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Clinical Trials: Not Just for Registration

By Steve Butts

The pressure on companies to quickly launch new pharmaceutical and medical device products has never been greater. While industry veterans understand the market and shareholder pressures that have caused this, product managers are still left holding the bag. If they launch quickly without key information to deal with eventual market issues, it is an unsuccessful launch. Conversely, if they have the right information, it is a successful one. That's because the same high-speed information sources that help marketers quickly create product awareness are the same ones that can doom a launch. If early adopting physicians have less-than-stellar first experiences, news travels fast and it is doubly hard to change physician beliefs about the value of a new product in their patients.

To deal with this issue and arm themselves with the right information, marketers over the last five years have involved themselves earlier in clinical development. While this has improved product valuations--and better guidance for medical teams on clinical endpoints and product labeling---a best practices approach means that another issue should be addressed at the same time.

One is to keep in mind that physicians frequently prescribe new products to patients in the "Tough to Treat" category. That's great if a new product works perfectly in all of them, but you know what happens if it only works in half of the patients and the physician was expecting something different. The word gets around even if NO other product successfully performed in those patients. To short-circuit this, best practices marketers learn in advance how customers will first use the product. Then they make sure they acquire data on those patients in the clinical trials. Prepared, they can then say (for example) "since it worked in half of the patients where no other product helped, just imagine what you might see if you used it in the target patient population".

The bottom line is that in today's market you need data and information about your product in your target patients, and also in the likely candidates for your brand from the physicians' point-of-view. You do that by getting to know your customers and how they think very early in the process, and then use that information to design your clinical protocols. That way, everyone knows what is going to happen and you know how to set expectations when talking with your customers.

If you would like to share your experience in these issues, or discuss how you can ensure a successful product launch, send an email to rkeefe@tcgbiopharma.com.

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