Can Older Users Use Electronic Clinical Outcome Assessments (eCOA)?

Katie Garner, Bill Byrom
CRF Bracket, UK, Finland and USA

Abstract

Objectives
Sponsors and study teams have raised general concerns such as 'how will older users manage eCOA?' along with specific concerns relating to eyesight, hearing, confidence, recall, fatigue, dexterity, mobility and concomitant disorders. CRF Health undertook research in 2017 to identify potential challenges, opportunities and best practice for eCOA and older people.

Methods
CRF Health undertook scripted user interviews and completed a study of compliance data.

Results
The findings from these interviews can be grouped into the following themes:

1. General
2. Technology
3. Engagement and motivation
4. Learning

A study of compliance data shows that studies with an infant population or an older population have higher compliance than other age groups.

Conclusions
Sponsors and trial sites sometimes raise concerns about older populations using eCOA. However, eCOA offers a large number of natural, configurable and design solutions which can benefit the subject, the quality of data collected as well as the smooth running of the trial.

Introduction

A clinical outcome assessment (COA) measures a patient’s symptoms, as well as their mental state, or the effects of a disease, condition or medical treatment on a patient. Some are unobservable concepts, such as pain intensity, moods or feelings, and eating habits. Today’s regulatory guidelines strongly encourage clinical trial sponsors to adopt electronic means of capturing patient and clinician reported outcomes over traditional paper questionnaires and eCOA, or electronic clinical outcome assessment, is now a widely accepted method of data collection in trials.

eCOA is an accepted method of data collection in clinical trials, however sponsors sometimes ask whether older users can manage electronic data collection.

Method

CRF Health met with a local community group consisting of individuals over 55 and invited volunteers to be interviewed about their experience and attitudes with touchscreen devices.

Members of this group and others from the local community were interviewed individually using a standard script developed by the User Experience team at CRF Health.

The research objectives were designed to explore:

1. What, if any, reluctance is there to using electronic and touch-screen media?
2. How remote consultations might be undertaken effectively (such as site visits or remote consenting in trials).
3. What formal aspects of a learning experience tend to make the learning process difficult or easier?

Interviewees were between the ages of 65 and 83. Female, and male. The interviews lasted between 30 minutes and 1 hour and the interviewees were asked standard questions in three sections following the research objectives.

Conclusion

Concerns such as lack of confidence with technology are specific to eCOA but many concerns apply equally or perhaps more significantly to paper.

Research and feedback from older users tells us that if the correct training and modifications are made to their mobile devices and to the trial design and delivery then these subjects are more than capable of managing eCOA.

eCOA offers additional opportunities to use technical features, software design and study delivery design to help reduce or resolve some of the challenges older patients face.

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• 90% of individuals were already using tablets to keep in touch with friends and family
• There was a general preference for tablets over smartphones (which some perceived as “fiddly”)
• They indicated that they preferred the larger size of the tablet, and that tablets were easier to manage and more familiar
• No one reported problems with charging devices
• Negative feedback received about recorded voice messages
• Most subjects had experienced remote appointments with doctors and were very positive about them - especially for ongoing issues. It meant that they were not reliant on lifts / buses or having to go out in bad weather which could be unpleasant or result in a fall or illness

A study of compliance data shows that studies with an infant population or an older population have higher compliance than other age groups.

Infant Population - 93.2%,
Older Users - 88.0%,
general population - 81.4%.