

The Value of Conducting Post-Marketing Clinical Research On Marketing Strategy Development

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Those of us who are marketing executives in the pharmaceutical industry acknowledge the importance of post-marketing clinical research studies to further assess real-time use of a product. In an industry that is heavily regulated and scrutinized, pharmaceutical brands must not only go through Phase I-III clinical research to validate the drug's safety and tolerability in a smaller subset of a diseased population, but testing of the product to monitor its safety and effectiveness in a real-world setting once and after the product is approved for marketing. Post-marketing clinical research, used interchangeably with Phase IV testing, is a phase that takes place after a product is available on the market for public use and is subsequently used to track a product's safety and tolerability in a real-world setting. Marketers in this industry know that the research needed to market and sell a drug product is quite different than research needed to gain the Food & Drug Administration's (FDA) approval.¹ In addition to post-marketing surveillance, Phase IV clinical studies are also helpful in developing marketing strategy for a product. Post-marketing research gives insight into all kinds of questions and concerns raised by the FDA. Not only does it allow companies to monitor for real-time effectiveness, long term safety and tolerability, but it may also give rise to evidence of possible new indications and new markets for which the drug product had not been initially approved. Just as Phase IV clinical research is

¹ Desphande, Ravi, PharmD, *Bridging the Gap between Clinical and Marketing Initiatives*; Canadian Pharmaceutical Marketing, spring 2003, p39.

used for conventional pharmaceutical medicines, it is just as important and should be equally important in the research phase of a natural product such as nutraceuticals, botanicals and dietary supplements.

The Necessity for Phase IV Research

Talking about Phase IV research raises the question as to why it is needed in the first place. Before drugs are marketed, drugs are considered drug candidates. During Phases I, II, and III of the drug candidate's life cycle, clinical research is designed to test and validate how safe and effective it is. As you know, these processes can take many, many years, filled with many trials and errors. If a drug candidate has successfully sustained this and makes it way to market, and becomes a drug product, there are many important and unanswered questions that are, in essence, very time-sensitive. These questions include mainly safety and efficacy concerns by the FDA: how safe and effective is the drug's use in a diseased population with varying degrees of illness? How safe and effective is it when used by a patient with more than one illness or those taking multiple drugs? How does the drug product compare in safety, efficacy and tolerability with other products in its class? What are the risks vs. benefits of the drug? Do the benefits outweigh the risks? Companies who face the daily challenges of answering these questions depend on the conduct of post-approval research for answers. Second, they see the importance of working with their medical counterparts to access such data and create a transparent decision-making process.² Accessible clinical data makes it possible for a company to quickly and effectively answer post-approval FDA questions and may make a difference

² Best Practices LLC, *Report Summary - Launching Pharmaceutical Megabrands: Best Practices in Marketing Blockbusters 2004 Edition*, p2, accessed at <http://www3.best-in-class.com/>

between market success and failure of the product.³ But these questions must also be dealt with by marketers when strategizing a marketing plan targeted to its primary market. In the pharmaceutical industry, time equals money, indeed.

The Value of Clinical Research

You may be asking, “What value does clinical research have on marketing the product?” The value is tremendous, to say the least. In the pharmaceutical world, clinical research is the one of the bridges to the gap in marketing (the other being marketing research) namely between the product and customer. Richard K. Thomas defines marketing as “the process of planning and executing the [product] conception, pricing, promotion and distribution [place] of ideas, goods, and services to create exchanges...,”⁴ between the customer and buyer. This is essentially referred to as the four (4) P’s of marketing (product, price, promotion, and place). By answering many unknowns about the drug (mentioned earlier), many insights and analytics regarding the product, price, promotion, and place can be drawn to develop marketing strategies to essentially connect the product with the customer. The role of clinical research in marketing medicines is to aid that connection. What makes marketing medicines so uniquely different from other product marketing is that the FDA is the intermediary. The FDA decides the fate of a drug candidate or product entering the marketplace based on the supporting clinical evidence presented by the company and gives the final ‘yea or nay.’ Pharmaceutical companies are obligated under the Pharmaceutical Research and Manufacturers of America (PhRMA) code to be informative,

³ EMC Perspective, *Leveraging the Value of Data from Clinical Trials*, Accessed at <http://www.emc.com/collateral/emc-perspective/h4338-clinical-trials-ep.pdf>

⁴ Thomas, Richard K. *Health Services Marketing: A Practitioner’s Guide*; New York: Springer Science & Business Media, LLC, 2008.

ethical and professional when marketing medicines to physicians.⁵ Clinical research essentially represents those three. Clinical research takes out the risk of compromising patient care when presenting information and educating clinicians about a drug's use and health benefits. It provides the hard scientific evidence needed in order for healthcare professionals to make sound and informed decisions about medical treatment for their patients. The company's commitment to medical research also makes the company more trustworthy to the medical community. Companies who utilize clinical research data can also benefit from the tons of insight into how a product is different from others indicated to treat the same illness(es), what its attributes are compared with competing brands, how a product should be competitively positioned based on its attributes, how a company should promote the product to its primary constituents, e.g. physicians, patients and payer organizations (health plans and insurance companies), etc. Clinical research plays a huge role in formulating marketing strategy, as the data gives insight into customer/consumer needs and competitive positioning, and also what aspect of the drug product's profile should be emphasized when targeting marketing campaigns to key customers and consumers.⁶

How Clinical Research Can Be Used As a Dissemination & Education Tool to Key Target

Groups

⁵ Pharmaceutical Research & Manufacturers of America: Code on Interactions with Healthcare Professionals. Accessed on March 20, 2009, at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>

⁶ Best Practices LLC, *Report Summary - Launching Pharmaceutical Megabrands: Best Practices in Marketing Blockbusters 2004 Edition*, p2, accessed at <http://www3.best-in-class.com/>.

Clinical research data provides the most up-to-date scientific intelligence on the product's mechanism of action, effectiveness and safety profile to key groups and decision-makers. Those key target groups and decision makers include physicians, payers, buyers, key opinion leaders (KOLs), the company's sales force and even the FDA. It is important for the pharmaceutical industry as an educational tool for and information dissemination to their primary constituents in, but not limited to these aspects:

1. *Physicians*: It is ideal, especially for pharmaceutical companies that healthcare professionals base their prescribing decisions on supporting evidence provided by clinical data,⁷ however, healthcare professionals are expected to base their patient care “solely on each patient's medical needs and their medical knowledge and experience.”⁸ The PhRMA code also reinforces that professional exchanges with the medical community is designed to benefit patients and enhance the overall medical practice. Thus, there is great opportunity for companies to interact with physicians and provide scientific and educational information as well as medical education through clinical research. The more robust the clinical evidence, the better the case is for that drug to be on top of mind when a physician is making a prescribing decision. Building professional relationships with the medical community is critical for these companies because it opens up opportunity for life altering products to be accessible to patients who need them and subsequently earn more return on investment.

⁷ Maxwell, Simon R J Evidence based medicine is the goal, but *prescribers still need education, experience, and common sense*; BMJ 2005;331:247-248.

⁸ Pharmaceutical Research & Manufacturers of America: Code on Interactions with Healthcare Professionals. Access on March 20, 2009, at <http://www.phrma.org/files/PhRMA%20Marketing%20Code%202008.pdf>



2. Payers: A payer’s responsibility is to provide healthcare that is effective, affordable and satisfactory to as many people as possible. When new products have entered the market, payers (healthcare insurance providers) are primarily concerned with 1). Evidence that demonstrates a product’s clinical safety and effectiveness; 2). Cost-effectiveness – payers need to know and be reassured“...that their dollars are being spent wisely” and; 3). How clinical research findings can be translated to medical practice from a disease prevention and management perspective.¹⁰ Findings from traditional clinical trial research are paramount for health plans in addressing and determining all of the above concerns. However in today’s medical culture where the paradigm has shifted from the physician to the patient, health plan companies see the need to become more patient-centered and to shift the way in which they provide care. Representatives from major health plan companies have argued that more non-traditional clinical research needs to be available,¹¹ especially when it is time to make crucial decisions around how to effectively deliver healthcare, what services to cover and recommend to the insured. That is to say more research needs to be focused and done around the patient. These include behavioral research on physicians in a clinical setting and how to change their behavior, health services research that looks at ways in which to improve the delivery of healthcare, and

⁹ Tunis, Sean, Korn, Allan, and Ommaya, Alex, *The Role of Purchasers and Payers in the Clinical Research Enterprise: Based on a Workshop of the Clinical Research Roundtable*; Board on Health Sciences Policy, 2002, p30.

¹⁰ Tunis, Sean, Korn, Allan, and Ommaya, Alex, *The Role of Purchasers and Payers in the Clinical Research Enterprise: Based on a Workshop of the Clinical Research Roundtable*; Board on Health Sciences Policy, 2002, p29.

¹¹ Tunis, Sean, Korn, Allan, and Ommaya, Alex, *The Role of Purchasers and Payers in the Clinical Research Enterprise: Based on a Workshop of the Clinical Research Roundtable*; Board on Health Sciences Policy, 2002, p29-37.



other forms of public health and outcomes research.¹² This presents huge opportunities for pharmaceutical companies to work with in-house and external researchers to fund and spearhead these kinds of research to address these concerns.

3. KOLs: Effectively marketed clinical data to KOLs is a huge factor in gaining full product support going forward. A crucial demographic, KOLs are expert physicians who have influence over medical practice. They must be a well sought out group for the pharmaceutical industry because they “set the pace for industry trends.”¹³ They can share a wealth of information and insight “ranging from clinical science to advertising concepts” and provide “highly credible exposure for a product in the medical community through speaking engagements, articles in medical journals and general practice.”¹⁴ Engaging them in qualitative market research and more importantly medical symposiums with the latest clinical research early and throughout the product’s lifecycle could mean invaluable feedback and insight throughout the life of a product and thus increased marketing exposure in clinical practice.
4. Sales Team: Although not a target group, the sales force must nonetheless be a number one priority for any company engaging in direct to physician sales to their target market. The sales team essentially acts as the spokesperson between the company/product and the physician, thus time must be invested to proactively and continuously keep members of

¹² Tunis, Sean, Korn, Allan, and Ommaya, Alex, *The Role of Purchasers and Payers in the Clinical Research Enterprise: Based on a Workshop of the Clinical Research Roundtable*; Board on Health Sciences Policy, 2002, p29-37.

¹³ Schwebach, Gary, MD, *Qualitative Market Landscaping Helps Pharma Grow Better Brands*, <http://www.gs-research.com/pdf/ORCAWinter-Pharma.pdf>, Winter 2007, p2.

¹⁴ Schwebach, Gary, MD, *Qualitative Market Landscaping Helps Pharma Grow Better Brands*, <http://www.gs-research.com/pdf/ORCAWinter-Pharma.pdf>, Winter 2007, p2.



the sales force educated on the benefits of the product. Clinical research provides the company's sales force with newest data to go out and effectively disseminate and educate physicians on the product. The degree of success of the pharmaceutical company's sales team directly influences the revenue generated for the company and the longevity of the brand.

5. Buyers: Clinical research is and will have increasing importance for distributors when helping consumers understand labels and products. With increasing consumer demand for natural products, there is more need for in-store nutrition knowledge within the retail sector. Retailers must be well-informed about the products they distribute and sell. Before point-of-sale, retailers have an important role in explaining nutrition labels to consumers. This presents loads of opportunity for natural product suppliers to utilize clinical research, in conjunction with market and outcomes research to train and educate their distributors using their product's clinical trial data. Opportunities such as advertising displays, promotional items, leaflets, pamphlets, videos, etc. can be used by distributors so in turn they can market to their consumers.
6. FDA: Clinical research also serves as a dissemination tool to provide evidence to the FDA when a pharmaceutical company is interested in expanding a drug's clinical indications (another condition that the drug can treat that is different from the condition(s) it was initially approved for). If the drug product is fortunate to have such additional benefits, it can open up a whole new market, and thus yield increased product value and the potential of limitless return on investment.

Post-Marketing Research - Pharmaceuticals vs. Natural Products : Similarities & Differences

You may be asking, how pharmaceutical post-marketing clinical research compares with post-marketing research for natural products having health benefit indications. Post-marketing research will answer similar, if not the same, types of questions. Sure, the FDA approval process is very different for natural products, there is no Phase I – Phase III product lifecycle per se, but the marketing success of the natural product industry, like any other industry, is influenced by the product, price, promotion and place that marketing strategy is designed to address. The stakeholders for the natural products industry remains the same as for pharmaceutical, e.g. consumers (patients), physicians and/or complimentary health professionals (naturopathic, holistic, homeopathic, herbal practitioners, etc.) and buyers, with slight emphasis on one market over the other. Each of these groups still must be tapped into and convinced in the post-marketing phase of the product with clinical data to get their acceptance, buy-in, and ultimately, their sales.

It is no surprise that Phase IV clinical research has become the fastest growing area of clinical research today.¹⁵ It is such a major part of the pharmaceutical drug commercialization process because of the questions that the clinical data will answer for the FDA, but also because of the many opportunities it creates to effectively market to physicians, patients, payers, buyers, KOLs, the sales team and the FDA. The same goes for dietary supplements and other nutraceuticals with health claims. In a growing industry that is saturated with competition,

¹⁵ Cutting Edge Information. Mastering Phase IV Clinical Trials. Accessed on March 18, 2009, at <http://www.cuttingedgeinfo.com/postmarketingtrials/>

where consumers are inundated with choices, and where there are too many channels of product distribution available, clinical research becomes paramount in distinguishing a product from its competition, strategically positioning the product against the standard, and enhancing the product's attributes, among others.

Nutraceutical Medical Research, LLC is the only dedicated, full-service, nutraceutical-focused contract (clinical) research organization. We serve the natural product, dietary supplement, nutraceutical, cosmeceutical and pharmaceutical industries. NMR will help, 1. Differentiate your product in the marketplace; 2. Enhance your product's sustainability; 3. Increase your ROI; 4. Meet your goals for attracting new buyers and users; 5. Strategically position your product and brand.

To find out more about how post-marketing clinical research can help increase your product value and the specific types of research that can be done for your particular product, please contact us at:



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