

The Value of Postmarketing Studies

By Timothy Pratt, PhD

Recently, Timothy Pratt, Ph.D., chief marketing officer and principal scientific advisor of MedNet Solutions, Inc., was asked to speak at a meeting.

“What gave me pause for a moment was the topic: the value of postmarketing studies and registries,” he says. “It wasn’t that I’d never thought about the topic. What concerned me was that it should even be a question. I was being invited to speak to an organization – a very large one, mind you – where a department was advocating setting up a postmarketing research initiative, but the broader corporation didn’t see the value in it. I was being asked to describe my experiences in an effort to garner support.”

The presumption that postmarketing research is valuable is as intuitive and self-evident as EDC can save a lot of time and money and integrated CDMS/CTMS systems are the best, he says.

But the assumption of the value of postmarketing initiatives is not universally shared, he acknowledges.

“Let’s start with a fundamental premise: This is marketing,” Dr. Pratt says. “With that statement I have probably offended, or at the very least raised the hackles of, innumerable scientists, researchers, engineers, and government officials – most of whom regard marketing as an insidious, if necessary, evil. I will contend that all activities of all companies are inherently marketing based, and so a major problem of perception exists.”

A Working Definition

Marketing is fundamentally about profitably matching what the company is capable of with what consumers want and are willing to pay for.

“This bedrock concept carries with it far-reaching ramifications: essentially, that the corporation that better markets by meeting more customers’ needs versus the competition will be the most successful,” he says. “When everyone – from the secretaries to the clean-room workers, to the scientists, to the accountants, to even those who have marketing in their titles – recognizes they are ultimately working to meet the needs of the customers, they are engaging in marketing.”

Successful companies make a concerted effort to help their people understand how they meet customers’ needs in some

form or another. They do this because the company that markets the best wins.

There are different points of view as to how to do this. A popular one in many companies is the better mousetrap paradigm: build it and they will come. He says this is especially attractive to those who live in a world of formulas and machines.

“Unfortunately, if what has been built does not meet someone’s needs, it doesn’t matter how elegant an engineering or chemical feat the company has performed, it simply won’t sell,” Dr. Pratt says. Even if it does meet a need, if the sub-elements of marketing aren’t in place – the promotion, price, and distribution, and others – the product will fail. In my old stomping grounds of medical devices, this became clear when ground-breaking new pacemakers and defibrillators were released, yet the predicted market share shifts never took place.”

Those device products were much less successful than they could have been because of the better mousetrap paradigm, he says. Essentially, they were put into the marketplace with minimal clinical data – just enough to get the products approved – and some sales rep training. There were precious few approved claims to be made and even less sponsored postmarketing research to get any.

Customers’ needs were considered in designing the product itself, just as pharma companies consider new indication needs/better solutions in developing new drugs; but he says scant attention, if any at all, was paid to postmarketing elements of customers’ needs.

“In the arena of clinical research, the epitome of the mousetrap paradigm is conducting an approval trial and then releasing the product with little or no follow-up,” he says. “It is a rare product that sells itself, and most business leaders say no product does.”

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Why Physicians Participate

All products require post approval marketing; and if marketing is all about meeting the customers' needs, then that's a great place to start, Dr. Pratt says.

"I suggest that physicians, for the most part, want to do research, and in marketing speak, a want is an unmet need," he says. "Pharma companies know that physicians love to do research on new drugs. Just consider the burden of work when all the requests for funding investigator-initiated trials come flooding in after every new drug is released. Sometimes, if the company won't fund the research, physicians find a way to do it themselves."

This, he says, begs questions beyond the characteristics of the actual product: what are the drivers for physicians to engage in research, and why is it such a big deal?

"It's a big deal because, in conducting research physicians get kudos – from their peers, from their referral base, and from their patients," he says.

Acclaim can come in many forms: publication in medical journals, speaking at dinners/symposia, even in-clinic promotion. In the highly competitive medical-care arena, many physicians believe it is important to be able to assure patients and referral physicians alike that they are staying current in their chosen fields and indeed continually are searching for the best ways to effect the best patient care. Active participation in ongoing research is considered to be an effective mechanism to give such assurance.

"It has been my experience that many physicians who participate in research choose to frame and display manuscripts and abstracts of their work in their clinics," he says. "It is frequently a topic of discussion at referral dinners where they market their services to their customers, the referring physicians; this is vital to their ongoing successful practice. Indeed, I also have seen the newsletters supporting current research placed in patient waiting areas, especially when the clinic is 'profiled' as the site of the month."

For academic institution physicians, engagement in research may actually be a requirement of their ongoing employment. These physicians are not subject to a large degree of referral pressures but are required to publish a certain amount of original research every year. "Publish or perish" takes on a whole new meaning when they need something to publish from (i.e., research). Beyond National Institutes of Health grants or endowments, the primary mechanism to effect the conduct and publication of large-scale original research is corporate sponsorship.

Varying factors – from the use of sophisticated Bayesian statistical models driving down sample sizes, to the conduct of studies outside the United States as a regulatory strategy, to individual rep/MSLs lobbying for their physicians' involvement – may conspire to limit opportunities for physicians to participate in approval studies and engage in research.

"When focus centers are also thrown into the mix, the likelihood of involving the physician from rural Idaho, irrespective of skills or background, is low," he says. "Generally speaking, so much rides on product approval, from a corporate perspective, that few if any risks are willing to be taken. That is not without some justification, given the patient benefit and money involved."

This means that participation in the supporting research is often restricted to a small segment of the available physicians.

Proactive Postmarketing Initiatives

Proactive development and deployment of postmarketing research initiatives is a simple, cost-effective solution, with multiple internal and external benefits. For physicians, their needs as outlined above can be met. For the pharmaceutical companies, the benefits can be even more extensive. On the tactical level, the process of inviting physicians to participate can afford the reps or MSLs the opportunity to engage their customers in a discussion about a topic they are interested in.

In this scenario, no one is trying to sell physicians anything, so they are much more likely to make time to discuss the concept.

"Given that the concept will revolve around the sponsor company's drug or device, promotion – although not overt – will necessarily occur," he says. "The attractiveness of legitimate, research-initiative discussions as a door-opener should not be underestimated; I have frequently seen physicians who refuse to meet with company representatives for any reason enthusiastically respond to such an invitation."

On the strategic level, benefits are multitudinous. Postmarketing research can be legitimately positioned as giving back to the medical community (corporate philanthropy); ongoing concern over real-world performance and monitoring; averting the mandate for, or complying with, an existing, regulatory body request or regulatory submission; and more, including tax credits.

"While at a previous company, a carefully designed and conducted initiative led to R&D tax credits for the entire postmarketing research expenditure; successful submissions to regulatory bodies; and publications of multiple papers, abstracts, and posters," Dr. Pratt says. "Thousands of centers

and physicians who would not have otherwise been able to engage in research had the opportunity to partner with us. We were able to reach out and touch a significant percentage of the customer base that was otherwise very difficult to engage. By virtue of the cost-effective, easy-to-use, and flexible data capture and reporting methodology we employed, we had enthusiastic participation from physicians from around the globe.

“Happily, as a consequence of the postmarket - research activity, significantly more physicians became aware of our products and their capabilities; and concomitantly major regional shifts in market share took place, even outside the confines of the research, primarily as a result of physician awareness,” he continues.

What Makes A Successful Study

Dr. Pratt stresses that companies should never fall into the trap, however, of regarding postmarketing research as simple.

All too often, postmarketing research is viewed as a cost-overhead or merely as a vehicle for overt promotion. Only good quality, well-constructed postmarketing research will be successful in the long term and keep companies out of hot water with the Department of Justice and Office of Inspector General in the short term.

“Concern over DOJ/OIG compliance has led some companies to scale back dramatically on postmarketing research, but the DOJ and OIG have no interest in shutting down legitimate postmarketing research,” he says. “Their interest is in halting the abuses associated with assorted boondoggles of the past. These were flash-in the-pan-successes anyway since someone else can always outspend you.”

Good quality initiatives, the type that engage physicians and meet their needs, are characterized in essence by:

- Dealing with a legitimate area of scientific inquiry ;
- Being of significant interest to both physicians and corporate customers as a general whole ;
- Balancing the scientifically desirable with resource availability;
- Providing information for future product development/ improvement;
- Supporting the strategic product/therapy direction of the company; and
- Complying with relevant regulations for the testing of human subjects.

There are many other elements to successfully constructing postmarketing research, including investigator selection, center characteristics, publication planning, deployment modalities, support materials and meetings, data capture, and reporting considerations.

“In so far as the sponsor corporation puts some horsepower behind these activities, large-scale conduct can become easy; but the arena is no less simple than that of approval research and, in some ways, more complex,” he says. “Postmarketing research is a valuable and profitable mechanism by which corporations can meet customers’ needs and, at the same time, meet multiple internal tactical and strategic needs of their own.

“Properly constructed and employed, this sort of activity can move market share, earn tax credits, gain kudos, and more,” he continues. “It’s marketing. It’s what good corporations are all about.”