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# The Signal

## Exploring the Potential of Non-Consumer Smartphones in Clinical Trials: A User-Focused Evaluation | Katie Garner

Clinical trials demand a standardized approach to data collection, especially when it comes to patient-reported outcomes (PRO). In the ever-evolving landscape of mobile technologies, smartphones play a pivotal role in gathering crucial information from clinical trial participants. Much of the emphasis in recent years has centered on the advantages of a bring-your-own-device (BYOD) model in which clinical trial participants use their own smartphones to provide patient-reported outcomes data.

However, the rapid turnover of consumer devices poses a challenge for maintaining consistency across studies. That's where non-consumer smartphones could help: They offer the same global reach but with fewer model variants, enhanced performance, and extended longevity.

We selected and evaluated the Santok STK, a non-consumer device to explore its potential as a reliable tool for home-based ePRO measure administration. Here's what we learned from this usability testing.

### METHOD

Our approach was twofold: an in-house technical performance evaluation and external user testing. The former involved comparing the Santok STK with a high-end consumer smartphone, rating parameters like performance, ease of use, screen quality, battery life, and charging on a 0-5 scale. The latter engaged ten participants in defined tasks, assessing their experiences with the device and an associated ePRO app (Signant SmartSignals eCOA).

### RESULTS

Technical Performance Evaluation:

- The time to load a home screen and initiate the app met expectations.
- Within-app screen loads were instantaneous.
- Device weight aligned with consumer smartphones.
- The mean score of 3.8/5 met our technical performance acceptance criteria.

External User Testing:

- Participants found most tasks intuitive.
- Noteworthy performance in perceived screen loading speed (4.1/5), ease of use (3.9/5), touchscreen sensitivity (4.2/5), and screen clarity (4.3/5).
- The mean usability score of 3.7/5 affirmed that the Santok STK met usability and acceptability criteria across a representative sample of clinical trial participants.

## CONCLUSIONS

In the dynamic realm of clinical trials, mobile technologies like smartphones are indispensable elements for an eCOA strategy. Non-consumer devices such as the Santok STK offer unique advantages, and our rigorous evaluation confirmed its suitability for ePRO data collection. As Senior Manager of Site and Patient Research at Signant Health, I'm excited about the potential this holds for ensuring complete and compliant data collection in our clinical trials.

Below, you can download a copy of my poster I presented recently at ISPOR Europe. You might also be interested in my Site & Patient Research eBook containing additional research summaries.

Stay tuned for more research and conclusions as we explore eCOA solutions to optimize participation experience for sites and patients, two of the most important stakeholders in clinical research!

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**USABILITY TESTING OF A NON-CONSUMER SMARTPHONE DEVICE FOR ePRO DATA COLLECTION**

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**INTRODUCTION**

Non-consumer smartphone devices are used in a number of industries and provide important benefits in terms of global reach with fewer country-specific model variants and guaranteed model longevity. Popular consumer smartphones are superseded regularly and with little notice, which is undesirable for clinical trial studies where it is often desirable to use a common device across patients to collect patient reported data electronically.

An essential element of successful electronic patient reported outcome (ePRO) implementation is the usability of the hardware provided. This evaluation was conducted to assess the performance and essential usability properties of a non-consumer device, the Santok STK to determine its utility for home-based ePRO measure administration.

**METHODS**

1. In-house technical performance evaluation of the Santok STK was conducted using a high-end consumer smartphone as a benchmark. Parameters tested included: initial impression, performance, ease of use, screen quality, battery life and charging. Each evaluation item was summarized to a score on a 0-5 scale. Item scores were combined to give parameter scores for specific usability domains, and an overall score for each device.

2. External user testing of the Santok STK was conducted with ten participants who were recruited and consented (Ages: 13-77 years; Sex: 5F, 5M; Smartphone familiarity: Android: n = 4, iOS: n = 6; educational level: range).

Participants were asked to complete defined tasks, including turning on the device, opening an app, moving between display screens, answering questions on the app and checking internet and Bluetooth connectivity. They were individually observed and then interviewed on their experience of operating the device and using an associated ePRO app. An interview script was developed, tested and followed. Both quantitative and qualitative evaluations were made.

**RESULTS**

**1. Technical performance evaluation.**

- Time to load home screen, open and start the app from PIN entry was in line with expectations.
- Within-app screen loads were instantaneous.
- Device weight was in line with similar sized consumer smartphones.

**Mean score met technical performance acceptance criteria; 3.8/5, vs high-end consumer device 4/5. Fig 1.**

**FIGURE 1: IN-HOUSE PERFORMANCE TESTING**

Parameter scores can be interpreted as : 0: no response, 1: very slow / very poor, 2: slow / poor, 3: acceptable, 4: quick / good, 5: Immediate / excellent.

**2. External user testing.**

- Participants found most tasks easy and intuitive. The device performed particularly well on:
  - Perceived speed of screen loading. Score: 4.1/5.
  - Ease of use (score: 3.9/5), touchscreen sensitivity and accuracy. Score 4.2/5.
  - Screen clarity and brightness. Score 4.3/5.

**Mean score met usability acceptance criteria; 3.7/5. Fig 2.**

**FIGURE 2: EXTERNAL USER TESTING**

Participant scores can be interpreted as : 0: impossible / unacceptable, 1: very poor, 2: poor, 3: acceptable, 4: good, 5: very good. good.

**CONCLUSIONS**

Mobile technologies such as smartphones are increasingly being used to collect data from participants in clinical trials and non-consumer devices offer specific advantages over consumer alternatives. Ensuring that they offer acceptable performance and experience to clinical trial participants is an important component of solution usability, to ensure complete and compliant data collection in clinical trials.

Internal performance and external user testing found the non-consumer Santok STK device to be a suitable and acceptable device to supply to clinical trial participants for collecting ePRO data.

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