Can older users use electronic clinical outcome assessments (eCOA)?

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Abstract

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.

Introduction

Electronic clinical outcome assessment (eCOA) is an accepted method of data collection in clinical trials, however sponsors sometimes ask whether older users can manage electronic data collection.
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The research objectives were:

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

Methods

CRF Health undertook scripted user interviews and completed a study of compliance data.
Ten people were interviewed between the ages of 65 and 83.

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

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The need to provide low-burden solutions extends to site-staff involved in COPD clinical trials. Recent research suggests that investigative site work burden has increased annually by 10.5%4, with site staff not only having to ensure the right administration schedule is followed but also monitoring patients for worsening symptoms.

Our goal was to develop an electronic solution for the collection of data from patients in COPD clinical trials, which would decrease patient burden, ensure high quality data from key questionnaires, simplify the study flow for site staff and allow for flagging of exacerbations.

Chronic Obstructive Pulmonary Disease (COPD) is a multicomponent disease with a complicated presentation. While progressive airflow limitation is the defining feature of COPD, the actual consequences of the disease for patients are wide-ranging, from weight loss, exercise intolerance, exacerbations of their disease, impaired health-related quality of life, increased health resource use and death1. As a result, ensuring a proper understanding of the impact of the disease and any potential treatment on patients in a clinical trial is a significant challenge for sponsors.

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Discussion

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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 be benefit the subject, the quality of data collected as well as the smooth running of the trial.

Concerns such as lack of confidence with technology are specific to eCOA but many of them 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..

Discussion and conclusions

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