BY ELISABETH PENA VILLARROEL

MASTERPLAN

The Making of a Successful Publication Strategy

PUBLICATION PLANNING IS AN ESSENTIAL PART OF THE DRUG-DEVELOPMENT PROCESS. The results of the long, labor-intensive years of a clinical trial are announced to the industry and medical professionals through publication in medical journals.

Preparing trial results for publication requires early planning to ensure that important scientific data are communicated to the appropriate audience in a timely manner. Finding the right balance between faster publication and a credible vehicle for information, however has become confounded in recent times because of public concerns regarding transparency and authorship disclosures and the creation of clinical-trial registries and results databases.

"A significant challenge today facing the pharmaceutical industry is the negative impact the publicity has had on our relationships with medical journals and readers," says Philip Ross, Ph.D., senior director and acting head, medical communications department, at Merck Research Laboratories. "This impact is making our job of getting key scientific information to the people who need it — practicing doctors — more difficult but we are trying our best to navigate and respond to the concerns and constructively work through the challenges so we can achieve our mission — serving patients."

Public concerns with industry transparency issues are still evident.

"Changing perceptions surrounding the publication of industry-sponsored study data is a key challenge that the industry, and publication planners, are currently currently tackling," Dr. Ross says.

"Changing this perception won't happen over night; it will take time, and right now the journals ask for disclosures and we are happy to provide those," says Bhakti Kshatriya, Pharm.D., associate director, global medical affairs, OTC R&D, Novartis Consumer Health Inc. "Publication managers or planners often have clinical backgrounds, hence we always try to have a fair presentation of data."

Fair presentation of data, combined with a carefully constructed strategic publication plan, can lead to the successful communication of clinical-trial results.

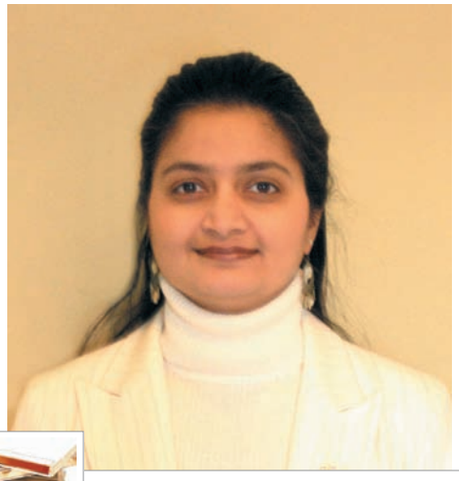
TOOLS OF THE TRADE

Experts agree that a successful publication plan, including initiating communication with the journal of choice, needs to begin a year to two years before the study data are expected to be available.

For Dr. Kshatriya, a successful publication plan takes into consideration three areas from the very beginning: treatment practice trends, drug and therapeutic class awareness, and the clinical development plan. The clinical development plan is the key component of the planning process, as it gives an overview of what

TIMOTHY BACON
PeerView

PUBLIC DISCLOSURE IS RESULTING IN AN INCREASED FOCUS ON SPEED AND EFFICIENCY OF THE PROCESS — GETTING A GOOD DRAFT AND SUBMISSION COMPLETED WITHIN 12 MONTHS AND THEN TRACKING THAT THROUGH TO A SUCCESSFUL PUBLICATION IN LESS THAN 24 MONTHS TO AVOID HAVING TO POST UNPUBLISHED RESULTS.



DR. BHAKTI KSHATRIYA
Novartis Consumer Health

FROM MY STANDPOINT, HAVING TRANSPARENCY BETWEEN AUTHORS, SPONSORS, AND PUBLISHERS IS THE KEY TO AVOID ANY ISSUES DURING THE PUBLICATION PROCESS.

NEIL MATHESON
Axis Healthcare Communications

THE MOST SUCCESSFUL PUBLICATION PLANS ARE THOSE THAT ARE IMPLEMENTED BY A COMMITTED AND FOCUSED PUBLICATION TEAM CONSISTING OF APPROPRIATE CLIENT PERSONNEL AND DRIVEN BY A WELL-ORGANIZED, HIGHLY DISCIPLINED, AND PROACTIVE AGENCY.

DR. PHILIP ROSS
Merck Research Laboratories

A PUBLICATION PLANNER'S FOCUS SHOULD BE ON THE DATA, THE VALUE OF NEW ANALYSES, AND REACHING THE RIGHT AUDIENCES IN A TIMELY MANNER WITH THIS INFORMATION.

data are currently available and what is expected in the future based upon ongoing and planned studies.

Most important to the success of a publication plan is a disciplined and motivated publication team that is committed to the process.

"While most pharma and biotech companies recognize the significant impact that the clear and consistent publication of results will have on subsequent commercialization efforts, many companies don't quite have the roles and responsibilities clearly articulated," says Timothy Bacon, president and CEO of PeerView. "This can result in conflicts within the team rather than clarity and commitment; we find that this is the biggest single stumbling block."

Another problem that can be resolved with a well-thoughtout publication plan is the issue of staffing for the publication workload.

Teams would benefit by starting the process earlier when data are available, resulting in a staggered workflow with only the late-breaking data sets needing to get fast-tracked across the legal, patent, and regulatory reviewers' desks in half a day, Mr. Bacon adds.

"Sometimes teams create their own problems by not having a good process in place," he says. "A realistic plan takes into account the factors that will impact success, such as delays caused by the internal review process."

Beyond the plan and process are the publications themselves. It is important to ensure that both positive and negative data are published expeditiously to support the successful commercialization of the product.

"The latter is of course dependent on a successful clinical-development plan with studies designed to provide the data required to support the positioning of the product at launch and beyond," says Neil Matheson, CEO of Axis Healthcare Communications.

ALL ABOUT THE DATA

Included in the early stages of a publication plan is communication with the journal's editors. Getting published in the most well-known journals requires early preparation and close work with the lead author, which is usually the primary investigator.

"It is extremely helpful to have the lead author send a letter to the editor of the journal we are interested in, along with an abstract based on the data, to give the editor an idea of the data we are trying to submit," Dr. Kshatriya says. "We then get a response from the editor saying whether he or she is interested in the data or thinks the information is appropriate for the journal. With early buy in from the editor, the process becomes that much easier."

Julia Ralston, president and CEO of MedErgy HealthGroup, has also found that early contact with a journal's editor facilitates the publishing process.

"The author who is handling journal communications can establish contact with the editor to see if an article is of interest," she says. "While an editor is not going to indicate likelihood of acceptance prior to peer review, he or she will more likely provide an indication of interest if the author makes the call directly."

But regardless of the lead time or early communications with a journal, getting published is all about the data in the end.

"There is a misconception, and one that both industry and many agencies share, that there is something that can be done to enhance the chance of publication beyond the two most fundamental factors — the quality of the data and the way the data are presented, and the selection of the appropriate journal based on a thorough assessment of the journal's editorial focus," Mr. Matheson says. "Too often clients have unrealistic expectations about the type of journal they want to submit to and employ an emotional decision-making process rather than a disciplined assessment of the appropriate journals."

Ms. Ralston agrees, adding that one of the most difficult points to get people to accept is the reality of aligning journal choice with how the data set adds to the scientific evidence base.

"The natural tendency is to want to publish in a journal that is perhaps over-matched to the contribution of the data to the literature

base," she says. "It's important that publication planners consider things from the editor's perspective and ask the tough question: is this really of interest to the readers?"

Dora Shankman, president and CEO of Shankman Marketing and Media Resources, agrees that knowing the journals' audiences and the applicability of the data to the audience greatly improve the chances of being published.

"Companies should make sure they know the audience they want to reach and the audi-

PUBLICATION PLANNING: COMING OF AGE

THE PRACTICE OF PUBLICATION PLANNING AS PART OF THE DEVELOPMENT AND COMMERCIALIZATION OF A NEW COMPOUND OR MEDICAL DEVICE HAS MOVED FROM OPTIONAL TO MANDATORY. This growing importance of publications has been accompanied by the increasing value of a well-executed publication plan as a mechanism to ensure a robust bibliography for new products and medical devices. With this comes the necessity to ensure complete transparency around the publication process.

One of the key issues today is ensuring the transparency of authors and all others who contribute to the development of a clinical paper. The focus on ethical standards and disclosure has fallen on journal editors largely because, according to one industry source, 76% of physicians cite peer-review journals as their most important source of medical information. In scientific writing, the designation of author is defined as someone who takes responsibility for the content rather than an originator of the work. In fact, the publishing of study results requires the involvement of a multitude of people. It is the responsibility of the lead author to disclose all contributors and, thereby, promote a level of transparency that will allow readers to make informed decisions.

The most qualified professionals should be recruited for each stage of a clinical study and its resulting publication. The writing aspect is a key component in this process and, at times, has been a contentious issue under the misnomer of ghost writing. As long as a medical writer is appropriately acknowledged, there is no "ghost." An article is likely to be more clear, succinct, and timely if a professional medical writer is assisting the investigator. The investigator's responsibility, however, is to disclose that these services were used and take full responsibility for what ultimately is published. The role of publication planners is to make sure the investigator knows what is appropriate to disclose according to the journal guidelines and is informed of this at the inception of the work.

Quality of information and supporting data were listed as the most important aspects of an article among queried clinicians, with pharmaceutical sponsorship listed last out of seven choices. Based on this industry survey, some responsibility shifts to journal editors to understand that industry sponsorship and the use of professional medical writers does not equal biased reporting or a lack of scientific integrity. In fact, the goal should be to have the journal editors view the involvement of industry and use of a medical writer as a stamp of professionalism and assurance that the article has been written with the utmost integrity and credibility.

The issue of credibility is at the forefront of medical publishing and must also be addressed. In addition to full disclosure, other ways that pharmaceutical companies can increase their credibility, according to experts, is to ensure that all study protocols are posted on clinical-trial registries, avoid redundant publications, and be forthright about disclosure with their investigators. Their relationship with the principal investigator is of primary importance to the integrity of the trial and resulting publication. Investigators must have access to all data, and they must be confidant that the decision about what to publish is ultimately theirs. Publication planners can assist in this area as well by acting as a liaison between the sponsor and investigator and assisting both parties in maintaining awareness of journal guidelines and assisting them in making informed decisions.

An issue that has been in the press recently is the role of review articles in relation to pharmaceutical sponsorship. Review articles allow for more interpretation of study results and, therefore, have more potential for bias. Pharmaceutical companies have been accused of using review articles to promote their drugs in various ways. Publication planners can assist pharmaceutical companies in accepting accountability and ensuring transparency. As long as all pertinent information and contributors of an article are disclosed, it is inappropriate to deny publication of possibly helpful information based on whether a pharmaceutical company has sponsored the review.

The future of publication planning lies in its commitment to act as the guardian of transparency, integrity, and enforcement of good publication practices. It is an important and exciting time to be involved in publication planning.

ROBERT NORRIS
Complete Health Communications Inc.

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JULIA RALSTON
MedErgy HealthGroup

ENSURING ALIGNMENT OF A MULTIFUNCTIONAL TEAM REPRESENTING ALL APPROPRIATE SUBJECT MATTER EXPERTS IS CRITICAL FOR A SUCCESSFUL PUBLICATION PLAN. THIS ENSURES AN APPROPRIATE COURSE OF SCIENTIFIC DATA DISSEMINATION IS CREATED AT THE OUTSET.

ence that the journals they are submitting abstracts to reach," she says.

Ms. Shankman also explains that because researchers spend years developing different hypotheses, and are respected by their peers and colleagues, it is more important to publish in a highly respected journal versus a journal with a higher circulation that is a throw away.

"Most physicians believe the prestige of the publication is extremely important when being published and when being referenced after the published data are complete," she says. "It is key to look at the timeliness of the editorial, submission deadlines for authors, and the sources for the research and data."

MEASURING METRICS

There are a number of different methods for measuring the success of a publication plan. Current trends point to a shift from volume-related metrics to quality-based metrics; however, a focus on quantity is still an important part of many publication planners' toolboxes.

Dr. Kshatriya has found that there are no standard metrics across the industry and has used a number of quantitative metrics, such as a scorecard, to measure the number of papers submitted versus the number of papers published, the number of abstracts submitted versus the number of abstracts accepted, and so on.

The use of metrics in publication planning is evolving rapidly as responsibility for the process moves from the marketing to the medical department.

"Brand managers have been incentivized on metrics such as the number of publications on an annual basis or the quality of the journals where articles were published, rather than more sophisticated metrics, such as quality of the manuscript in terms of the manner in which data are presented, the number of times the data from the manuscript are referenced in follow-on papers, and the quality of correspondence to the journal relating to the article in the months following publication," Mr. Matheson says.

The main goal of a successful publications initiative is the communication of key findings such that they are relevant and practical to the physician, Mr. Bacon says. This is most likely to result in improvement in his or her clinical performance and a subsequent improvement in patient outcomes.

"Clients now are discussing how many abstracts are too many," he says. "A number of clients are focusing on the quality of the abstracts and publications rather than quantity; I think this is a very good trend."

At Merck, the different therapeutic teams look at whether the publications are able to meet all of their most important needs.

"The number of papers is not as important as making sure that we address the major issues that a therapeutic field is facing," Dr. Ross says.

Once metrics are determined and results are available, Ms. Shankman says it is important to communicate the success of the plan to all concerned parties at the pharmaceutical company, particularly the salesforce, key opin-

Sound Bites from the Field

PHARMAVOICE ASKED MEDICAL COMMUNICATIONS EXPERTS WHAT IS THE LARGEST CHALLENGE PUBLICATION PLANNERS ARE FACING AND WILL FACE OVER THE NEXT FIVE YEARS.

CHRIS DICKEY, DRPH, is VP and General Manager, Medical Intelligence Solutions, New York, a division of Jobson Medical Information LLC that provides access to a single database of preclinical and clinical information from thousands of medical meetings and peer-reviewed journals across the world, enabling comprehensive, timely surveillance of scientific developments, treatment trends, competitors' clinical messages, and clinical data. For more information, visit medintelsolutions.com.

"New data on drugs and diseases are being released at a growing number of small and remote medical meetings. Publication planners will consequently have a difficult time staying on top of the therapeutic landscape and staying in touch with opinion leaders in that field over the next five years without access to a comprehensive and current repository of meeting information. The best companies will combine the ability to track this expanding volume of data with the navigational expertise to develop effective publication plans."

DAN DONOVAN is President of Envision Pharma Inc., Southport, Conn., a scientific communications and technology company providing commercially focused, strategically driven scientific and software solutions to the pharmaceutical and biotechnology industries. For more information, visit envisionpharma.com.

"The environment in which publication planners work has changed dramatically over the last couple of years in both positive ways, such as clarification of author responsibilities, and elevation of the role of the publication specialist, as well as negative ways. Unfortunately, it is the negative that concerns me the most. The many tangentially involved groups that constitute the publications arena are increasingly at odds. And that discontent is inflamed by the present media-driven hysteria that drives public perception. The groups that I am referring to include the pharma/biotechnology/device industry, academia (authors), government (NIH and legislators), publishers, editors, and service professionals. Ever more, these groups are taking a 'my way or the highway' approach to issues that impact the publishing environment. In doing so, these groups are isolating themselves and digging their heels in around their own single-minded opinions, rather than coming to the table, trying to understand the positions of all of the players involved, and coming up with a solution that seeks to respect the position of the various groups and respond to the issues at hand."

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WHEN CHOOSING A JOURNAL TO PUBLISH CLINICAL-TRIALS RESULTS, IT IS KEY TO SELECT THE RIGHT PUBLICATION FOR THE AUDIENCE AND TO HAVE A COMPETITIVE ANALYSIS CONDUCTED TO VALIDATE WHAT IS BEING DONE IN THE THERAPEUTIC CATEGORY.

ion leaders, and the marketing team to ensure communications are consistent throughout the company's promotional and educational materials.

PUBLIC DISCLOSURE

Public registries for clinical trials are partly the result of the perception that the pharmaceutical industry only publishes the results of trials that show their drugs in the best light.

These developments not only impact publication planning but the whole process of scientific publishing, Mr. Matheson says.

"Making results available in public online databases is a huge issue that will take time to work through as it requires a major paradigm shift in terms of our approach to data dissemination and publishing as we know it," he says.

Despite the concerns about the impact on the publication process, the full disclosure required by clinical-trial registries is having a positive impact for some companies.

"I believe that public disclosure of clinical-trial information has a positive impact because we are able to publish our study information in a source that also is used by other pharmaceutical companies," Dr. Kshatriya says. "It often takes months and years to get a study published, so from a timing perspective the registries give us a good opportunity to have the study methodology and similar information already communicated to the medical community, and at the same time it gives us an opportunity to know what else is going on and what other studies are being conducted."

Some in the industry have observed that the trial registration and results posting requirements are helping to push manuscript development along more quickly than in the past, so the results and conclusions can be published in a peer-reviewed journal before the data results are released on the trial-results database (clinicalstudyresults.org).

Dr. Ross has observed this effect at Merck.

"When the coauthors see that the results are going to be posted and made public there is more of an incentive to move the full manuscript along," Dr. Ross says. "For many people, peer-reviewed publications remain the gold standard for reporting scientific results."

Ms. Ralston also has found that the industry has become more focused on publishing results promptly.

"In broad terms, the environment now provides for a more rigid and consistent framework, but I don't think it has altered our approach to publication planning per se," she says. " ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Experts on this topic

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