



Usability Testing: Steps Toward Ensuring Patient Inclusivity

Rachna Kaul, Eli Yohe Moore, Barbara Brandt, Alisa Heinzman, Elizabeth McCullough

Common Issues With eCOA Design: A Patient's Perspective

Rachna Kaul, Alisa Heinzman, Elizabeth McCullough, Brittanie Newton



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INTRODUCTION

Many Clinical Outcomes Assessments (COAs) are designed with the assumption that patients will complete the questionnaire in a printed paper format. To ensure patients are able to use a particular electronic application (app) to complete the same COA, and that the data collected is consistent with the paper version, we use additional types of testing. One of these testing varieties is Usability Testing (UT).

Usability Testing (UT) is a process which tests the device or application usability and functionality of electronic COA (eCOA) formats from the patient's perspective. UT can be done to test a specific study device, or study application on a variety of devices. UT qualitatively demonstrates that the content validity of a COA has been maintained during format migration, which can be requested or

recommended in labeling claim applications with the FDA or the EMA.

In light of an increase in the use of eCOAs, it becomes increasingly important to ensure that the UT service offered by Language Service Providers (LSPs) is simple and effective and caters to the diverse patient population across the globe. Understanding issues in eCOA builds from a patient's perspective helps strengthen the process of UT so that potential issues can be avoided during the study, enabling the capture of well-calibrated quality data.

The two articles in this e-book highlight two important aspects of the UT process- ensuring patient inclusivity and understanding common issues with eCOA designs directly from the patient experience.



USABILITY TESTING: STEPS TOWARD ENSURING PATIENT INCLUSIVITY

Rachna Kaul, Eli Yohe Moore, Barbara Brandt, Alisa Heinzman, Elizabeth McCullough

It is estimated that by 2026, there will be a 17% growth in the use of electronic clinical outcomes assessments (eCOAs).¹ Usability testing (UT) of eCOAs is performed to help the study sponsors determine if an eCOA is easy to understand, has an intuitive user interface and well-calibrated data capture, and collects quality data in an effective and patient-friendly manner.² "Inclusivity" is the goal to include many different types of people and treat them all fairly and equally.³ Patient populations across the globe show a great deal of disparity in terms of factors like age, gender, educational qualifications, technological access and literacy, physical abilities and languages spoken or read. In clinical trials with multiple sites across the globe, it is important to have a representative patient sample. Inclusion of patients of all genders, from young to old age, with differing educational levels, primary languages and countries of residence, and different physical abilities (particularly in regard to vision, motor function, and learning-related abilities), fall under the broad spectrum of "inclusivity" in UT. Ensuring patient inclusivity therefore fulfills the objective of a clinical trial, which is to collect quality and representative data from patients. UT helps achieve consistency in collection of representative and quality data, regardless of recruited patient population and device type with reduced bias across sites.

Where is the Disparity?

As discussed in a previous poster titled "Linguistic and cultural considerations when implementing global Bring Your Own Device (BYOD) study," there remains a high disparity in the availability of and fluency with technology⁴. In developed countries, mobile phones are used more than Personal Computers (PCs) or tablets;⁵ the older population is now catching up with the usage of personal electronic devices while the younger population use them ubiquitously.⁶

In developing countries, users of electronic devices tend to be well-educated and young. The majority of adults in developing countries either own or share a mobile phone, though those with secondary education or higher are more likely to have their own phone, as do younger individuals. Mobile phone ownership rates among women vary significantly across developing countries and PC or tablet access is relatively rare.⁷ Smartphones are the most common type of mobile devices used in developed countries, but in developing countries, usage of mobile phones that are not smartphones (let's call these "regular mobile phones") exceeds the usage of smartphones by approximately 38%.⁸

Inclusive Display & Design

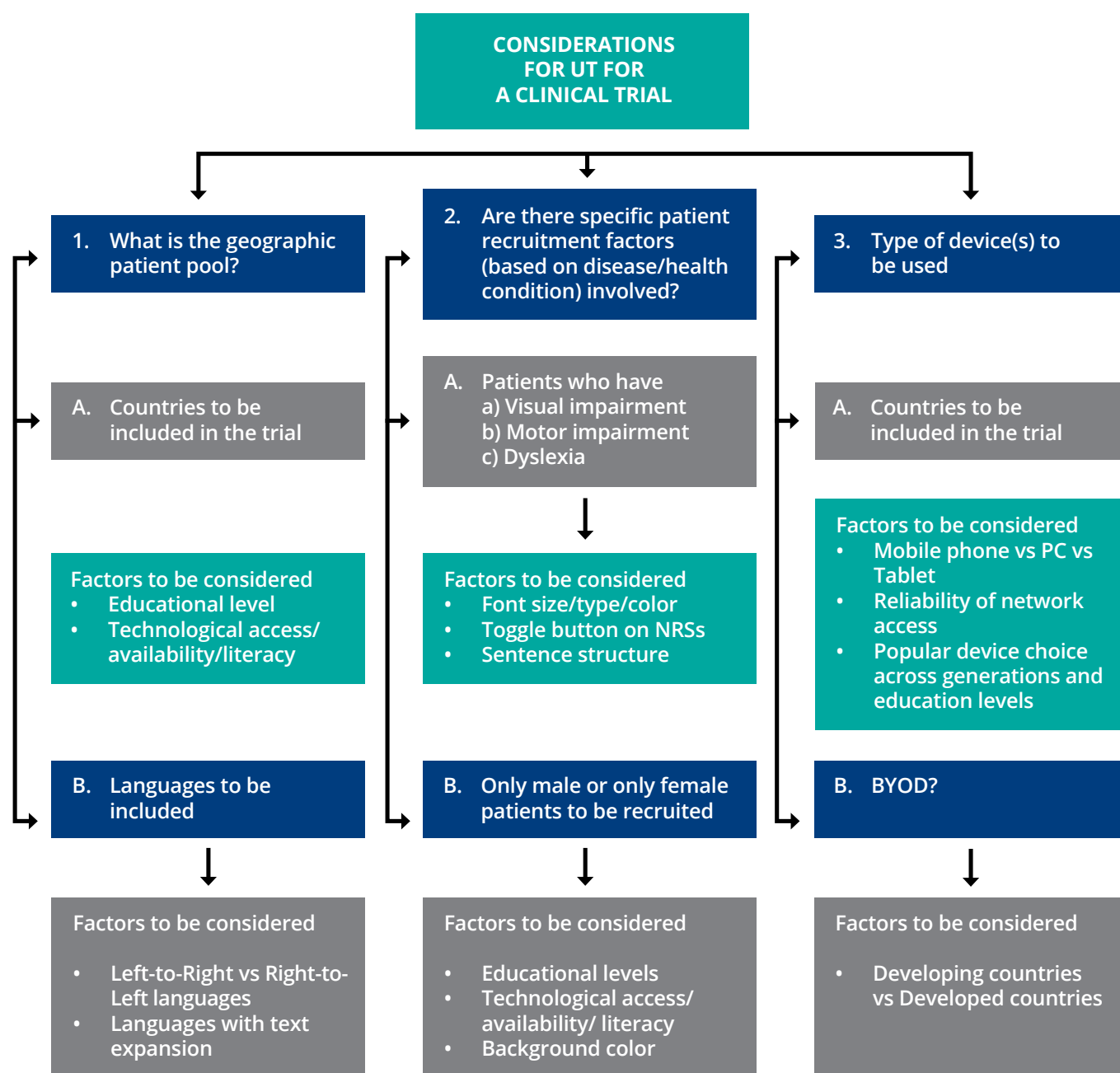
Studies have shown differences in preference of electronic device background and font colors between genders, with females preferring pink background and lighter font colors on screens as compared to the grey background and darker font colors (like black or blue) preferred by males.^{9,10} Though there is need for additional collaborative data regarding the background or font preference by male and female patients globally, in clinical trials where both female and male patients are to be recruited, keeping gender-neutral background (like white) and font (like green) colors, may render unbiased data. Similarly, in clinical trials specifically targeted at female or male patients, using gender-preferred colors and contrast settings for eCOA backgrounds and fonts may provide greater response rates.

For patients with visual impairment, certain display and design settings like larger font sizes, larger button sizes and accompanying audio instructions are useful. New touch display technology incorporating tactile, vibrotactile and haptic displays are being used to address the access gap of visually impaired and dyslexic individuals in accessing information on websites that have non-textual content (maps, graphic, online presentations etc.).¹¹ The application of screen readers used to make web content more accessible to the visually impaired is also gaining popularity.¹² Extending the applications of touch display technology and screen readers in eCOAs will help visually impaired and dyslexic patients answering these eCOAs.

Connection between UT and Inclusivity

Availability of technology by itself doesn't determine digital literacy; accessibility and receptiveness to technology contributes as well. Access to electronic devices is influenced by patients' country, age, education level and socio-economic status. Based on a patient's access to and usage of electronic device(s), there may be disparity in their comfort and confidence in using the device(s), which is reflected in UT. Clinical trials that have a broad clinical site base, spread across multiple countries with different levels of development (and hence accessibility of electronic devices), can particularly benefit from UT performed in these individual countries.

In the context of UT, inclusivity is a driving factor ensuring that both explicit and implicit issues faced by the patients during UT interviews are addressed before the eCOAs go live and capture actual clinical data. RWS Life Sciences discussed



the importance of updated user-experience-focused methods of UT interviewing in a previous paper.¹³ Explicit issues (for example, patients' difficulties in logging into the device, navigating among several questionnaires, selecting an answer, going back or forward, etc.) are problems that are obvious and expressed by the patients, while implicit issues (for example, patient's inability to manoeuvre the toggle selection, having to retype or reselect the answer as what they typed did not match what they wanted to type, secondary to small font size or bigger fingers, etc.) are problems that are subtle and observed by the interviewer without the patient directly referring to these. Taking into account both explicit and implicit issues helps to improve the administration of eCOAs.

How Do We Achieve This?

Our role as a UT service provider begins at the outset, when a study sponsor or eCOA vendor approaches us for

advice on UT project setup. For patient recruitment, we suggest the inclusion of both females and males, covering both younger and older age groups, and including patients with high as well as low educational qualification levels. In clinical trials that will use the BYOD (bring your own device) approach, we recommend checking electronic device, brand, and popularity across your clinical site locales, considering that in some developing countries, family members share electronic devices and one may or may not exclusively own them. We also provide recommendations for testing specific device type(s) (regular mobile phone vs smartphone vs PC vs tablet) based on the countries or regions where the clinical trial will be conducted. Ideally, we recommend UT be conducted in English as well as some key languages like the ones that use left-to-right script (Arabic, Urdu), scripts with complex characters (Japanese, Chinese) and longer sentence structures (Indian languages). However, currently most sponsors opt to only pursue UT on the English source. To overcome the effects that co-morbidities with a disease

may have on electronic device usage, we recommend the inclusion of otherwise healthy patients as well as those who may have some level of visual and/or motor and/or learning impairment (like dyslexia) as a co-morbidity. For example, in a clinical trial involving diabetes mellitus (DM) patients, we may recommend recruiting patients who have DM without any co-morbidity and also those who have DM with co-morbidities (tremors and visual impairment secondary to peripheral neuropathy).

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COMMON ISSUES WITH eCOA DESIGN: A PATIENT'S PERSPECTIVE

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RWS has provided usability testing (UT) since 2013 across a variety of devices and eCOA platforms. Over the course of working on these UT projects, we have encountered a variety of issues reported by the patients who tested the electronic devices to determine the ease of answering questionnaires on these devices. In the section below we've compiled a list of the issues most frequently reported by patients while using different electronic devices to answer questionnaires.

Issues commonly reported during UT:

1. Device preference
2. Device functionality issues
3. Challenges related to server connectivity or responsiveness
4. Difficulty logging in to the eCOA application
5. Website or application navigation challenges
6. Issues with submitting responses
7. Slider functionality issues
8. Anchors on NRS not clear
9. Cut-off NRS lines, images, tiles
10. Inconsistent orientation of NRS and VAS scales
11. Unrestricted use of free text fields
12. Font size
13. Button placement
14. Missing "Back" button
15. Font color issues
16. Unresponsive response option buttons
17. Missing progress bar

Though there is no definitive pattern in which these issues are reported, we've come across some issues more frequently being reported by older respondents or those with motor impairment. Integrating the concept of "inclusivity" discussed in the previous section, we emphasise that all the issues noted here should be addressed to ensure patients of any age, gender, education level, location, or socio-economic status should be able to easily answer questionnaires on electronic devices. While deciding on devices for use in clinical trials, due consideration should be given to older patients or those with motor or physical impairments.

The following section includes descriptions and images of the issues that RWS most commonly encounters during UT.

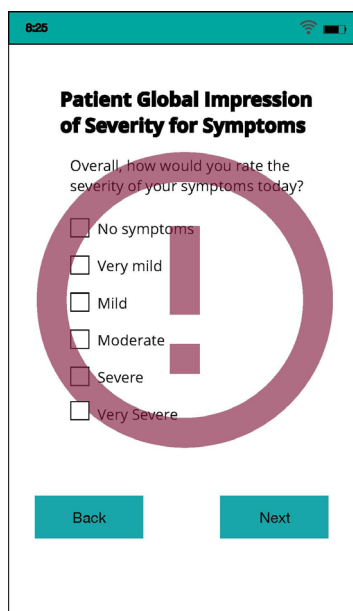


1. Device Preference

RWS has observed that older adults in the US often report a preference for tablets rather than smartphones during usability testing. This is because older adults are more likely to own tablets rather than smartphones¹. It is likely that these adults will prefer to answer a medical questionnaire on a tablet instead of a smartphone because of their greater familiarity with tablets. Patients who suffer from motor impairments have also demonstrated a preference for answering questionnaires on tablets, and some patients have also expressed a preference for using a lightweight device over a heavy one.

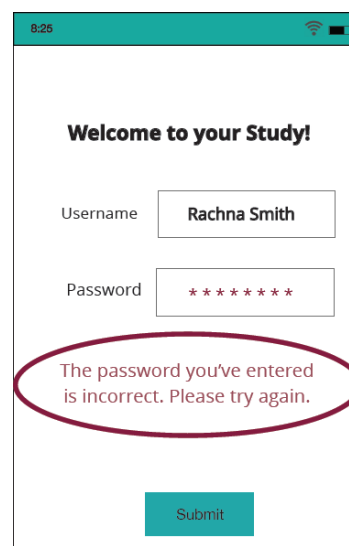
2. Device Functionality Issues

Sometimes patients report that the device to be used for answering questionnaires doesn't work. Some examples of reported issues include the device not turning on and frozen screens.



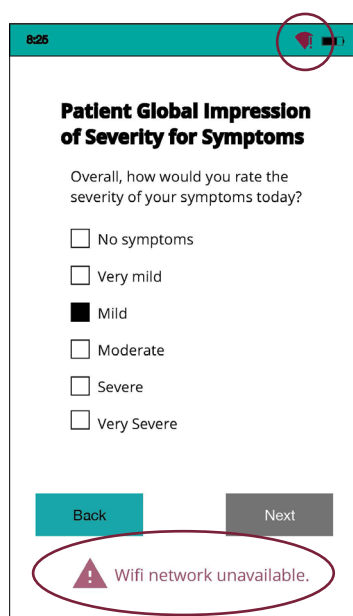
4. Difficulty Logging in to the eCOA Application

Another issue commonly reported during UT is difficulty logging into the eCOA application. In some cases a patient has had to log in multiple times in order to enter their responses and this has been reported as "frustrating".



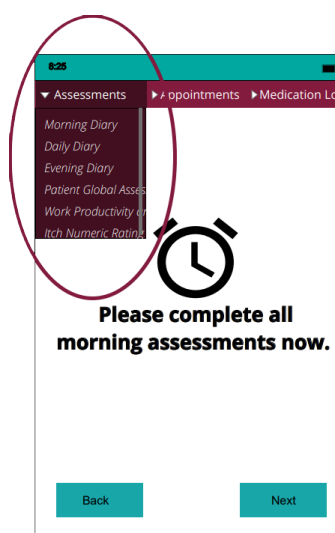
3. Challenges Related to Server Connectivity or Responsiveness

While completing UT interviews, some patients have reported issues with internet connectivity. In some instances, patients also experienced slow response rates from the eCOA application leading to lags in screen load time.



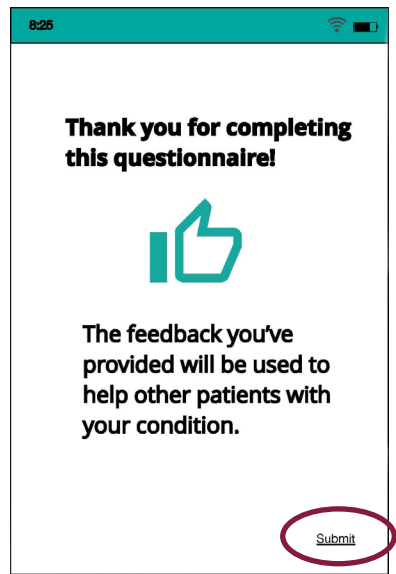
5. Website or Application Navigation Issues

Sometimes patients are asked to complete multiple eCOAs during a particular timeframe and may need to navigate within the mobile app or website to locate all eCOAs. Whenever navigation within an application or website is required, any navigational inconsistencies or divergence from UI/UX best practice guidelines can disorient a user. In our testing, older patients have reported this type of navigation as cumbersome, time-consuming, and tedious.



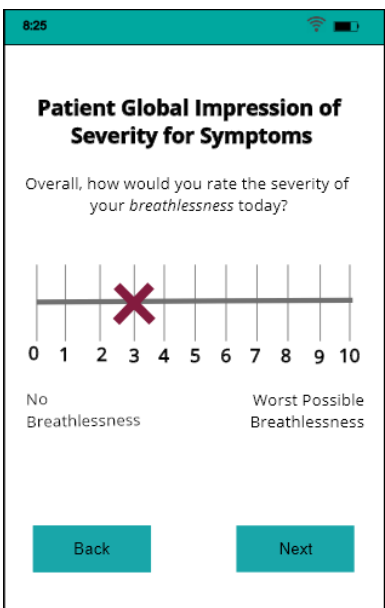
6. Issues with Submitting Responses

Some patients have reported to RWS that it is difficult to submit their answers to the questionnaire upon completing it. Some common causes for this challenge are the size or location of the “Submit” button making it difficult to see, delays in submission completion, and lack of an alert notifying the patient that the submission was not completed.



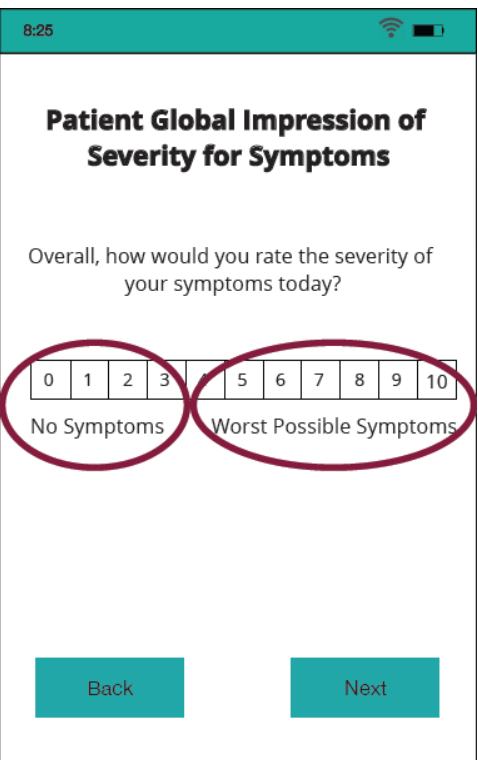
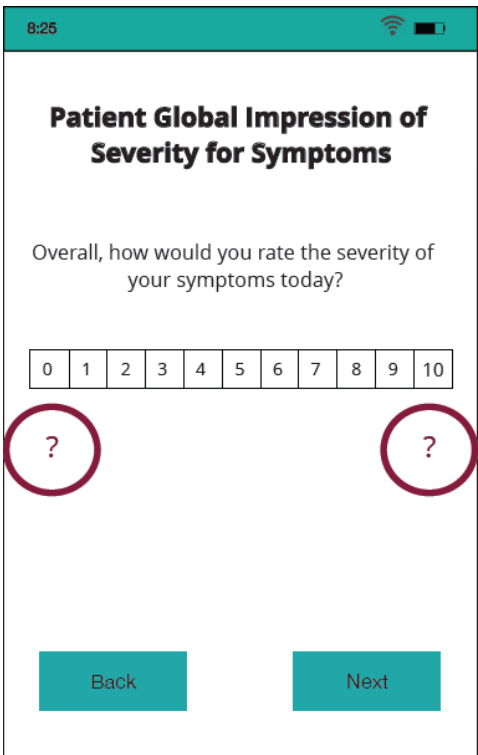
7. Slider Functionality Issues

Care must be taken when designing numeric rating scales (NRS)- and visual analogue scales (VAS)-based questions using a slider. The patient should be able to enter their answer by both using the slider and direct tapping on the number of choice. RWS has observed patients reporting either or both methods not working.



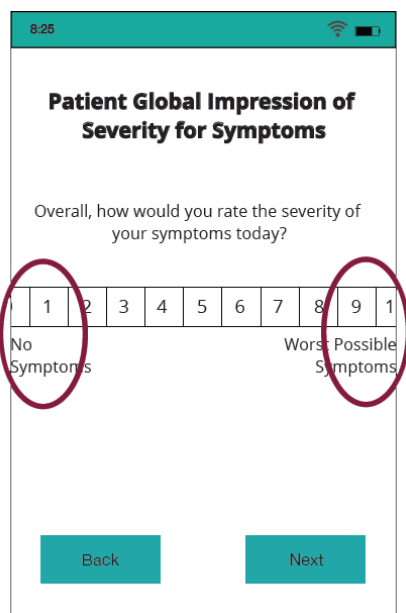
8. Anchors on NRS or VAS Not Clear

Missing or poorly positioned anchors on NRS or VAS are a common UT finding. These issues can confuse patients and make it difficult for them to accurately select a response option.



9. Cut-off NRS Lines, Titles, or Images

Another common problem with eCOA design is cut-off text or images. Some issues reported during UT are cut-off NRS lines making it difficult to select an answer, and confusion caused by cut-off questionnaire titles or cut-off images.



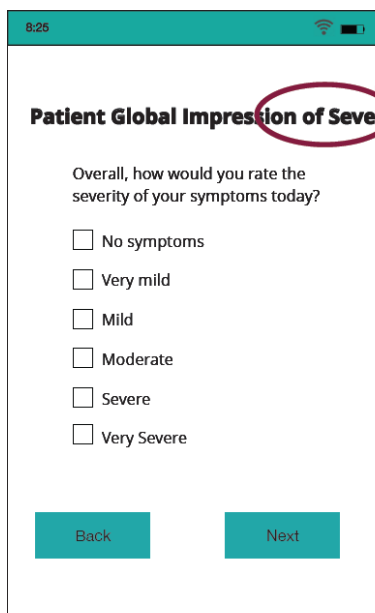
Patient Global Impression of Severity for Symptoms

Overall, how would you rate the severity of your symptoms today?

1 2 3 4 5 6 7 8 9 10

No Symptoms Worst Possible Symptoms

Back Next



Patient Global Impression of Severity for Symptoms

Overall, how would you rate the severity of your symptoms today?

☐ No symptoms

☐ Very mild

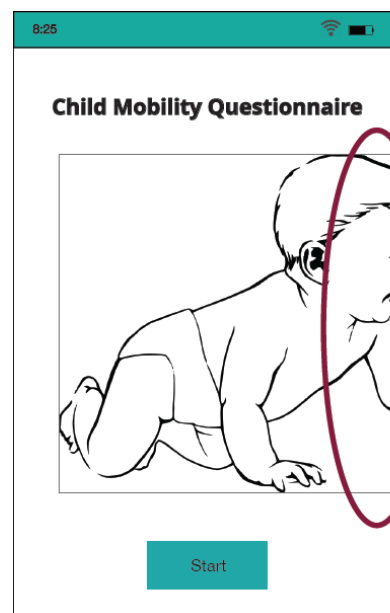
☐ Mild

☐ Moderate

☐ Severe

☐ Very Severe

Back Next

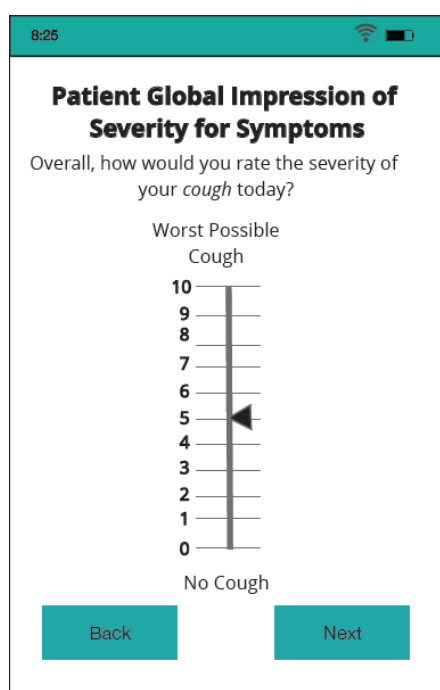


Child Mobility Questionnaire

Start

10. Inconsistent Orientation of NRS and VAS Scales

Sometimes the orientation of NRS and VAS scales in the same instrument is inconsistent between screens. Patients have noted to RWS that they find this confusing.



Patient Global Impression of Severity for Symptoms

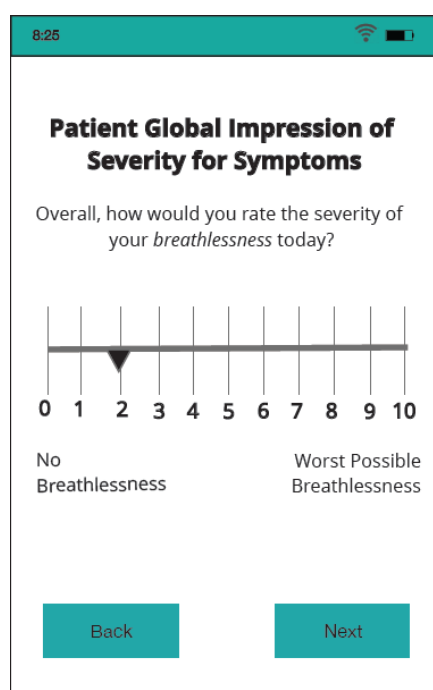
Overall, how would you rate the severity of your cough today?

Worst Possible Cough

10 9 8 7 6 5 4 3 2 1 0

No Cough

Back Next



Patient Global Impression of Severity for Symptoms

Overall, how would you rate the severity of your breathlessness today?


0 1 2 3 4 5 6 7 8 9 10

No Breathlessness Worst Possible Breathlessness

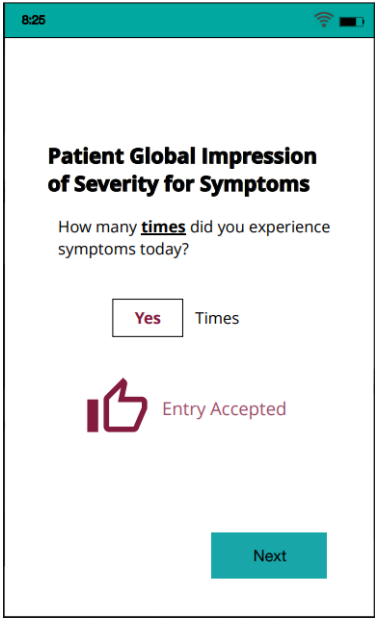
Back Next

11. Unrestricted Use of Free Text Fields

Some questionnaire questions require a number to be entered as an answer (e.g. number of inhaler puffs used, number of tablets taken, etc.). It is important for the possible entries on these questions to be restricted to integers so that patients can only enter the correct data type. RWS has observed during UT instances of the answer field accepting inappropriate answers like decimals or fractions, and text entries like “yes/no”. Unrestricted use of free text fields in this way can lead to loss of important study data.




DONT accept unusable entries (text in a numeric field).




Patient Global Impression of Severity for Symptoms

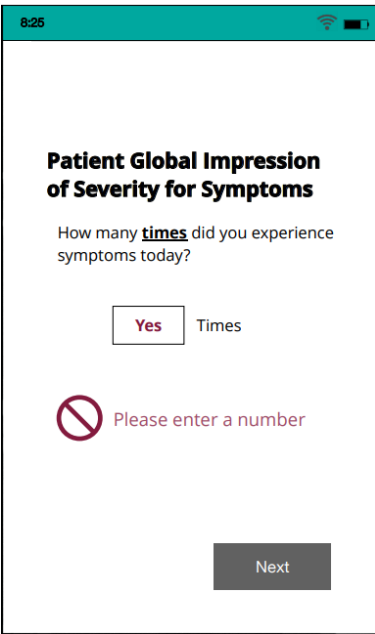
How many times did you experience symptoms today?

Times

 Entry Accepted




DO remind users of data type required (the number of times).



Patient Global Impression of Severity for Symptoms

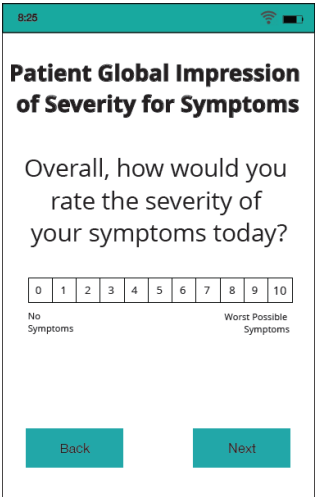
How many times did you experience symptoms today?

Times

 Please enter a number

12. Font Size

Patients have reported that font size is too big, too small, or not uniform across screens.



Patient Global Impression of Severity for Symptoms

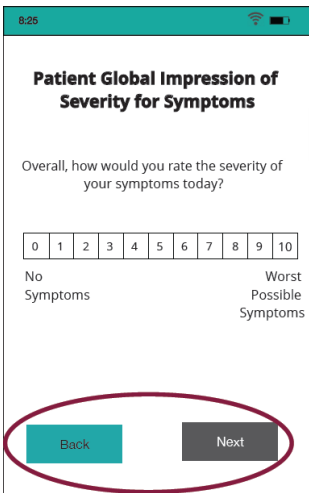
Overall, how would you rate the severity of your symptoms today?

0 1 2 3 4 5 6 7 8 9 10

No Symptoms Worst Possible Symptoms

13. Inconsistent Button Placement

In some cases, patients have reported challenges related to the placement of buttons. For example, patients reported that a button was placed far too low on the screen and they didn't realise that they had to scroll down to find it. In other instances, they reported inconsistency in button placement on screens, with them appearing at the bottom on some screens and at the top in others.

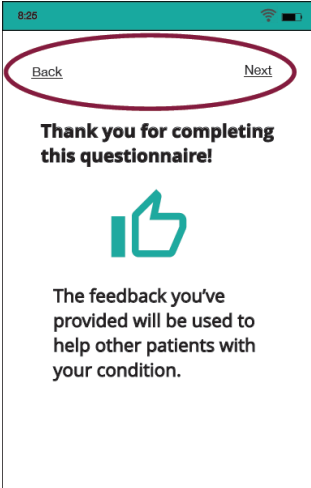


Patient Global Impression of Severity for Symptoms


Overall, how would you rate the severity of your symptoms today?

0 1 2 3 4 5 6 7 8 9 10

No Symptoms Worst Possible Symptoms



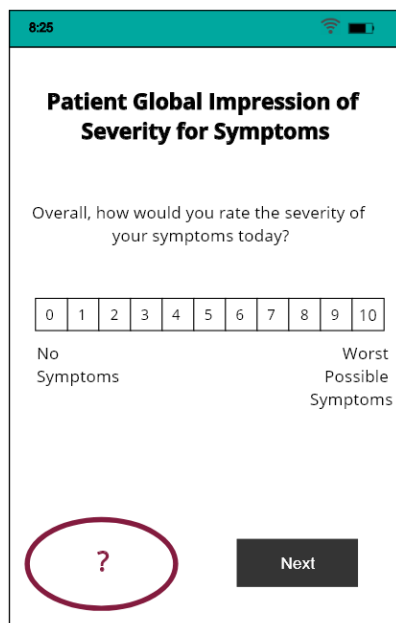
Thank you for completing this questionnaire!



The feedback you've provided will be used to help other patients with your condition.

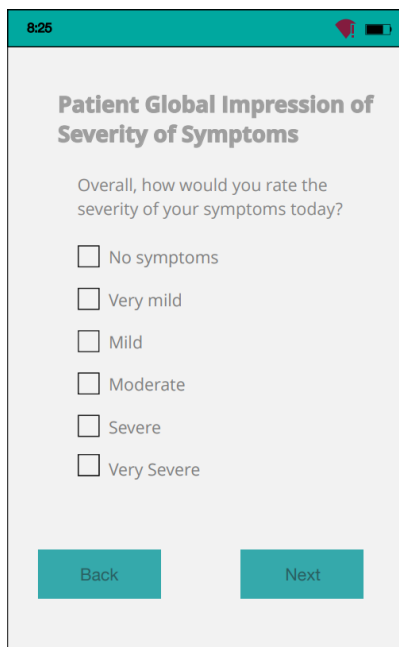
14. Missing “Back” Button

Patients have reported that they weren’t able to go back to a previous screen to change an answer because there was no “back” button on the screen.



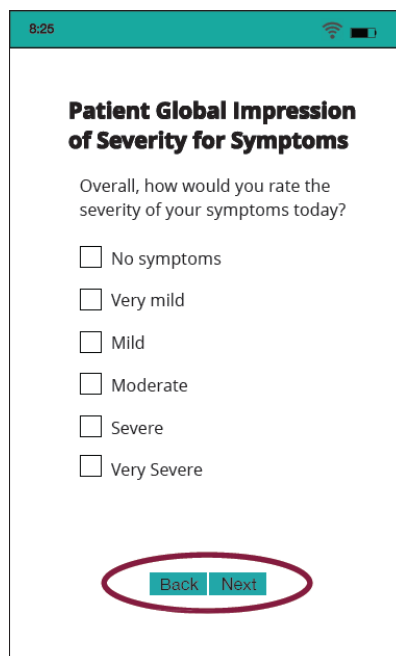
15. Accessibility Issues Related to Color Contrast

Patients have reported issues with font colors, either these being too light or non-uniform across the questionnaire. Font colors that are too light may pose a challenge to some patients in accurately responding to the questions. eCOA builds should have a contrast ratio of at least 4.5:1, in accordance with the W3C success criterion.²



16. Unresponsive Response Option Buttons

Patients may report that response options are non-selectable. RWS has observed patients getting irritated because tapping on their chosen response option did not select it as a response. Common causes for this are delays between tapping the response option and the device registering the response, inconsistent hot spot size between buttons, and unselectable response options.



17. Progress Bar Not Present

Patients have reported that a progress bar was not present or was too light to help them determine the progress of the questionnaire completion.

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