SIGNANT HEALTH

THE EVIDENCE GENERATION COMPANY™

SIGNANT'S PATIENT & SITE RESEARCH COMPENDIUM

Designing user-friendly solutions to achieve clinical research goals

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INTRODUCTION

Digital enablement technology solutions are now widely adopted and applied in today's clinical trials.

But how can sponsors and clinical research organizations ensure such technologies address the needs and goals of its most pivotal stakeholders – patients and research sites?

To understand if our solutions meet Signant patients' and sites' usability and acceptability expectations, we routinely engage with sponsors, sites, and potential or current trial participants in qualitative research.

We ask them questions about our solutions' features, functionality, design, and usage experience.

These research outcomes have helped to shape design recommendations for Signant SmartSignals solutions and provide tangible evidence that the quality and reliability of our offerings are optimized for patient and site use.

Signant Health is committed to the quality of the user experience and to generating the evidence that sponsors need to satisfy regulatory requirements for usability.

PATIENT RESEARCH

Signant's Clinical Trial Patient & Site Perspectives Research

ePRO & OLDER PEOPLE

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

To determine the acceptability of electronic collection of PRO measures in older populations, explore preferences and challenges that might affect learning and device use when recording PROs, and establish 'fit-for-purpose' functionality in this population.

METHODOLOGY

Signant performed semi-structured, one-to-one interviews of twelve UK-based, potential clinical trial participants between the ages of 63 and 83. All of the participants reported at least one physical limitation and all had some degree of deteriorating eyesight.

DATE

2020

COMMON AGE-SPECIFIC CONCERNS:

"How will older people manage in a trial?"

"The older population simply won't use it."

RESULTS & IMPACT

- General health and attitude are the most important factors in terms of interacting with technology, not age: **90% of the participants were familiar with touch screen devices, all had internet at home, and none reported problems with charging devices.**
- 70% of the older participants interviewed were already familiar with tablet devices and reported that the larger screens on tablet devices help with vision or dexterity challenges.
- Older users are less likely to learn a new technology solution by experimentation. Interactive and multimedia-based training, along with hands-on practice, repetition, and accessible training materials help older users gain confidence and mitigate "performance anxiety." Enabling time to repeat training to consolidate confidence is a key success driver.
- Other studies have shown that older participants are among the most compliant at 91.5% compliance with daily BYOD-based eDiary completion[1].

"90% of participants were already familiar with touch screen devices"

STUDY & eCOA DESIGN RECOMMENDATIONS FOR OLDER PEOPLE:

1. Consider using tablets and bring-your-own device strategies to capture ePRO.
2. Employ reminders and alarms to promote adherence.
3. Prioritize training participants using multiple delivery modes, allow more than one supervised hands-on run through of the solution, and provide materials for ongoing reference.
4. Consider segmenting the population by age bands into 'younger-older', 'middle-older' and 'oldest-older'.

EXPLORE THE FULL DETAILS OF THIS RESEARCH AND THE RESULTING RECOMMENDATIONS:

READ THE eBOOK | GET PEER-REVIEWED PAPER

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. J Comp Eff Res. 2020; 9(4): 307-315.

Signant's Clinical Trial Patient & Site Perspectives Research

PATIENT PERSPECTIVES ON ePRO FUNCTIONALITY & USABILITY IN ONCOLOGY TRIALS

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

Understand the challenges experienced by oncology patients that affect device use for recording patient-reported outcomes (PROs) and whether functionality is 'fit-for-purpose' in this population.

Determine best practices for patient-reported outcome measure (PROM) implementation to support oncology patients and optimize data quality.

METHODOLOGY

An independent usability testing organization performed semi-structured, one-to-one interviews with seven participants aged 30-68 who had experienced a cancer diagnosis and who had undergone or were currently undergoing treatment. Participants tested Signant Health's eCOA application on a tablet and a smartphone. The interviews were recorded and underwent thematic analysis.

DATE

2020

Patient Voice: Challenges

"Fatigue hits you out of nowhere"

"The numbness in the fingers makes precise actions very difficult & frustrating"

"I prefer to use a phone...sometimes you don't want to do all the writing and it's more easy to tap"

RESULTS & IMPACT

Our research found that:

- Most participants reported that the factors that impacted their ability to interact with an ePRO solution included: peripheral neuropathy of the hands, fatigue and/or concentration and memory issues, and the time-point in their treatment cycle.
- Participants had a positive attitude towards electronic patient-reported outcome measures (PROMs) compared to paper.
- Participants, as well as caregivers completing PROMs on their behalf, preferred bring-your-own-device.
- No participants reported readability issues with the information on the devices.

Patient Voice: Solution Design

"The bigger the buttons, the better"

"I think you should be able to go in when you can...sometimes you cannot do things in set times"

STUDY & eCOA DESIGN RECOMMENDATIONS:

1. Utilize large, well-spaced buttons.
2. Present all question text and response options together to reduce the reliance on participants needing to remember the question recall period.
3. Enable some flexibility in the time window that participants complete the eDiary/questionnaire.
4. Allow users to pause a diary/questionnaire and return to complete at a later time.
5. Provide a stylus so that patients have this option.
6. If suitable, implement PROMs on the participant's own device (BYOD).
7. Offer automated completion reminders.
8. Consider that participants may prefer to not complete PROMs, rather than asking for caregiver assistance.

Explore the full details of this research and our perspectives on the recent FDA draft guidance on the use of PROMs in oncology trials:

GET PEER-REVIEWED PAPER

DOWNLOAD WHITE PAPER

Mowlem FD, Sanderson B, Platko JV, Byrom B. Optimizing electronic capture of patient-reported outcome measures in oncology clinical trials: lessons learned from a qualitative study. J Comp Eff Res. 2020; 9(17): 1195-1204.

Signant's Clinical Trial Patient & Site Perspectives Research

USABILITY FEEDBACK ON A PULSE OXIMETER AND A PULSE OXIMETRY APP

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

Sensors, wearables, and smartphone apps are increasingly being used to collect data from participants in clinical trials. Ensuring that trial participants can operate these devices is important to ensure complete and compliant data collection. This usability study was conducted to assess the usability of the Masimo MightySat® Pulse Oximeter and a pulse oximetry app for use by participants in clinical trials.

METHODOLOGY

Signant Health conducted in-house testing, as well as external user testing with 10 participants who were recruited and consented to participate, including:

- 5 female and 5 male patients, aged 13-77 years, with various education levels and smartphone familiarity of Android (n=4) and iOS (n=6)

Participants were observed and individually questioned on their completion of the following tasks:

1. Measurement of oxygen levels at rest using the pulse oximeter.
2. Completion of a training module on the Signant Health pulse oximetry app.
3. Measurement of oxygen levels at rest and after a short walk using the pulse oximeter with the pulse oximetry app.

Quantitative and qualitative evaluations were made of their experience.

The feedback was then analyzed, summarized, and presented as findings.

DATE

2022

RESULTS & IMPACT

The pulse oximeter met usability acceptance criteria with a mean score of 4.2 out of 5. The device performed particularly well on comfort on finger (score: 4.8 out of 5), speed of generating a result (score: 4.7 out of 5), screen clarity (score: 4.4 out of 5) and ease of turning on (score 4.3 out of 5).

The pulse oximeter and oximetry app also met usability acceptance criteria when used in combination. Mean score; 3.7 out of 5. The combination performed particularly well on ease of following instructions to generate a resting measurement (score: 4.1 out of 5) and post walk measurement (score: 4.2 out of 5).

DESIGN RECOMMENDATIONS AND CONCLUSIONS

Sensors and wearables can facilitate deeper insights into clinical conditions and treatment efficacy. However, the solution being offered must be acceptable to participants and easy for them to use.

- Sensors and Wearable devices should be simple and intuitive for the patient to use
- Data transfer between devices should be quick, reliable, and seamless
- On-screen instructions to patients should be short, simple, and accessible for all.

Our usability study demonstrated that the MightySat® pulse oximeter and Signant Health pulse oximetry app are suitable and acceptable products for use in clinical trials for the collection of clinical data in unsupervised conditions.

Signant's Clinical Trial Patient & Site Perspectives Research

USABILITY OF SANTOK STK MOBILE DEVICE FOR ADMINISTRATION OF ePRO MEASURES

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

Signant Health has introduced a custom handheld mobile device as an alternative to the consumer devices that are currently used to administer home-based ePRO measures. Our device ensures global reach and provides customers with the important benefit of guaranteed model longevity, which is not assured with consumer devices that can be phased out or discontinued with little notice. An essential element of successful ePRO implementation is the usability of the provided hardware. Signant's evaluation was conducted to assess essential usability properties of the STK X3 device to determine its utility.

METHODOLOGY

Signant Health conducted in-house testing, as well as external user testing with 10 participants who were recruited and consented to participate, including:

- 5 female and 5 male patients, aged 13-77 years, with various education levels and smartphone familiarity of Android (n=4) and iOS (n=6)

Participants were observed and individually questioned on their use of an eCOA app running on the STK device to derive quantitative and qualitative evaluations of their experience. The feedback was analyzed, summarized, and presented as findings.

DATE

2022

RESULTS & IMPACT

The STK device performed acceptably in internal and external usability testing, which was in line with expectations on all evaluated aspects, including:

- Time required to load the home screen, open the app, and start the app from PIN entry. The use of a circling icon demonstrated that software was loading.
- The speed of moving between screens within the app, once the app was open.
- Ease of turning on and off the device, charging, and understanding on-screen icons (e.g., connectivity).
- Similar device weight to comparable consumer smartphones.

The device performed particularly well on:

- Perceived speed of screen loading
- Ease of use
- Touchscreen sensitivity and accuracy
- Screen clarity and brightness.

ePRO MOBILE DEVICE FINDINGS & CONCLUSION:

- Mobile technologies such as smartphones are being used more frequently to collect data from clinical trial patients. It is important to ensure that patients can operate and use such devices to determine solution usability and assure complete, compliant data collection.
- The STK device is a suitable and acceptable device that can be supplied to clinical trials for eCOA data capture.

Notes:
Acceptability criteria was established with reference to a high-end consumer smartphone device.

A full technical report is available to customers on request.

Signant's Clinical Trial Patient & Site Perspectives Research

DEVELOPMENT & PATIENT USABILITY ASSESSMENT OF SIGNANT'S ELECTRONIC PARKINSON'S DISEASE MOTOR SYMPTOMS DIARY

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

Develop an electronic version of a patient-reported motor symptoms diary for Parkinson's Disease (PD) trials, designed to operate on provisioned smartphone devices provided to the patient for use away from the clinic. Evaluate usability and acceptability by patients.

METHODOLOGY

Signant Health obtained permission by the scale license holder, Dr. Robert A. Hauser (University of South Florida, FL), to evaluate patient acceptance and usability of an electronic version of a home diary commonly used by patients in PD trials to report fluctuations in their motor symptoms. Ten PD patients over the age of 60 participated in qualitative interviews, providing feedback on the accessibility and usability of the electronic diary as provisioned on a smartphone. Criteria they evaluated included touchscreen interactions, alarms, layout and presentation, ease-of-use, and recall period.

DATE

2014

USABILITY STUDY FINDINGS

Summary of Usability Study Findings

Item	Finding
Paper vs. Electronic	The use of an electronic device for PROs, was the preferred choice not only for the patients but also their caregivers.
General Usability	The subjects enjoyed using the eDiary and a strong majority indicated that they were more likely to want to use a mobile device compared to paper if they were taking part in a clinical trial. Patients were asked how they felt about having to fill in the eDiary every 30 minutes for up to three days before a clinic visit and most had no real concerns with this schedule of assessment.
Layout and Navigation	The feedback on the general layout of the eDiary and the font sizes, position, size and spacing of objects was acceptable, even in the presence of tremor. Patients liked the ability to tap with a knuckle instead of a stylus or fingertip in the presence of tremor. Patients found the app easy to navigate, and the smartphone easy to use after training.
Recall Period	Patients generally agreed that, if they had a mobile device with regular alarms to remind them to record their data, they were more likely to accurately record their ON/OFF periods and presence of dyskinesias. With a paper questionnaire, they would be tempted to fill it in once a day.
Security	Patients liked that they had the option of a personal PIN code, which only they had access to.
Alarm Sounds	Patients liked the concept of being able to select their own alarm sound and settings from options available.
Stylus vs. Finger	Most patients found it relatively easy to navigate the device with their fingers. The stylus proved to be unpopular.
Quotes	"An electronic device would be my preferred method to use, if I was taking part in a Clinical trial. The layout is nice, and I like the bird alarm." "It's nice to touch and I like gadgets, sounds good to me." "This device is definitely better than scribbling on a piece of paper and I can see myself using it."

Signant's Clinical Trial Patient & Site Perspectives Research

DEVELOPMENT & PATIENT USABILITY ASSESSMENT OF SIGNANT'S ELECTRONIC PARKINSON'S DISEASE MOTOR SYMPTOMS DIARY

CONCLUSIONS

- The Signant PD Motor Symptoms diary was developed in line with documented industry ePRO design best practice principles, alongside additional learnings from qualitative research conducted by Signant in this patient population.
- Sufficient evidence supports the measurement equivalence of instruments migrated to electronic screen-based formats from paper when ePRO design best practices are followed.
- Usability testing provided strong evidence that Signant's electronic Hauser diary is acceptable and usable in Parkinson's disease patients.

DESIGN RECOMMENDATIONS

Design principles incorporated in Signant's PD Motor Symptoms diary for use by Parkinson's patients include:

- Ability to navigate using finger (or knuckle) as opposed to using a stylus.
- Diary touch areas that can accept feedback from the knuckles, not just the fingertips – making it easier to use for patients with small joint mobility issues and tremor.
- Diary touch areas that are large and separated sufficiently to enhance usability.
- eDiary alarms every 30 minutes if no entry is made, with an option to silence the alarms for periods of sleep.
- Good font sizes and color contrast to enable good readability.
- Ability to accommodate a maximum recall period (defined on a per-study basis) to limit retrospective entry within appropriate limits. Recommendation: 4 hours.
- Ease to review and enter data for multiple timepoints quickly and easily via a single screen.
- Use of status symbols to ensure patients can easily see which time points have been completed and what they reported. This ensures time points are not unintentionally left unanswered.

Signant's Clinical Trial Patient & Site Perspectives Research

eCOA INSIGHTS FROM PATIENTS WITH DIABETES, INCLUDING OLDER ADULTS

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

To develop an eCOA solution that improves the quality of data capture in diabetes clinical trials that is focused on patient usability, explore preferences and challenges that might affect use and data quality, and establish 'fit-for-purpose' functionality in this population.

METHODOLOGY

Signant Health developed a diabetes-specific, event-driven eDiary for collecting data from blood glucose meters as well as patient-reported outcomes in diabetes clinical trials. Research was then conducted with patients with diabetes, including older adults, as summarized below:

- Study 1: Survey of 7 patients to understand diabetes management (aged 40-66 years)
- Study 2: Assessment of eDiary with diabetes focus group of 4 patients (aged 33-80 years)
- Study 3: Independent usability research of eDiary with 8 patients (aged 11-67 years)
- Study 4: Independent usability research of eDiary with 16 patients (aged: 19-71 years)

DATE

2014-2019

RESULTS & IMPACT

Our research found that:

- Patients with diabetes are usually actively engaged in their own disease management.
- Patients find that managing study blood glucose measurement devices and study mobile devices alongside their existing personal devices is burdensome.
- Patients find that the amount and frequency of data collection in diabetes trials can be burdensome.
- Focus groups and usability studies highlighted the benefit of event-driven blood glucose measurement reporting over unstructured reporting to mirror the patient's experience and reduce cognitive burden.
- Patients preferred an electronic solution for data collection.

eCOA DESIGN RECOMMENDATIONS FOR POPULATIONS WITH DIABETES:

1. Design an electronic solution that minimizes the number of devices required for data collection and automatically triggers a survey form for hypo/hyperglycemic events.
2. Design an electronic solution that fits with the patients' experience to minimize the burden associated with diabetes trial participation.
3. Test solutions with patients to obtain feedback on ease of use and to drive improvements.

Signant's Clinical Trial Patient & Site Perspectives Research

BLOOD PRESSURE MONITOR USABILITY RESEARCH

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

Test three blood pressure monitors to help identify usability characteristics as part of the evaluation process to identify a suitable blood pressure monitor to collect blood pressure data remotely from participants in clinical trials.

METHODOLOGY

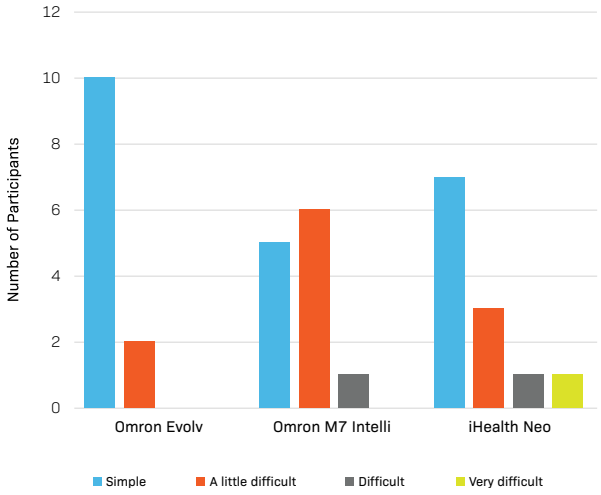
Signant Health conducted usability testing of three commercially available blood pressure monitors. The study involved 12 participants (male (3), female (9)) aged 25-51 years old to assess how the devices performed when carrying out tasks that might typically be encountered when collecting data in a clinical trial.

DATE

2019

RESULTS & IMPACT

- Qualitative feedback demonstrated that ease of operation, speed of operation, and form factor all contributed towards the perspectives of usability and the overall preference of the devices.
- Our research found that across the 12 participants, there was a clear and significant ($p<0.05$) preference for the Omron Evolv device (mean score (0-10 scale): 8.5 +/- 1.27) versus both the Omron M7 (mean score: 5.6 +/- 2.12) and iHealth Neo device (mean score: 6.0 +/- 2.40). However, all the devices were found to be acceptable.



STUDY & eCOA DESIGN RECOMMENDATIONS:

A participant's perspective of usability should be a key factor in choosing an appropriate device for use in a clinical trial. Usability is likely to impact compliance and the quality of the data collected.

Overall mean impression rating (0-10)	
Evolv	8.33
M7	5.67
Neo	5.83

Participants rated ease-of-use on a scale of 0-10, with 0 being "don't like" and 10 being "really like".

Signant's Clinical Trial Patient & Site Perspectives Research

eCOA CLINICAL TRIAL PARTICIPANT APP - USER FEEDBACK IN PRODUCT DEVELOPMENT

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

To explore how participants across multiple age ranges interact with Signant's clinical trial app for eCOA, and to determine its acceptability to users.

METHODOLOGY

1. An independent product testing organization conducted usability testing of Signant eCOA app, hosted on provisioned devices with eight participants in Finland aged 32-71. Each participant tested the application twice – once initially, and then they completed a second evaluation following interface adjustments.
2. In a separate, related product study, Signant tested its eCOA app, with twelve adult participants in the UK via provisioned Android devices. Six male and six female participants aged 30-66+ navigated through various features and functions of the app, including menu navigation, scrolling, and dashboards. Researchers observed and assessed several aspects of usage including accessibility by age, effectiveness/efficiency, learnability/memorability, and error prevention and handling.

DATE

2017

RESULTS & IMPACT

Findings from both studies were used to provide evidence of the acceptability of the app interface. Opportunities for product and design improvements were identified and provided to Signant's Research and Development and Product Development teams.

Feature	Aspect	Finding
Participant age	Accessibility by age	The older group of testers interacted with the app in the same way as the other age groups. No additional challenges were encountered.
Main navigation	Effectiveness/Efficiency	The interaction with the main menu was very good, proceed with this approach.
Feature menu	Learnability/Memorability	All users interacted well with the navigation, they didn't have any problems. The feature menu offers a flexible, easy to use solution, proceed with this type of navigation.
Navigation between questions on forms	Learnability/Memorability/ Error prevention & handling (using the next button at the bottom and the back button at the top to navigate between questions)	The users didn't have any problem with the back button or with the next button, proceed with this approach.
Back button	Learnability/Memorability/ Error prevention & handling	The outcome was very good, in general, the users didn't experience any challenges, proceed with the navigation proposed.
Dashboard	Effectiveness/Efficiency	The users didn't have any problem interacting with the dashboard and understanding the dashboard information.
Scrolling	Learnability/Memorability	Some users had slight difficulty the first time they had to scroll but they learned very quickly. Scrollable screens need to be very clear.

Signant's Clinical Trial Patient & Site Perspectives Research

eCOA CLINICAL TRIAL PARTICIPANT APP - USER FEEDBACK IN PRODUCT DEVELOPMENT

PARTICIPANT FEEDBACK:

"It has been improved a lot since the first time. Looks professional. The layout is clear."
Female | Aged 62

"I felt that it is too easy! It is simple and clear. If in real use I would of course understand more about the study."
Male | Aged 66

- All users interacted well with the app's main and feature menus and navigated between questions on forms without encountering issues.
- All users interacted well with the app's dashboard and understood the information presented there.
- A small number of users had initial difficulty using the scrolling function on the app, but they were able to learn how to use it very quickly.
- The older group (66+) interacted with the app in the same way that the other age groups did, without encountering additional challenges.

eCOA APP AND ePRO DESIGN RECOMMENDATIONS FOR ADULT AGE GROUPS

1. Implement flexible, easy-to-use solutions to enable easy log-in/log-out from the app and access to other features.
2. 'Next' and 'back' buttons at the bottom of forms help participants easily navigate between questions or app features.
3. Ensure that scrollable screens are easy to identify and use.
4. Older people do not need a specific design implementation – if the app design and instructions are clear and intuitive.

See page 11 for research and findings specific to older adult age groups.

Discover Signant's eCOA study design solutions to optimize participant experience:

GET RESOURCES

Signant's Clinical Trial Patient & Site Perspectives Research

ePRO USABILITY ACROSS PATIENT POPULATIONS

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

To assess the acceptable usability properties of eCOA software as part of study-specific cognitive interview & usability studies.

METHODOLOGY

Contract research organizations performed usability testing of Signant Health solutions with 241 participants from individual patient populations across 21 indication-specific trials conducted in the U.S. and UK. The disease indications included asthma, breast cancer, chronic idiopathic constipation, ulcerative colitis, and others.

DATE

2013-2018

RESULTS & IMPACT

Our research found that:

- In all studies, the solution was independently reported to pass patient usability assessment.
- No changes were required to display clarity, navigation, operation, and completion without help.

ePRO APP DESIGN RECOMMENDATIONS FOR VARIOUS PATIENT POPULATIONS

- There is a reduced need to routinely conduct cognitive interview and usability studies when implementing minor changes during instrument migration. Application of design best practices and selection of vendor solutions with a good user interface as well as user experience properties that have already been assessed in a representative group can enable many instrument migrations to be accepted without formal validation studies (instead, conduct a structured expert screen review).

For more on ePRO best practices that support Signant's approach to instrument migration, access the 2018 scientific journal article co-authored by Bill Byrom below.

READ JOURNAL ARTICLE

Signant's Clinical Trial Patient & Site Perspectives Research

INSIGHTS FROM HELPDESK ON THE PATIENT BYOD ePRO EXPERIENCE

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

To explore the types of challenges that clinical trial participants faced in a BYOD app study of over 1 year duration and identify opportunities for training and improving the user experience, service delivery, and product development.

METHODOLOGY

Helpdesk statistics from a BYOD app study 47,000 patients in more than 8 countries were analyzed, specifically looking at the number of calls that clinical trial patients made to the helpdesk, their reasons for calling, and the speed of resolution.

DATE

2022

RESULTS & IMPACT

Our research found that:

- Over 3,000 patient helpdesk calls were received – of those, over 90% were resolved immediately upon first contact.
- The largest percentage of calls (46%) were related to app installation or the activation code on a BYOD device.
- Just over 22% were for PIN reset instructions, while just over 13% were for questions or issues related to the training system.
- Approximately 10% called regarding with questions relating to the differences between daily and weekly diaries, or to request a new app activation code after changing their BYOD device.

RESEARCH CONCLUSIONS AND RECOMMENDATIONS

- This analysis serves to summarize common issues related to patients' app use on BYOD that require helpdesk assistance. Specifically, installing and activating the app at the start of the study, and due to mid-study device changes where they occurred.
- This research also confirms that our patient helpdesk is well-equipped to deal efficiently with these issues, at the scale we might anticipate.
- The research findings further demonstrate the suitability of Signant's software and service offerings to support BYOD eCOA.

SITE RESEARCH

Signant's Clinical Trial Patient & Site Perspectives Research

INSIGHTS FOR SIGNANT SMARTSIGNALS PRODUCT VISIONING

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

To identify pain points and challenges encountered by sites and gather feedback on potential solutions. Findings from this research study were used during product planning for Signant SmartSignals clinical trials technology.

METHODOLOGY

An independent consultant invited a group of 10 site personnel in the U.S., Canada, Spain, and The Netherlands to participate in 60-to-90-minute interviews to explore key pain points for trial sites as well as opportunities for improvement.

DATE

2022

RESULTS & IMPACT

Key findings:

- Site staff felt burdened by the number of applications and tools they needed to use when participating in clinical trials and emphasized the need for more integration.
- Each tool for each sponsor required unique logins/passwords. Coordinators found it difficult to remember and manage their account information, and reported writing login details on post-it notes.
- The lack of integrated tools led to duplicated work and/or data entry.
- Site-patient communication was fragmented.
- Site-sponsor communication was not optimal.

PRODUCT PLANNING & DESIGN RECOMMENDATIONS

- The ability to integrate clinical solutions, such as eCOA and RTSM, are key to streamlined operations and simplified workflows.
- Single sign-on tools can improve the site's user experience.
- Site staff and clinical trial participants will benefit from a single dashboard interface for all trial activities, from onboarding, consent, and COA data capture to patient engagement, site visit scheduling, and drug delivery.
- A single dashboard will help sites efficiently manage trial needs and streamline interactions with patients.
- Solutions should be designed with patient engagement and communication in mind to improve communication between stakeholders.

Signant's Clinical Trial Patient & Site Perspectives Research

SITE FEEDBACK FROM AN APP STUDY: BRING-YOUR-OWN-DEVICE (BYOD) VS. PROVISIONED DEVICE USE

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

To gather feedback on the attitudes and experiences of site personnel involved in two global trials using an App on a BYOD or provisioned device to collect patient-reported outcomes, with the aim of understanding and alleviating potential pain points. Findings from this study were applied to the continuous improvement of product capabilities, training, and trial best practices.

METHODOLOGY

12 clinical trial coordinators involved in a seven-month-long vaccine study or a 3-month-long rheumatoid arthritis study in the U.S., Poland, and Sweden were interviewed using a semi-structured interview guide to explore their attitudes towards BYOD, differences in workflow between BYOD and PD, decision-making criteria for BYOD vs. PD, and the benefits and challenges that were experienced.

The interviews were audio-recorded and transcribed. The transcriptions were then analyzed, and the findings categorized into themes.

DATE

2020

RESULTS & IMPACT

Key findings:

- Site staff found BYOD use to be straightforward.
- Most respondents (10/12) found BYOD to be a very acceptable data capture method with benefits, including:
  - Good engagement and higher completion compliance
  - More timely responses
  - Participants' proficiency with a single, familiar device of their own
  - Increased reliability of data sending with better network/internet connections
- Only 2 out of 12 respondents had no preference between BYOD and PD.
- It was not burdensome to manage access to the eCOA technology and devices – participants with suitable technology nearly always chose the BYOD option.
- Participant setup and site workflow was smooth for BYOD and provisioned devices. Although the workflow was different for each, there was no significant time increase in onboarding patients on BYOD vs. PD.
- Training materials were found to be simple, accessible, and intuitive.

APP DESIGN RECOMMENDATIONS

- Communicate the advantages of BYOD to sites and in participant materials to clarify the benefits, facilitate conversations, and guide 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 device to BYOD based on a change in participant preference or change in their access to suitable smartphone technology.
- Provide screenshots of the app and participant handbooks for site reference.

Explore the full details of this research and resulting recommendations:

READ THE WHITE PAPER

Signant's Clinical Trial Patient & Site Perspectives Research

SPONSOR & SITE USABILITY FEEDBACK ON eCONSENT

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

To learn how a sponsor and site interacted with Signant's eConsent system, identify the challenges and benefits they experienced, and determine whether the solution was an acceptable method for capturing remote consent.

METHODOLOGY

Signant Health conducted feedback interviews with three staff members at York Teaching Hospital NHS Foundation Trust, UK, who had used Signant's eConsent system in the roles of Sponsor, Site Manager, and Study Nurse. Semi-structured scripts were used to conduct qualitative research interviews to gather feedback on the participant experience as well as the perceived experience of the patients they consented. The feedback was then analyzed, summarized, and presented as findings and recommendations.

DATE

2021

RESULTS & IMPACT

Our research found these benefits:

- All participants easily articulated the benefits of eConsent for sponsors and sites.
- Participants found the platform easy to use, appreciated the traceability it provided, and liked the sponsor management and flagging features.
- There was less follow-up needed for incomplete consents and patient withdrawal.
- It was easy and straightforward to include eConsent in the ethics approval process.
- The site felt that their patients were more likely to retain the information provided using the eConsent system and were also more likely to remember where they wanted to ask clarification questions by using the flagging feature (as compared to their experiences with traditional paper processes).

Our research also found these challenges:

- On-site signature workflow between patient and site was optimized based on feedback from the hands-on site experience.

CONCLUSIONS:

1. Log in and password management processes should be intuitive and user friendly. The eConsent login process was simplified to improve the user experience.
2. Internet connection should be reliable to ensure that the eConsent process runs smoothly. The eConsent internet connection setup was redesigned to use a SIM card in the eConsent device by default, so it does not need to rely on site internet capability.
3. Sponsors and Sites can easily recognize the benefits of eConsent over traditional paper processes including more complete consents with less follow-up, better tracking of recruitment, improved facilitation and tracking of patient questions, and perceived improved retention of information by patients.

OTHER RESEARCH

Signant's Clinical Trial Patient & Site Perspectives Research

HOME-BASED PERFORMANCE OUTCOME MEASURES FOR MOVEMENT USING SMARTPHONE SENSORS

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

To develop and test a digital solution for measuring and collecting home-based performance observations associated with a timed outdoor test, to then facilitate the use of derived distance, step count, and rest duration measures as endpoints for clinical trials.

METHODOLOGY

Signant Health produced initial tests and proof of concept work during pilot solution development, then conducted a study with a small number of research participants in the UK to collect data that would guide algorithm development work using data from the smartphone's on-board sensors. For each short walk test, the pilot app was installed on a provisioned smartphone and worn in a zipped waist bag at the small of the back. Data was sampled from the device's accelerometer and GPS. The actual distance covered, and number of steps taken was also measured by an independent observer.

DATE

2021

RESULTS & IMPACT

Our research found that:

- Smartphone sensors can be leveraged to develop new clinical endpoint measures, offering the possibility to:
  - Measure things that were previously difficult or impossible to measure.
  - Measure more frequently by enabling assessments from home.
  - Study elected patient functioning in real-world conditions that may complement established in-clinic tests.
- Smartphone apps accessing built-in sensors may enable convenient measurement without the need to supply an additional peripheral device, such as a wearable.
- Our findings demonstrated the reliability and precision of the combined proof of concept app usage, protocol, and algorithms to derive distance traveled and steps taken under a number of conditions within the short walk test protocol.

HOME-BASED MEASURE DESIGN RECOMMENDATIONS:

- The research identified design principles which all such systems must address if the aim is to repurpose consumer smartphones as clinical performance measurement devices.
- For GPS-derived measurements, GPS must activate ahead of the start of the walk to ensure that the device has line-of-sight access to sufficient satellites to ensure appropriate accuracy and precision.

EXPLORE THE FULL DETAILS OF THIS RESEARCH AND THE RESULTING RECOMMENDATIONS:

READ THE ARTICLE

Max A. Little, Sami Volotinen, Brad Sanderson, Ulla Huopaniemi, Florence Mowlem, Jennifer Olt, Bill Byrom (2021). Novel algorithms deriving clinical performance measures from smartphone sensor data collected under a walking test. https://doi.org/10.1101/2021.10.21.465337

Signant's Clinical Trial Patient & Site Perspectives Research

IMPACT OF RATER TRAINING ON MEASUREMENT RELIABILITY IN DERMATOLOGY TRIALS

THEME

Rater Training & Scoring Reliability

RESEARCH OBJECTIVE

To measure how rater training can improve the accuracy of subjective clinician-reported outcomes (ClinROs) that are routinely used as primary endpoints in dermatology clinical trials.

METHODOLOGY

Signant Health evaluated training data from a key endpoint measure in a national dermatology clinical trial, where investigators were trained and certified on the administration and scoring of a single clinician-reported scale. This training consisted of a detailed explanation of the scale followed by a consensus building exercise with expert trainers and dermatologists, where body images with varying degrees of skin symptoms were used for the purpose of calibration.

Afterwards, investigators were asked to take a quiz to establish competence and intra-rater reliability, and those who did not achieve a certain score or higher were retrained. The impact of retraining on their assessment accuracy was measured via Kappa coefficients – a total of 94 clinicians' scores were compared to those from an expert panel through weighted kappa analyses.

DATE

2018

RESULTS & IMPACT

Our research found that:

- Prior to additional training, rater scores were variable and lacked agreement (Kappa coefficients ranged from 0.33 to 1.00 with a mean of 0.87 and standard deviation of 0.10).
- Additional training improved raters' accuracy (Kappa coefficients ranged from 0.84 to 0.98 with a mean of 0.96 and standard deviation of 0.01).
- This improvement in accuracy was significant between the before and after additional training scores (paired t-test comparing pre- and post-training kappa coefficients found a significant increase: MD = 0.09, 95% CI [0.07, 0.11]. $p < .0001$).

RATER TRAINING PROGRAM RECOMMENDATIONS:

- It is paramount to ensure scoring reliability and consistency in clinical trials that rely on ClinROs for inclusion criteria as well as for disease progression monitoring.
- Sponsors should consider rater retraining to optimize endpoint reliability from subjective ClinROs that assess the severity of symptoms.
- The variability in ClinRO assessments can be high, and our research suggests that the standardization of rater training can greatly improve data quality in dermatology research.

Signant's Clinical Trial Patient & Site Perspectives Research

BYOD & PROVISIONED DEVICE USAGE FOR eCOA WEB/MOBILE APP

THEME

Technology Acceptability & Usability

RESEARCH OBJECTIVE

To understand site and subject behavior towards use of bring-your-own-devices (BYOD) and provisioned devices (PD), including access behavior and usage of the eCOA web versus app implementations by country and by clinical site.

METHODOLOGY

With reference to two large clinical trials, Signant Health analyzed BYOD versus PD usage data and how BYOD may impact compliance data. The first study investigated usage of the eCOA web implementation on both BYOD and PD, while the second monitored usage of the app implementation on both BYOD and PD.

DATE

2018

RESULTS & IMPACT

Our research found that:

- Site acceptance is clearly a factor in BYOD uptake. With the eCOA app implementation, many sites did not use BYOD and instead provided PD to over 75% of their participants. In fact, rate of provisioning was 100% for nearly half of the 300+ participating sites.
- With eCOA web implementation, most patients (89%) used their own mobile devices or personal computers. Country-specific uptake trends did not match smartphone market penetration data, suggesting again that site acceptance rate may be the biggest factor affecting BYOD uptake.
- BYOD compliance rates were slightly higher than with PD, indicating that patient control over their own device and features such as muted notifications does not significantly impact ePRO compliance.

eCOA BYOD STUDY IMPLEMENTATION RECOMMENDATIONS

- Researchers seeking to employ BYOD approaches should pay attention to ensuring sites buy in and understand the use of BYOD.
- All site staff should be provided with sufficient training and support to ensure optimal BYOD uptake.
- Consider other factors besides site buy-in that may influence BYOD uptake, including age and geography of participants or acceptance rates of web-browser use versus an app download.

Explore the full details of this research and resulting recommendations:

READ RESEARCH ARTICLE

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ABOUT SIGNANT HEALTH

Signant Health is the evidence generation company. We are focused on leveraging software, deep therapeutic and scientific knowledge, and operational expertise to consistently capture, aggregate, and reveal quality evidence for clinical studies across traditional, virtual, and hybrid trial models. For more than 20 years, over 600 sponsors and CROs of all sizes – including all Top 20 pharma – have trusted Signant solutions for remote and site-based eCOA, EDC, eConsent, RTSM, supply chain management, and data quality analytics. Learn more at www.signanthealth.com.