The Rewards of Engaging Patients in Clinical Development and Beyond

THE PHARMACEUTICAL INDUSTRY HAS MADE great strides in engaging patients during the commercialization of marketed drugs. But the industry is only beginning to recognize the benefits that can flow from patient engagement during the clinical development process.

Those benefits include the establishment of durable relationships with patient groups, the chance to understand patient needs within a given disease area and incorporating those insights into trial protocols, and the opportunity to break down silos by bridging the planning of clinical development with commercial activities.[1]

However, pharma's initiatives with regard to engaging patients in clinical trials are at an early stage, and as with any incipient movement that requires both cultural and structural change, it faces some hurdles. Chief among these are organizational resistance to change, inexperience in working with patient groups, and varying degrees of willingness to incorporate the patient's voice in clinical trial planning.

Numerous stakeholders have a role to play in raising awareness about clinical trial opportunities, including clinical sites, physician practices, patient groups, small and large drug companies, CROs, and non-profit service organizations like CISCRP (The Center for Information and Study on Clinical Research Participation).

Pharma in particular has begun to organize its efforts to promote patient involvement in clinical trials around five basic goals:

- Engage patients in research design
- Make patient engagement patient-centric
- Build general awareness about clinical research
- Create valuable relationships with patients
- Formalize patient engagement activities for the long-term

What does it mean to incorporate patient needs into clinical trial planning? It might mean arranging transportation for some patients to clinical trial sites or lessening the test burden. For a patient suffering from multiple sclerosis, MRI scans for brain lesions are not top of mind; they are more likely to want clinical outcomes that are more meaningful to them, like tests to measure how fatigued they are over a period of time.[2]

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Bringing the patient's voice into protocol planning improves the research experience for them, leading to better compliance, while also easing the clinical development path.

Before a patient has consented to participate in a clinical trial, he or she must first know about it. Patient awareness programs have come a long way. Many physician investigators recognize that different strategies are appropriate for different audiences. Individual sites and programs have to settle on a strategy based on the type of study they're doing. Television, radio, newspapers, and social media are good for reaching the general public; those same methods plus newsletters, brochures or, in the case of cancer, presence on a tumor board can be effective in reaching the clinical audience for many types of trials.[3]

A recent commercial for Bristol-Myers Squibb's Opdivo, an immunotherapeutic against cancer, closed with the narrator thanking the patients and physicians who participated in the Opdivo clinical trial. That served the double purpose of raising awareness about the drug and also acknowledging the partners – patients and physicians – who were instrumental in its success.

Culture change in all organizations with a stake in recruiting patients will help assure that trials are fully enrolled. Physician practices can reward their high-recruiting physicians with an additional title. Sites can use clinical navigators or clinical research nurses to identify trial-eligible patients. Patient advocates can invite patients and family members to events at a site to learn about the research being conducted and its significance for patients and the larger community.

The key to raising awareness about clinical trials and giving patients the information they need to make an informed decision lies in building relationships. Sponsors and CROs need to reach out to physicians and other healthcare providers as partners who can help spread the word and also help patients navigate the research system. CISCRP has found that over 50% of survey respondents would prefer to hear about clinical trial opportunities from their primary care physician.[4]

Patient groups are another trusted source for clinical research information; moreover, they have passionate, motivated memberships. Forward- looking pharma companies recognize that patients' perspectives can benefit preclinical and clinical research, post-launch marketing, and even portfolio planning.

Stakeholders in the clinical trial process are beginning to understand that the benefits of patient engagement, of harnessing the patient's perspective, can begin in early discovery and move through the drug development cycle and the marketing of drugs to providers. There is even value in articulating the patient view of value for payers.

[1] Patient Engagement: How Soon Do You Start? (Interview with Julie Adrian.) Scrip Pharma Intelligence. November 30, 2016

[2] Transparency Life Sciences Wants to Change How We Design and Execute Clinical Trials. Clinical Informatics News. July 7, 2016

[3] ASCO. Enhancing Clinical Trial Awareness and Outreach. Journal of Oncology Practice. Vol 5, Issue 4, 2009

[4] Centerwatch. Is There Really a Shortage of Study Volunteers? CenterWatch Monthly. Vol 22, Issue 8. August 1, 2015

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