How Bring Your Own Device and Other Innovations ARE IMPROVING PATIENT ENGAGEMENT

Improving how patients participate in clinical trials is an essential challenge for the industry. The past few years have seen an encouraging shift of attention to the various ways we can improve patient engagement in research programs.

In the past, patient engagement focused on how we recruit subjects for clinical trials, and small interventions that could be used to ensure subjects remained active in clinical trials until they were complete. But improving the overall experience expands that to include ways we can increase compliance, ensure medication adherence, and give patients the opportunity to understand how their participation, and their data, impact a clinical development program.

Designing clinical trials with a patients experience in mind is the new imperative for drug developers and the other stakeholders who help execute clinical trials. Better ways to collect data, interventions to help patients remember to take their study medications and complete diaries, and training and education on diseases and clinical trial processes, can all help improve the experience.

Why Engagement Works

Improving patient engagement makes trials better for those who volunteer. But it is also a way to improve the quality of our research programs and the evidence we collect. Recruitment, compliance, adherence, retention, data collection, are all fundamental concepts that, when done poorly or not addressed, can jeopardize a research study. Providing an integrated patient engagement solution, as part of a clinical technology plan, helps to efficiently begin solving for these problems.

A recent paper in the Journal of the American Medical Association examined the impact of using SMS text messaging in improving medication adherence. The results showed a 50% increase in adherence rates when text messaging was used, and high level of acceptance amongst the participants who received the text messages. Text messaging can also be used to improve study procedure and patient diary compliance. In one recent Bracket study, daily diary reporting compliance is close to 95% in a program where patients receive text reminders when they haven't reported their data.

Making Patient Participation Seamless

The adoption of "Bring Your Own Device" or BYOD in clinical trials has been slow, but the topic generates a fair amount of discussion and debate. The pragmatic case for simply allowing patients in research programs to use their own smartphones as tools to collect and report data is straightforward. But there are numerous considerations that make this a hard decision.

BYOD is gaining acceptance. The prevalence of smartphones, and the desire to gather more and better data, is certainly a component of how this is evolving. Every stakeholder involved in the research process has something to gain by improving how we do this. For patients, it in many cases will simplify their experience of participating in a research program. For investigators, it reduces the logistical burden of managing and provisioning devices to their patients during the trial recruitment process. And for sponsors, it reduces the costs associated with gathering data.

Last year, the ePRO Consortium, a group of eCOA providers working under the umbrella of the Critical Path Institute, published a comprehensive paper detailing BYOD considerations, and carefully articulating how and when to navigate through any potential challenges. Some important findings;

- Reducing cost is an important benefit, but not the only benefit.
- Privacy concerns in some cases can be amplified when using BYOD.
- "Mixed Modes" concerns regarding mea-

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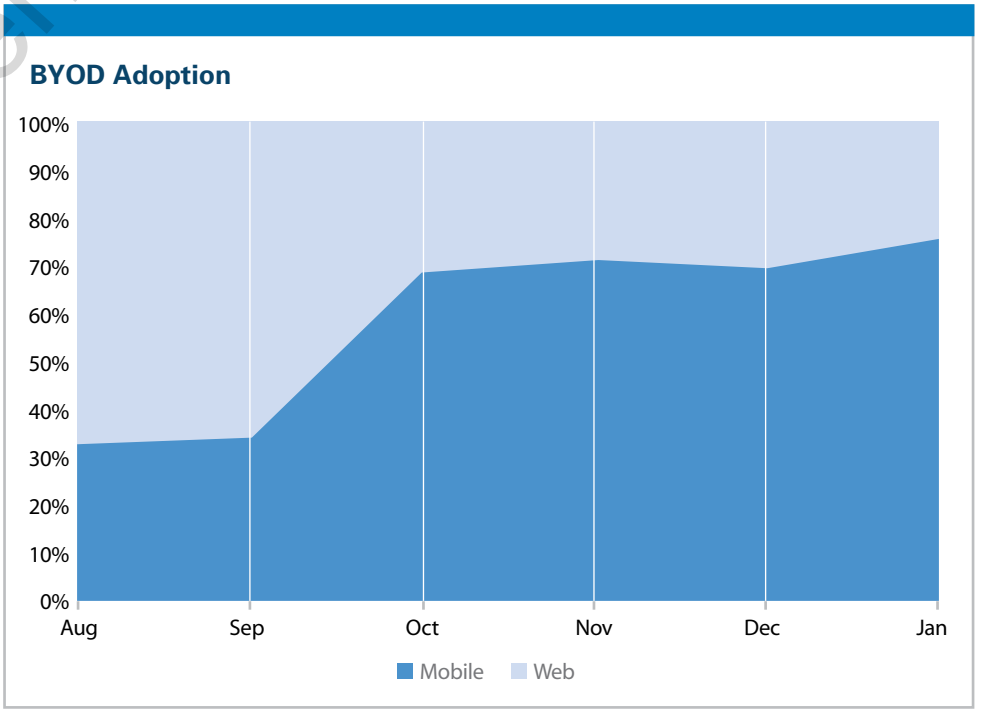

surement equivalence require specific planning and accommodation.

While these considerations, and regulatory opaqueness, have slowed adoption, there are many instances where BYOD has been successful, either in its implementation or in the eventual success of a clinical trial.

Implementing BYOD

Identifying the right situation for BYOD is the key to success. The limitations and considerations outlined earlier are important constraints. For example, some clinical outcomes require very specific validation and equivalence studies before they are converted to electronic modalities.

In many cases, that equivalence work may be very specific to certain device screen sizes or input tools — these are much harder to control in a BYOD setting, of course.

But many diaries are simple. And when combined with effective patient reminders, whether through app alerts or text messaging, the patient burden when reporting with their own phone will be much lower, as opposed to carrying a second, dedicated trial device.

What Are the Results?

And now that it is being used in the real world, evidence is being collected that BYOD works. In a recent study supported by Bracket that gave patients the option of using a web portal or a downloadable app to report data, patients overwhelmingly preferred the mobile app over time. At the beginning of the study less than half of the patient diary entries were made using the app. As the study progressed, patients began to shift away from the web portal, and at study closeout more than 80% of the patient diaries were collected through the BYOD alternative. In addition to patient acceptance of the technology, dosing and medication reminders that were included in this program resulted in nearly 100% medication adherence rate.

And will investigators accept this? Anecdotally, the feedback is good so far. And in a paper published earlier this year in the journal Anaesthesia, BYOD was found to be effective, and the authors noted that "feedback suggested that all investigators found the data collection method intuitive, convenient, and easy to use."

Driving Adoption and Improving Patient Experience

The Tufts Center for the Study of Drug Development reports that pharma and biotech companies are shifting their focus to adopt more patient-centric initiatives, with slight increases in sponsors, which are executing patient-centric studies, and a significant increase in the number of drug developers that are planning to implement better patient engagement programs. And as we continue to innovate, and introduce new evidence about the outcomes of these new approaches, all stakeholders will begin to understand how these small steps are helping, and what else we can do to improve all of our research programs. PV

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