SIGNANT HEALTH
THE EVIDENCE GENERATION COMPANY™

The Signal

Five Considerations for BYOD Studies

In our drive to make trial participation simpler, a bring-your-own-device (BYOD) model is thought to be a convenient approach for trial participants to complete patient-reported outcome measures in clinical trials. Carrying and remembering to charge a second device in addition to a personal smartphone may be inconvenient for some – but is that a view shared by all?

We discuss this along with some other BYOD-related questions and considerations.

Do patients prefer BYOD?

While there is no clear answer to this question, two published BYOD studies provide some insight. Byrom et al. (2018)[1] reported that in a study of 155 patients suffering chronic pain, 45% of patients felt that using their own device would be more convenient compared with 15% preferring a provisioned device (40% had no preference). Additionally, Newton et al. (2018)[2] reported a study of 64 COPD patients showed no clear device preference, with 45.6% preferring a provisioned device and 50.9% preferring BYOD (n=2 had no preference). In this second study, the most common reason for preferring a provisioned device was it was "dedicated" to the study, while the "convenience" of carrying a single device was the main reason for preferring BYOD.

Is BYOD acceptable to patients, including the ones who prefer a provisioned approach? In the Byrom study[1], 94% of patients (146 of 155) stated that they would "definitely" or "probably" download an app on their own mobile device for a forthcoming clinical trial. This level of acceptance is also mirrored in the high BYOD uptake rate seen in studies Signant Health supports – with 80% using BYOD and 20% opting for a provisioned device.

Does BYOD result in better completion rates?

Completion rates are typically very similar between BYOD and provisioned users, with a trend in favor of BYOD. For example, one large BYOD study involving over 10,000 patients between the ages of 50 to 85 in more than 20 countries had daily diary completion rates of 85% and 84% for patients using BYOD and provisioned devices respectively.[3]

At Signant, we provide provisioned devices to patients who do not have or are unwilling to use a compatible smartphone of their own in BYOD studies. While this may not be a randomized comparison, it does give us some useful insights into completion behaviour between patients using BYOD and those using a provisioned device.

What support do sites implementing BYOD need?

Sites implementing BYOD can benefit from training materials and patient setup guidance. After interviewing a group of sites on their experience using our BYOD solution, we learned the sites felt that with Signant's support, BYOD did not take any longer than provisioned devices, and that their teams did not associate BYOD with increased burden. They did, however, note that reminding patients to confirm their app store credentials ahead of the clinic visit was important.

This feedback challenges the perception that BYOD is a more burdensome process for sites, requiring more patient support and technology troubleshooting.

Do regulators accept BYOD data?

Up until recently, the industry has been unaware of successful drug applications that use BYOD data, causing some concern that regulators will not accept the data. This year though, the industry's largest BYOD study – that for COVID-19 vaccine development in 43,000+ participants – collected primary safety data using a reactogenicity diary completed by patients using Signant's platform.[4] This vaccine received emergency use authorization by agencies around the world, including FDA, EMA, and MHRA.

This is an encouraging indicator for future research, and it underlines our scientific beliefs that data collected through BYOD can be just as robust and reliable as the data collected using provisioned devices.

Do I need evidence to support the validity of BYOD?
For new BYOD studies, it's likely that researchers can rely on existing evidence as opposed to conducting a specific qualitative or quantitative study, as long as ePRO design best practices are followed.[7] A sensible practice may be to compile a summary of supporting published evidence and provide a demonstration that implementation best practices were applied, such as an ePRO screen report.

The reason behind this is that growing evidence supports the measurement equivalence of patient-reported outcomes data collected using different administration modes as well as various shapes and sizes of electronic devices.[5] The first formal BYOD equivalence study strongly supported the measurement equivalence across a broad range of devices and instruments composed of the common response scale types (verbal rating scales, numeric rating scales, and visual analogue scales) in over 150 patients.[1] This has since been verified by a second study conducted by the Critical Path Institute.[6]

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