IEEE LifeSciences

Rethinking "Patient Centricity"

Using Technologies to Distribute Clinical Trial Results Direct to Patient

FEB2016
By Sujay Jadhav

"Recognizing the need for more patient centricity in clinical trials also requires that we acknowledge both the challenges and possibilities inherent in implementation. Understanding the boundaries between sharing information and privacy concerns will be crucial as initiatives progress, and emerging technologies for data sharing will make balancing these competing concerns even more complex."

The drug development community is increasingly turning to patient engagement or "patient centricity" approaches to optimize clinical trials costs and improve research outcomes. The active participation of patients in clinical research can potentially lead to improvements in the credibility of results, higher rates of enrollment and retention, and ultimately, lower trial costs. Sponsors have been taking the initiative to get in touch with patients to better understand and reinvent the clinical trial process. And governments are also taking action. In 2010, the U.S. government created the Patient Outcomes Research Institute (PCORI) with a US$3 billion budget to support research designed to help doctors and patients make informed healthcare decisions. A central goal of PCORI is ensuring that patients are involved in driving decisions such as determining research priorities, reviewing grants, and providing input on issues that relate to PCORI's mission. Joe Selby, executive director of PCORI, outlined the importance of patient engagement for his organization in a guest blog for healthcare policy journal Health Affairs: "We've made engagement a cornerstone of our research. Every research study we fund must include a plan to engage patients, their clinicians and others across the healthcare community to ensure the research focuses on practical questions.[1]

But what does "patient centricity" actually mean? It is not just about improving the patient experience to ensure maximum retention or enrollment figures. For many patients involved in a clinical trial, participation is not just an "experience" like others in life where the typical consumer has choices and can change their mind. It is a treatment option selected after careful consideration with one, perhaps numerous physicians. It is the end of long road and the beginning of a new journey—a journey filled with optimism and above all hope. Often patients think broadly about the impact their participation may have on medical research in the therapeutic area. Will I help others in the future? And of course, there is individual concern, including how did I respond relative to the other patients to this therapy? Did I respond more positively or less than the average patient?

Did others experience an adverse event, or my adverse event? Why or why not? It is fundamentally about the results, the data, how that patient experienced the investigational product relative to others in the study, and ultimately, what the outcome suggests about the current standard of care. Patients want…no, need to understand these things. Having experienced the clinical trial process with several family members it doesn't feel "patient centric" but rather more "black box" where information about the larger study is divulged at best periodically in a non-systematic fashion.

Recognizing the need to elevate patient centricity, emerging players are beginning to address the need for greater data transparency with the patient. For example, Be the Partner, a Cambridge-based startup, recently announced a new Patient Relationship Management Platform designed to enable transparency and create new opportunities to foster a long-term relationship between sponsors and patients. In particular, the platform enables data sharing and communication between de-identified study participants and pharmaceutical companies. Other providers, such as Clariness, provide patient portals for education, communication, and information sources designed to support patient engagement and general information sharing.

Despite the emergence of such platforms, there is little information about the specifics of the implementation. Numerous issues come to mind when you consider the monumental task of enabling access to anonymized, yet personalized clinical trial results to patient participants. If I am a patient, what process is required to request such results? What is the format of the results and mechanism by which the information is transmitted (e.g., paper, cloud based platforms, secure email)? Who can I contact if I have questions or want to discuss the results—or are they publicly available? Will such mechanisms be a barrier to enrollment, as patients concerned about privacy purposely avoid "transparent" clinical trials that publish results on demand to any participant?

Equally perplexing, once the information is in the hands of the patient, how can you guarantee that it is not shared on social media outlets? Who owns the data? Traditionally, clinical trial data is considered the property of the investigators and the entities that sponsored the research. This model is based on dissemination via print publication, the origins of which date back to the seventeenth century. In today's environment of pervasive electronic knowledge exchange (combined with the push for data transparency from regulators, researchers, and patients themselves), change is inevitable. Emerging platforms such as CureClick are actually promoting the use of peer-to-peer crowdsourcing to share clinical trial information with the goal of driving patient recruitment. According to the website, CureClick is the world's first crowdsourced clinical trial recruitment platform that is designed to empower influential health advocates with tools and resources to spread the word about clinical trials seeking volunteers. In doing so, such platforms actually encourage information exchange between "influencers" and potential participants in a clinical research study.

What stops a participant from sharing private health data via such outlets? Harnessing our innate desire for connection to new information, social and technology platforms may also be a threat to the future of patient centricity. Enabling direct-to-patient dissemination of results will require a careful consideration of the overall process, from the time when the patient requests the information, to how it is received, to which support system(s) enable the patient to understand and interpret it, and finally to how it may be shared appropriately in an increasingly connected digital world.

So, what is the medical community saying about reporting results directly to the patient? In January 2015, the Institute of Medicine issued a consensus, peer-reviewed, publicly available report that recommends how to promote responsible clinical trial data sharing while minimizing its risks and burdens.[2] The report distinguished sharing trial data from sharing a summary of trial results (which is already expected) and defines data sharing, which does not necessarily mean posting data on a public website without conditions. The report focuses specifics on dissemination of data to the research community but lacks specificity when it comes to sharing results with the lay public.

For example, one recommendation states that "lay summaries of results should be made available to trial participants concurrently with the sharing of summary-level results, no later than 12 months after study completion." It is not clear what is meant by "lay summaries of results" and how that information is disseminated is open to interpretation and will certainly vary by sponsor. Fundamentally, the report recommends the use of operational strategies such as data use agreements to mitigate the risks and enhance the benefits of data sharing. Will such agreements include clauses prohibiting study participants to discuss experiences in the trial via social media?

Clearly the issue is no longer whether sponsors should share clinical trial data but instead what specific data to share, when the data should be shared, and with what controls and safeguards. And in the digital era, information sharing with the crowd is part of normal life. In that context, can you enforce data sharing agreements with patients? And don't forget that all of this takes time and effort; hence, do we anticipate a rise in study costs due to data transparency mandates? Today the medical community is focused mainly on disseminating study data to the research community. But direct to patient data dissemination may represent an even greater challenge. Getting the data to the patient is only part of the battle; what they do with the data after they get it is another issue. As technology providers such as CureClick have recognized, what patients do with their data in social media may impact recruitment and ultimately, the success of a clinical trial.

Emerging technologies will only continue to push the envelope, creating data sharing scenarios via social media that may not be anticipated in advance. With momentum in the data transparency movement on the rise, new models will have to emerge to support data sharing while protecting patient privacy, particularly on social media outlets. In the end, patient centricity and patient privacy may be aspirational goals at odds with one another, requiring a multifaceted balancing act for sponsors and data stewards.

References

1. 'PCORI's Research Will Answer Patients' Real-World Questions', Health Affairs Blog, March 25, 2014. Online.
2. Institute of Medicine (IOM) Committee on Strategies for Responsible Sharing of Clinical Trial Data. IOM website. Online. 2015.

Sujay Jadhav
CEO | goBalto

Sujay Jadhav, *CEO of goBalto, has more than 20 years of experience at leading Silicon Valley software providers, with a life-sciences focus. Jadhav was most recently senior vice president of global corporate strategy and development at Model N, where he filled multiple roles, from corporate development to overseeing their life-sciences analytics and SaaS business unit. His career has also included strategic consulting at Booz Allen Hamilton, product strategy at Commerce-One and general management roles at Singapore Telecom. He received his undergraduate degree from the University of South Australia and an MBA from Harvard University..*