in the process as possible—the best time is generally during phase 2 trials. At that stage, the pharmaceutical company and publication partner can determine when and to whom to release data to start building a story of the company’s research. Validity of a drug’s claims is based on a groundswell of information, starting with preclinical data and moving through phase 2 and pivotal phase 3 trials. With well-qualified marketers on board, a top-tier publication-planning agency can ensure that data are communicated in the best light and perspective at every stage.

An eye toward future indications will help pave the way for these indications, if properly integrated into the planning process. For example, if phase 3 data for arthritis drug X suggest it may be beneficial in the treatment of juvenile as well as adult arthritis, early messages can be constructed so as to coordinate and be consistent with messages that may be introduced later. The same is true for side-effect information. To use arthritis drug X as an example: If the drug has a side effect of working as a muscle relaxant, there may be a possible future indication for pain relief associated with muscle tension. Care should be taken to ensure that language describing side effects is positioned from the beginning to become the groundwork for future indications.

Another consideration for product managers is the ownership of data and coordination between global and national clinical and marketing groups. The publication agency should foster collaboration between groups to ensure optimal article placement for both global and national audiences. This takes expertise in recognizing the reach of each publication vehicle and how best to coordinate global and national publication plans.

Several considerations are key to a successful collaboration between a product manager and a publication planning partner. Following are some recommendations for the product manager.

The Plan Must Be Accessible. The publication plan is a timeline that must be easily accessible. If those involved in the publication-planning process do not know where they fit on the plan, it is useless. It must be a working tool that is updated often, not just a theoretical tool in a binder sitting on someone’s desk.

Identify Those Who Need Access. It must be determined up front who needs access to the plan, when they need access, and how they will obtain access. Many companies distribute updated timelines to team members by way of E-mail at key intervals, whereas others have set up a website on which team members can post their status and progress.

Hold Meetings. Confirm that all global and national team members understand the need for routine meetings or teleconferences, and determine what the challenges will be before the process starts. Preparing for these challenges is crucial to efficient project management.

Appoint a Point Person. A “point person” must be named as the go-to person who supervises the entire process, alerts the team to potential conflicts or difficulties, and answers queries or directs them to the most appropriate source.

Conclusion
In a marketing environment that is falling under increasing scrutiny from all sides, detailed publication planning and well-coordinated execution at all stages are as crucial to success as the product itself. An effective, efficient process will put a product on track for successful publication, making its arrival to the marketplace a strong one and its lifecycle long.

Wendy Balter, President
Phone: (212) 886-3047
E-mail: wbalter@ghgroup.com

Marsha Scott, PhD, Director, Scientific Services, Phase Five Communications, 114 Fifth Avenue, New York, New York 10011
Phone: (212) 886-3487
E-mail: mscott@ghgroup.com
URL: www.ghgroup.com

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.