Life Science Leader

How Patients Will Revolutionize Next-Generation Clinical Research

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By Jae Chung

Often when we think about inefficiencies in the clinical trial process, we focus on the role of the sponsor or CRO, a particular aspect of the value chain, or new technologies that promote data sharing and faster decision making. While these are critical aspects that drive day-to-day operations, there is another aspect of the value chain that we may be neglecting: the patient side.

In study startup, we talk about patient enrollment targets, recruiting strategies, and the like, often in abstract terms. We look at the data and consider aggregate numbers that drive decision making. For example, a study may target a particular investigator or site due to the PI's research or availability of patients at that location. But are we really thinking about this from a patient-centric perspective or more from a site-centric perspective? For example, with what we've learned as an industry about the struggles and concerns patients have with clinical trials, shouldn't we make it easier for prospective participants to engage with the study sponsor before, during, and after the study?

Let's think about the whole process from the point of view of a patient with a devastating disease, say an advanced cancer with a particular genotype that has been characterized. The patient's physician says there are a handful of clinical studies to consider, two for targeted therapies and another that offers an immunotherapy. There is also an FDA-approved medication, which may be available as an off-label option. The doctor is leaning towards the immunotherapy option that is in Phase I but gives the patient the choice in the end. So how does the patient go about making that decision? Are there other upcoming clinical trials that the physician does not know about? Where does the patient go next?

Aside from ClinicalTrials.gov, there are other sources emerging that are designed to match clinical trial participants to studies and address this major issue. For example, ClinicalConnection connects researchers and patients. They have a trial finder, and you can join their site and be notified when trials become available. Other options include the Cancer Research Institute, SmartPatients, and CureClick. Some of these even offer a helpline or specialist navigators who help patients through the process.

But about the patient consulting with the study sponsor directly to get additional data such as if they have done any comparative studies, even in animals? How does the sponsor benefit from such a patient-centric focus?

First, it really takes patient engagement to the next level, in which *informed* patients are *highly engaged* patients who are more likely to comply with requirements, such as completing patient reported outcome questionnaires and attending follow up visits. That leads to better data integrity. Not only that, it could improve the number and diversity of enrollment, which increasingly is seen as a major issue in clinical research. One notable example was recently published by researchers at Harvard Medical School, whose research showed that that over the last decade, genetic testing may have disproportionately misdiagnosed hypertrophic cardiomyopathy (HCM) in black Americans due to lack of diversity in genetic studies. Recognizing the importance of the issue, the FDA has become a strong advocate for increased diversity in clinical research. In fact, 2016 was dubbed “The Year of Diversity in Clinical Trials” by the FDA.

Are there other potential up-sides? If a patient engages with a sponsor, even if they decide to forgo participation in that particular study, they may become a potential candidate for a future study – perhaps in a later phase or for an entirely different study. Beyond study startup, engaging the patient directly could have other benefits. What if you could invite patients to share their experiences with each other as part of the study via a closed, secure social media channel and also submit questions to the sponsor? This becomes another valuable data source and potential resource for mining trends that can be compared with endpoint information.

The end result? Turning our focus toward a true patient perspective gives us ways to think about innovative solutions for accelerating clinical research, at a time when the stakes are higher than ever for patients. And those patients may just hold the key to unlocking the next frontier in clinical research.

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