SIGNANT HEALTH
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WHITEPAPER

SITE PERSPECTIVES ON BYOD ePRO USE

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INTRODUCTION

With an interest in making study participation more convenient, more sponsors are implementing a Bring-Your-Own-Device (BYOD) study model in which participants use their own personal devices to submit assessments. Not only does this approach eliminate the burdens associated with unfamiliar provisioned devices, but it also means participants don't need to worry about charging and carrying a second device.

Collecting patient-reported outcomes (PRO) data via BYOD is thought to improve more than just convenience for trial participants - it may also drive compliance as participants are more likely to see study-related reminders on their own smartphone or tablet device.

Signant Health decided to conduct a qualitative study to further investigate the attitudes and experiences of site personnel involved in two global studies using BYOD to collect patient-reported outcomes, with an aim of understanding and alleviating potential pain points.

METHODS

An interview script was written and tested before site staff were recruited and consented. Then, interviews were conducted, audio recorded and transcribed. The transcriptions were analyzed and the findings categorized into themes.

We collected feedback from twelve site staff members who were involved in a seven-month-long vaccine study or a 3-month-long rheumatoid arthritis study. These Clinical Research Coordinators, Study Nurses, or Research Nurses were located in the US, Sweden, or Poland. Ten of the twelve interviews were conducted via telephone or video, while two were completed on paper.

The findings from this study were applied to the continuous improvement of product capabilities, training, and trial best practices.

RESULTS

While all participating sites welcomed technology, there was a strong preference towards BYOD as the staff found it less burdensome. However, sites gave the American, Swedish, and Polish participants their choice of BYOD or provisioned devices whenever suitable personal devices were available.

Participants did not express concern regarding data security, data usage, or the associated app costs. This is particularly interesting as these concerns were initially seen as BYOD adoption barriers. It's possible that today's prevalence of smartphones and apps have reduced these initial concerns.

BYOD VS. PROVISIONED DEVICE APP USE

A STUDY GOALS

- Compare attitudes towards BYOD and provisioned device usage
- Identify advantages and challenges associated with each approach
- Understand how site workflows for patient onboarding change depending on the selected technology
- Evaluate training materials
- Obtain overall feedback and improvement suggestions

B KEY FINDINGS

SETUP EXPERIENCE

Participants who chose BYOD needed to download the app at their site visit, after they had completed the consent process. For provisioned devices, sites needed to scan and record the device details for inventory tracking. Both approaches took roughly the same amount of time to complete.

One reported issue encountered during BYOD setup was that participants didn't remember their app store password. This could be mitigated by ensuring that reminders to access app store credentials were provided ahead of the clinic visit.

All site staff interviewed felt there was not a significant difference in time or complexity between the two approaches. However, they generally preferred the BYOD set up process because it required participants to be responsible for and more involved in device set up, reducing burdens for site staff. In fact, site staff could continue with other aspects of the visit administration while the participant was performing this activity.

TRAINING

All site staff commented that training would be useful to help them explain to participants the benefits of the BYOD approach and encourage its use. The site staff cited the benefits listed:

1. Participants do not need to carry an additional device
2. There's a greater familiarity with personal smartphones and tablets
3. Using the participant's own network provider is thought to lead to optimal connectivity for data submission (although global roaming SIM cards for provisioned devices can use multiple networks to ensure good connectivity)
4. An increase in data collection compliance can be expected

Some site staff perceived that participants upgrading or changing devices during the study might forget to reinstall the study eCOA app.

TECHNICAL

Most sites transitioned a number of participants from provisioned devices to BYOD mid-study due to phone upgrades or participants changing their preferences.

One site staff member reported that a small number of BYOD participants did not receive completion reminders, and only after investigation did they discover that they had silenced reminders in their device settings. Other participants complained of multiple reminders even though this helped them complete their data entry. Some participants requested to not receive push notifications until the site staff explained their importance.

COMPLIANCE

One staff member reported they had to keep reminding participants using provisioned devices who had turned off their phones or did not charge them to continue to make ePRO entries. One way to address this would be with a BYOD approach, since patients typically have their own personal phones charged and with them at all times.

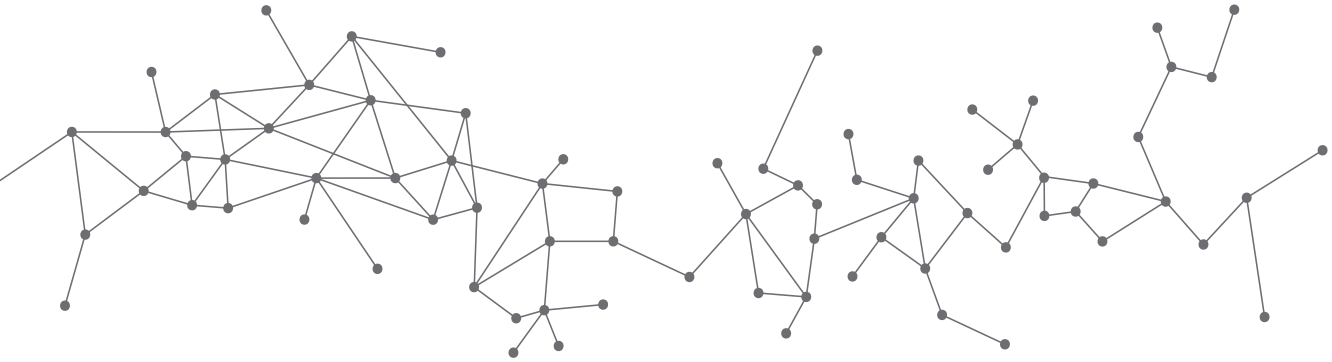
In regards to how BYOD addresses difficulties experienced with provisioned devices, one staff member stated:

> *"Everybody typically has their phone with them all the time, so it's just kind of an easier reminder it needs to be completed."*

AGE

In other studies, we have identified that older users are less likely to own a suitable smartphone, but are very able to use ePRO solutions after training[1]. You can learn more about research around older ePRO users in our **eBook**.

> *"The participants either had the technology or they didn't, and this mostly related to their age."*



C CONCLUSIONS

Site staff found BYOD use straightforward and participant setup and site workflow smooth for BYOD and provisioned devices alike. Training materials were found to be simple, accessible, and intuitive.

> *"I think [BYOD] just makes it easier for the participant. I think you're getting better data when they're interacting with something in a way that they're already used to."*

10 out 12 site staff preferred the BYOD approach over the use of provisioned devices.

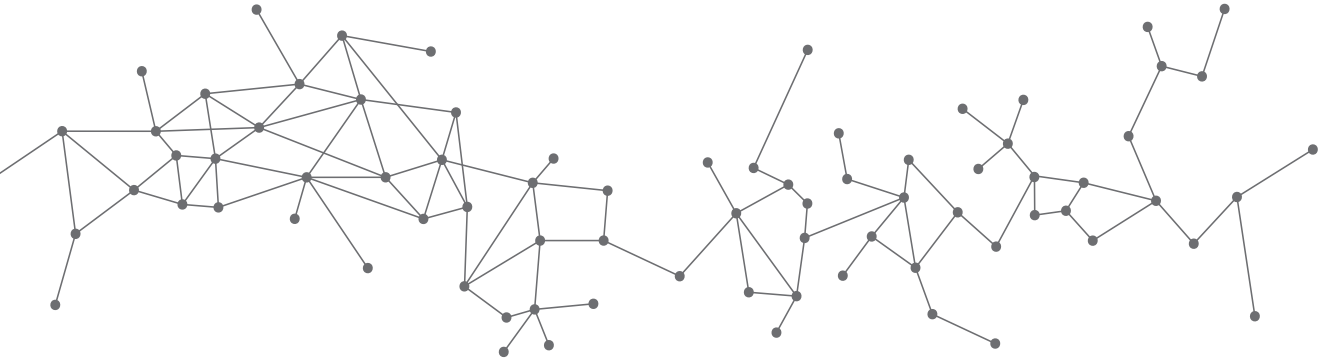
D RECOMMENDATIONS WHEN USING BYOD

PATIENT & SITE TRAINING

- Communicate the benefits of BYOD to sites and in participant materials to clarify the benefits and facilitate conversations and informed decision-making.
- Remind participants to remember app store credentials ahead of their study visit.
- Ensure a process is in place to enable participants to reactivate the ePRO app in the event of changing or upgrading their device.
- Enable effortless transition from provisioned to BYOD based on a change in participant access to suitable smartphone technology or participant preference.
- Provide screenshots of the app and participant handbooks for site reference.

DISCUSSION

This research is not only important to Signant Health and its customers, but also study participants as it fosters a deeper understanding of the clinical trial experience. Understanding site workflows and challenges allows us to make informed recommendations when it comes to collecting PRO data.



References:

[1]Garner K, Byrom B. Attitudes of older people/seniors to completion of electronic patient-reported outcome measures and use of mobile applications in clinical trials: results of a qualitative research study. Journal of Comparative Effectiveness Research. 9 (2020) https://www.futuremedicine.com/doi/10.2217/cer-2019-0155

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