SPEAKout

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TREATING THE WHOLE PATIENT:

A More Compelling Approach to Product Development

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Mark has more than 25 years' experience in healthcare marketing including extensive experience in oncology, immunology, neurology, and endocrinology.

Instead of focusing only on your product, consider the impact if your product was studied in tandem with an intervention that addresses whole patient needs. By taking this approach, you're formulating a plan to differentiate your company and help your brand standout even in a competitive environment.

The traditional world of product development is driven by the need to generate data that are required for regulatory approval. While this model has been consistent throughout the design and implementation of most clinical trials, it falls short in 3 key areas.

1. Clinical trials lack real-world context. While these trials are scientifically rigorous, they don't always reflect what is happening in the real world. Traditional clinical trials screen out large numbers of patients based on additional medications, concomitant conditions, age, or other factors. A real-world trial treats a higher percentage of patients and incorporates both the product and potentially a behavioral intervention.

2. Patient preferences are not considered. Clinical trials usually don't reflect what is important to the patient. The quality of a patient's life, his or her comfort with the treatment approach, and the level of stress and anxiety would be quite compelling; the clinical trial endpoints in a traditional clinical trial often lack these elements.

3. Behavioral science and psychosocial interventions are not incorporated. By continuing solely with a product-based clinical trial, pharma is missing an opportunity to enhance the impact of the product and generate more compelling evidence. Evidence-based behavioral approaches can be delivered in an intervention alongside the product and can impact treatment outcomes including adherence, quality of life, and in some cases, mortality. These are factors that matter to patients, physicians, and your brand.

Consider the impact if your product was studied with an intervention that addresses whole patient needs.

How can you position your clinical trials to accelerate brand adoption?

Research and development has not fully leveraged the patient in drug development. Companies may be checking off the patient-centric box by involving patients in the trial design and including patient endpoints, but the majority of trials are still being conducted in a product-centered manner. The goal has always been to satisfy the requirements for FDA approval based on product efficacy and safety.

Instead, try engaging patients earlier in the process. By doing this, you gain an understanding of what matters most to them. Quality of life, disease progression, treatment impact, stress, anxiety, support, and other factors are important to consider. A whole patient approach addresses these factors by incorporating evidence-based behavioral strategies. These methods improve clinical outcomes and support the clinical and nonclinical (psychosocial) needs of patients.

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What's the impact?

Payers prefer products that can reduce overall health costs. So, why not demonstrate how an evidence-based, whole patient approach can improve adherence? This powerful combination of product efficacy and real world outcomes can lead to improved reimbursement and formulary position.

Demonstrating superiority in a head-to-head study against a key competitor is very difficult and potentially risky, especially in a poorly differentiated category like diabetes. Superiority studies are also very expensive in comparison to adding a behavioral intervention to an existing trial.

A more viable approach to differentiating a product is by addressing patient needs through a behavioral intervention with your clinical study. Addressing patient needs can result in improved patient outcomes. By adding a behavioral intervention early in the clinical trial process, you generate more compelling clinical evidence to help generate sales and accelerate your brand.

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