

Personalized Medicine Requires Personalized Measurement



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CNS is the second largest area of pharmaceutical research, but the success rate has been low and approvals rare. In CNS drug development, it is common for investigational therapies to show promising effects in earlier trials, only to fail in the final stages of testing. Some of the reasons can be attributed to the technical difficulty of getting drug molecules to their targets across the blood-brain barrier, which in protecting the brain also protects the disease. However, the number of failed Phase III trials following exceptional Phase II results point to another underlying problem in CNS: having a drug that works is necessary to demonstrate efficacy at the magnitude that merits approval.

The data on non-adherence are staggering: 25%-50% of patients do not take their medication. Add to that the high rates of placebo response in psychiatric disorders, and it is no wonder that mental illness contributes the highest proportion of healthcare costs. Pharmaceutical companies now recognize the transformative potential of taking approved compounds and delivering them in innovative ways that help patients stay compliant. It is an applied approach to a patient-centered model of drug development.

The medical, social, and financial value of unlocking treatment adherence is one important takeaway; another important takeaway is methodological. The outcomes in CNS trials are subjective compared to other areas of medicine, with primary outcome measures based on clinician-observed or patient-reported questionnaires. Despite significant advancements, our trials are still haunted by the specter of high placebo response, patient misclassification, and unreliable outcomes.

A thriving niche has been established over the last decade in looking for solutions to these measurement problems. Our colleagues in this area have tried many approaches: making patient selection independent or consensus-based, improving outcome measures themselves, using technology solutions to enhance detection of change, training investigators to achieve standardization, training patients and caregivers to improve reliability of reporting, patenting adaptive protocol designs, etc. Similar to clinical practice, we have found that none of these solutions work if applied in isolation. With Phase II data, we can analyze underlying trends and quantify risks to outcome data. The important next step is to remain uncompromising in the focus of applying those insights to the selection of a calibrated set of measurement tools to be used in the trial.

Recent successes portend a new era of drug development, one in which treatment efficacy is established in the context of the patient's life and behavior. It is time for measurement science to follow and embrace the fact that how we measure outcomes will evolve from applying one solution to finding an empirical basis for a highly customized application of all of them, enabled by technology. Personalized medicine needs a personalized approach to measurement. ●

of an always-connected world. When an agency can consolidate all of these disciplines under one roof, it can create a more efficient and integrated solution, thereby reducing the burden on clients and delivering more effective and creative strategic solutions.”

Trust: The Make or Break Factor

Interestingly, when we asked our experts to identify the one aspect that could make or break a pharma client relationship, they all named the same factor: trust.

“The most important requirement in building and maintaining strong relationships with pharma clients is trust,” Dr. Purohit says. “Listening to the client can make or break the relationship. When clients make a request or provides feedback on something, you as the agency must put aside your own creative tendencies and impulses and listen to them. They have a deeper understanding of their vision and idea of success, as well as any sensitivities and internal politics that might come into play.”

For today's pharma marketers who have to work at the intersection of innovation and regulation, trust is key to successful client-agency relationships, Ms. Carter says. To effectively compete today, marketers should be leveraging the most effective engagement strategies and technologies; in many cases, these innovations can be the first within an organization. “Clients need to be able to trust that their agency partner fully understands the environment and can innovate responsibly to truly deliver marketing excellence required in 2018 and beyond,” she says.

Ms. Armstrong puts it simply: Building trust forms a relationship; losing trust breaks a relationship. “If clients feel as though they always need to get the agency up-to-speed or must explain implications of a market shift for their business, the more difficult it will be to build trust,” she adds. “Having a solid agency staffing plan in place — the right account leadership and support, the right strategy, the right scientific, and creative talent for the business — is critical to ensuring there is a foundation for a strong, trustful relationship.”

The groundwork for trust must start from the first meeting on, and continue throughout the engagement, as every interaction factors into the health and stability of the relationship, Ms. Carolonza adds. Earning trust takes time, dedication, and focus to build a trusting relationship, whether between a client and external agency, up the corporate ladder, or across functions and teams.

Ms. Pamus adds that communication is also a factor in building trust within a client-agency relationship.

“Poor communications will eventually foster an atmosphere of distrust and hostility,” she says. For example, if a new client doesn't provide its agency with the necessary in-house data to create the best brand story, or an agency fails to alert the client that it won't be able to deliver an initiative on time the relationship is sure to falter. Or if the client provides feedback that lacks specific examples of what they don't like, or the agency doesn't discuss cost overruns, but instead, sends a revised invoice, bad feelings can develop between the two parties. “The client will begin to believe that the agency ‘just can't get it right’ and will begin to lose confidence that their agency is the right partner for their brands,” Ms. Pamus concludes.

Strategic communications directly impact business objectives and are a critical function in today's complex multimedia world.

“To be truly strategic and maintain a strong relationship with pharmaceutical and life-sciences clients, it's necessary to come from a place of partnership,” Ms. Carolonza says. “Good agencies should always strive to become extensions of their clients' teams.” PV