



clinical trial
communications

Reality Check: Is It Newsworthy?

Publicizing clinical trial results can backfire if companies fail to ask themselves the tough questions.

Twenty years ago pharma companies assumed they should delay releasing news about clinical trials to the public until the scientific community could subject the findings to the rigors of peer review. But the imperative to speed time to market, the rise of patient activism, and pressure from external oversight agencies and internal finances made the industry change its mind. Today, Big

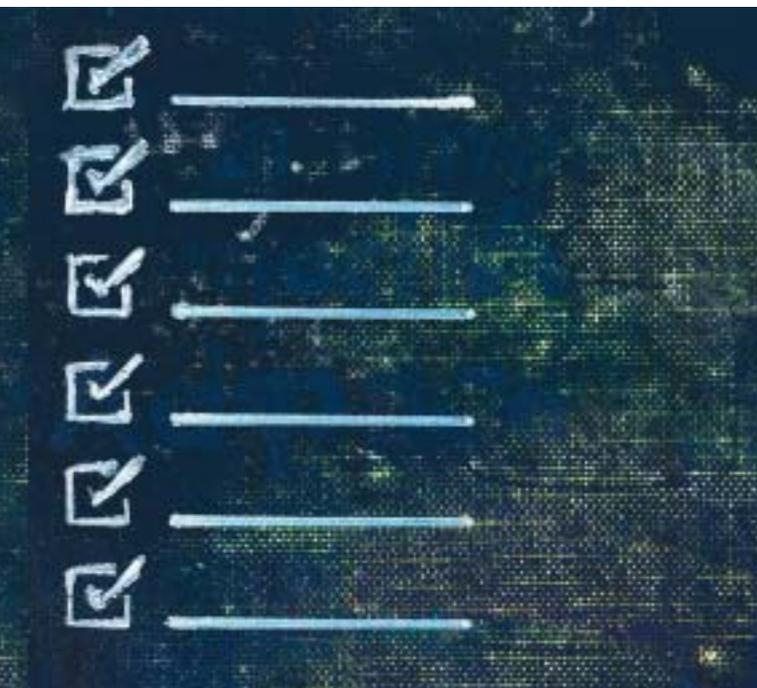
Pharma views clinical research findings as a major opportunity for positive publicity. Even smaller public companies, which are legally bound to keep shareholders informed, also distribute news releases about study results to the media. Sometimes, however, companies release information without thinking it through. This article will help them

understand the roles of in-house and consultant PR professionals in making sound and timely decisions about publicizing clinical research findings.

DESIRED OUTCOMES

If the goal of releasing news is to influence the financial community, companies must be prepared for searing analyses of that product's role in the market. They must also be ready for questions about their product's importance to the company's overall business strategy as well as probes into past and future marketing activities, including advertising and PR practices. If the goal is to quickly reach the medical community—doctors, after all, read the *Wall Street Journal*—companies need to decide if it's better to release the data to the press as soon as it is available or to wait until it is reviewed for publication in a scientific journal or presented at a medical meeting.

Regardless of the intended audience, the PR plan must walk a tightrope between careful dissemination of information to reporters from select "opinion-molding" news outlets, such as the *New York Times* or the *Pink Sheet* and a blanket release to all media.



Coinciding with the distribution decision is the question of whom the news should come from: Should it be the company, the principal investigator's institution, or both? When news comes directly from the company, corporate communications can control the release's content. On the other hand, journalists often perceive more objectivity in announcements from academic research centers. Thus, it is essential for companies to discuss publicity details early in clinical trial planning.

PR strategies must be consistent with regulatory guidelines, especially with companies' interpretations of the Food, Drug and Cosmetic Act. Although FDA provides no specific directives about releasing clinical data, companies should brief their regulatory affairs personnel early in the process to paint a clear picture of what the PR team plans to do and the information it will release.

All PR strategies must factor in predetermined measurements that the company will use to evaluate the program's success. Although measuring PR influence is often expensive, companies can agree on basic criteria, such as expecting news coverage to include specific messages.

COMPLEX SCIENCE

Most PR pros working in healthcare are not trained in science or medicine, yet they are asked to develop and "pitch" stories about complicated medical matters. Appreciating that complexity enhances the value of PR professionals with both pharma companies and journalists.

In his book *Reporting on Risk* (the Media Institute, 1990), the late Victor Cohn, science editor of the *Washington Post*, tried to describe the difficulties of being a competent science journalist. Cohn's rules for reporting also apply to PR pros working for pharma:

Uncertainty is a "first principle" of medical discovery. "Science," Cohn wrote, "is almost always uncertain or unknown to a degree. Nature is complicated, observation is inexact, and research is difficult. So information is rarely complete, and science is always an evolving story." Science communicators need to remind management of that, and be mindful that one study does not rewrite the world's knowledge of medicine. Recent studies about the safety and effectiveness of hormone replacement therapy, published in the *Journal of the American Medical Association*, and the current debate about the "best" treatments for hypertension underscore Cohn's point.

Understand probability. Knowing the power and subtlety of statistics is essential to good science communication. Scientists manage uncertainty by measuring probability. PR pros charged with clinical trial communications must be familiar with the tools that help determine probability, such as p-values and confidence intervals, and be able to explain their importance to journalists who are not experts in medical statistics. A lucid explanation of the mathematics behind a clinical trial earns PR pros enormous credibility with reporters.

Grasp the power of significance. Statisticians spend a lot of time determining how many people a study must include for it to be meaningful. It's easy to get misled or seduced by findings based on small studies or, worse yet, anecdotes disguised as discoveries. Healthcare PR pros must be aware that journalists are often skeptical of such findings.

Beware of bias. Bias does not involve deliberate misrepresentation, but it can indicate sloppy science. Several years ago, a Los Angeles medical center was delighted when a study showed it had one-third fewer coronary deaths than East Coast rivals, until it realized that

the study was of 30-day post discharge morbidity and mortality rates and that the center kept patients for shorter periods than East Coast hospitals did. That shortened the length of the study, naturally reducing the number of deaths as well.

Appreciate that the world is full of variation. It is extraordinarily difficult to find perfectly matched groups of people. Men and women react differ-

THE TOUGH QUESTIONS

Companies need to answer the following six questions before releasing clinical trial information:

1. Does the company have a public relations strategy?
2. Does the strategy account for the complexity of the science?
3. Does the PR plan address journalists' needs?
4. Is the company overreacting to "the siren song of the crowd?"
5. Does management understand the role of public relations?
6. Do the PR pros have the courage to say "No?"

SERGEL SAYS

Roger Sergel, a senior medical producer for ABC News, asks public relations professionals to run news through a seven-point checklist if they expect to see coverage:

1. What are the advantages of an investigational drug over what currently exists? If it does not improve patients' lives, cost less, or provide some other tangible benefit, it is not news.
2. How big is the improvement over existing therapy? It can be a small improvement in a large population or a dramatic improvement in a narrow disease area. Both make news.
3. What is the potential patient pool? Sergel notes that his editors always ask how many patients have the disease. They believe that a major advance in the treatment of congestive heart failure, a condition that affects hundreds of thousands, is more newsworthy than an advance in the treatment of a rare disease.
4. In what phase of research or regulatory filing is the treatment? Although the old rule of thumb suggested that only Phase III studies merited press coverage, Sergel says ABC now considers interesting treatments at earlier stages.
5. Who are the leading investigators and who are the biggest enrollers? If ABC News elects to tape a clinical trial site, it usually opts for sites with the largest patient base.
6. Has the news received earlier coverage? If NBC's "Dateline" has already aired it, ABC's 20/20 is unlikely to consider it unless the story comes with a new angle or "hook" for another program such as the evening news.
7. What will the audience see? TV needs visuals: patients certainly, but ideally, some demonstration of the how the treatment works or of the impact of the disease. If there are no dramatic pictures of the treatment or its effect, are compelling MRI images or videos of high-tech diagnostic equipment available?

ently to medicines. Environment and genetics can play a huge role in determining medical outcomes. Consequently, findings from one group of patients may not apply to others, so companies should be wary of how they and others speculate about the applications of trial findings. In the future, variations will be even more important, because they will be the subject of pharmacogenomics trials designed to learn more about the impact of individuals' genetic makeup or their propensity for particular diseases as well as therapeutic responses.

NEWS NEEDS

"Who in the world wrote that headline?" a reporter once complained about a press release. "It looks like it was drafted by lawyers." Well, it probably was. Communicators walk a tightrope between corporate policies and the needs of working journalists.

"Good public relations pros are basically good reporters," says Cathy Yarbrough, vice-president of communications and public affairs for Rockefeller University. "As a result, they will talk with not just one but several people involved in the study to obtain a range of viewpoints and comments—and more important information that can make or break the communications."

Although press releases must pass through the gauntlet of medical, regulatory, and legal reviews, they are useless if they fail to capture—in the headline and first paragraph—the importance of a clinical trial's findings to both the medical community and to the company sponsoring it. Although internal PR pros and their consultants must vigorously lobby pharma companies to ensure that press materials are useful, medical and regulatory staff must also understand journalists' needs for releases to be noticed and used.

Companies should not hide bad news on the third page of a press release, because it may backfire. The impression reporters get from that treatment is that the trial was not only unsuccessful but that the company was being less than forthright. A better strategy is to get bad news out quickly, with as little "spin" as possible.

Several years ago a medical device company received the unfortunate news that its product for treating a central nervous system disorder failed to meet its primary endpoint in a Phase III clinical trial. The CEO drafted a press release trying to rationalize the failure. That was a bad idea. First, it is nearly impossible, without weeks—if not months—of analysis, to objectively explain why a trial fails. Second, journalists have strong "spin detectors" and generally know when a company is trying to explain away poor results.

Journalists are a varied lot. Some, such as Lawrence Altman of the *New York Times*, Laurie Garrett of *Newsday*, and Robert Bazell of *NBC News* have advanced degrees in life sciences and require no tutoring. Others, even at large and medium-sized news outlets, have learned about their subjects on the beat or are generalists who lack awareness of the many subtleties of clinical research.

Wally Pfister, a media training pioneer who taught hundreds of doctors to

face journalists, used to say there are only three questions that matter to the average reporter: “So what?” “Who cares?” “What’s in it for me?” If a company can’t succinctly answer those questions, it has no story.

AVOID THE SIREN

Even the most seasoned PR pros can be seduced by the excitement of senior corporate managers or financial analysts who consider a new product “the next big thing.” But even when a company has great news to communicate, PR pros are careful to avoid getting swept up in the natural enthusiasm of individuals who may not be objective.

About ten years ago, a now defunct biotech company was investigating an interleukin-1 receptor antagonist for the treatment of sepsis. The company’s internal and external consultants advised it to be conservative about how it described its early stage trials, pending the outcome of Phase III trials that would be necessary for FDA approval. Everyone, from the CEO to the corporate communications staff, tried to do that. Yet, when financial analysts wrote glowing reports and journalists lined up for interviews, it was virtually impossible to mute the enthusiasm, and off-the-cuff statements slipped out. That “irrational exuberance” returned to haunt the company when the molecule failed to perform in late-stage trials.

NO NEWS BEFORE ITS TIME

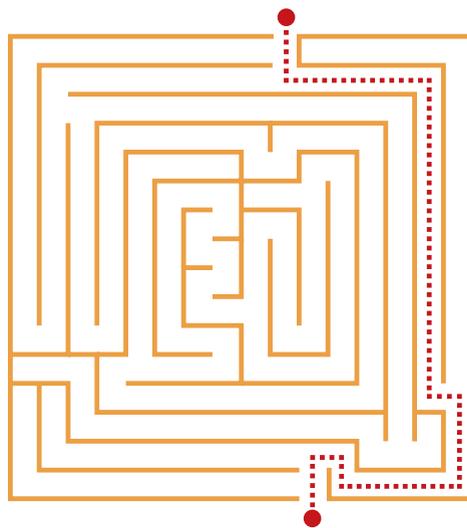
PR pros need the courage to ask the tough questions in preparation for releasing clinical trial data. They must be ready to vigorously defend their views and stand up to MDs, PhDs, and even CEOs if they believe that publicizing research data would not serve the company’s long-range interests. If they don’t ask question the trial’s relevance, the complexity of its design, or its importance to the company’s audiences, they are failing to perform an impor-

tant function of both internal and external PR advisors. That analysis will help lay the foundation for a successful PR strategy, not only for the trial communications but also for the company’s long-term success. ■

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