IMPLEMENTING NEW CLINICAL OUTCOME ASSESSMENT INSTRUMENTS ON ALTERNATIVE DATA COLLECTION MODES: THE ELECTRONIC IMPLEMENTATION ASSESSMENT AND MIGRATION PROCESS

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ePRO CONSORTIUM
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Abstract

AIMS:
The Critical Path Institute's (C-Path) ePRO Consortium, consisting of eight ePRO technology provider member firms, has developed a process for assessing the migratability of newly developed clinical outcome assessment (COA) instruments. The objective of the electronic implementation assessment is to evaluate the viability of implementing a COA instrument on currently available electronic data collection platforms. This research presents the electronic implementation assessment process and discusses subsequent migration to illustrate the issues that may arise during the migration from a paper-based instrument to an electronic platform.

METHODS:
As part of new COA instrument development, the electronic implementation assessment is conducted once a draft instrument has emerged from the item generation process and after the instrument has been assessed for translatability. The assessment provides an item- and instrument-level analysis of the instrument's suitability and potential issues for implementation on various electronic data collection platforms (i.e., tablet, handheld, interactive voice response (IVR), Web, and digital pen).

RESULTS:
The instruments emerging from the Depression and Irritable Bowel Syndrome (IBS) Working Groups within C-Path's PRO Consortium have undergone the electronic implementation assessment process. Some findings common to both instruments include: recommendations to modify the recall period or the way the recall period is presented to subjects; identifying the translated character length of some items that may pose a concern for small-screen devices; and indicating that bold and underlined text are rendered differently on various operating systems and cannot be rendered visually on an IVR platform. Issues unique to each of the instruments were also identified. The IBS instruments were subsequently migrated to a handheld (i.e., smartphone) device and further changes were made which improved the instruments for further testing.

CONCLUSIONS:
The PRO Consortium working groups reviewed the feedback provided in the electronic implementation assessments and revised the draft COA instruments prior to additional instrument testing. The electronic implementation assessment shows the ability to identify elements of COA instruments that should be considered for modification to allow for improved implementation on a variety of electronic data collection platforms to ensure the quality of data collected with these instruments in clinical trials.

Background

The Critical Path Institute is an independent, non-profit institute created in 2005 by the University of Arizona and the U.S. Food and Drug Administration. C-Path provides a pre-competitive space in which various stakeholders can work collaboratively to address the challenges of bringing new medical innovations to the public. C-Path has established several consortia, including the Patient-Reported Outcome (PRO) Consortium which is developing PRO instruments for use as primary or secondary endpoints in clinical trials for qualification by the FDA.

The ePRO Consortium was established within C-Path effective April 1st, 2011. The ePRO Consortium's members are firms that provide electronic data collection technologies and services to the medical products industry for capturing patient-reported outcome (PRO) endpoints in clinical trials. The mission of the ePRO Consortium is to advance the quality, practicality, and acceptability of electronic data capture (EDC) methods used in clinical trials for PRO endpoint assessment.

ePRO Consortium Members

ALMAC
Bracket
CRF HEALTH REAL PATIENT DATA 24/7
ERT Getting It Done. Right.
exco intouch Healthcare at your fingertips
ICON A Symbol of Excellence
medidata
PHT

Methods

One of the goals of the ePRO Consortium is to evaluate the feasibility of implementing the PRO instruments developed by the PRO Consortium on all electronic platforms. To meet this goal, the ePRO Consortium developed methodology for conducting this evaluation, called the Electronic Implementation Assessment. For this assessment, each member of the ePRO Consortium provides instrument-level and item-level feedback on the draft PRO instrument emerging from the PRO Consortium's Working Groups (WG). Ideally, the Electronic Implementation Assessment is conducted after the item generation process and after the instrument has undergone translatability assessment. The feedback is consolidated in a brief report and, along with a detailed feedback spreadsheet, is presented to the PRO Consortium WG for consideration.

Results

Issue	Proposed Changes to Instrument from Electronic Implementation Assessment	Resulting Changes
	Depression WG	
Length of Instrument, Length of Items	• The overall length of the questionnaire (35 items) does not lend itself to administration on an IVR platform due to the subject burden. o If a 24-hour recall version is created, the subject burden related to the length of the questionnaire is a concern, regardless of platform. • The translated character length of some items is a concern for implementation on a handheld device. o The subcommittee suggests exploring the fit of translated text of the longest items on small-screen devices.	No changes made; Instrument undergoing further testing
Item Format	• The bold text included in the items is a concern for the handheld and IVR platforms; the subcommittee suggests removing bold text. o The capability for bold and underlined text on handheld devices is dependent on the operating system. Further, if capable, various operating systems may render bold text differently. Bold text cannot be rendered on an IVR platform. • The subcommittee pointed out that the recall period is expressed in three different ways: 1) Over the past 7 days; 2) Overall, in the past 7 days; 3) Overall, during the past 7 days. o 'Over the past 7 days' is suggested as it conveys the same recall period but includes the fewest characters.	Bold and underlined text was removed; 'Over the past 7 days' selected for recall phrasing
Instructions	• The subcommittee suggests including instructions to alert the subject when the response set transitions from intensity to frequency o A transitional screen informing the respondent of the change in response set is suggested for visual devices. o Verbal instructions informing the respondent of the change in response set is suggested for the IVR platform.	No change made
	IBS WG	
Recall Period	• The 24-hour recall period proposed for IBS-C may present challenges for patients in clinical trials that may begin to experience multiple bowel movements in each day. The subcommittee suggests allowing event-based, real-time data capture of bowel movements (BM) for the IBS-C instrument. The end of day alarm will notify the patient of the number of BMs already reported for that day and inquire about any missed BM entries and details prior to the abdominal discomfort items (similar to that outlined for the IBS-D instrument).	IBS-C instrument changed to event-based recall
Instrument-Platform Compatibility	• A paper or digital pen version of the IBS-C instrument does not lend itself to daily administration due to the concatenation (last/first/second etc.) that is necessary for questions 2 to 5. • Field-based assessments (e.g., daily diary) do not lend themselves to paper or digital pen administration. • The tablet platform may not be optimal for event-based reporting due to the cumbersome nature of carrying the device at all times. • A web platform may not be optimal for event-based reporting, which would depend on the availability of a computer and internet connection at the time of the event.	Change to event-based recall solved concatenation issue; minimum screen size recommended
Item Format	• Including the text and pictures for the Bristol Stool Form Scale (BSFS) presents a challenge to fit on one screen when implemented on a handheld device. If IVR is considered, a card with the stool images could be provided to subjects when answering the BSFS.	Text was shortened to fit with images on one screen
Item Format	• The questions related to abdominal symptoms include a numeric rating scale (NRS) with textual anchors. Due to the length of text for the anchors, the text will wrap and likely extend inward under the scale on a handheld device. o The subcommittee suggests considering shortening the text for the anchors. o The items also could be displayed in landscape format.	Included an indicator arrow for each anchor at the ends of the scale
Length of Items, Item Format	• The translated character length of some items is a concern for implementation on a handheld device. o The subcommittee suggests exploring the fit of translated text (e.g., German or Russian) of the longest items on small-screen devices. • The underlined text included in the items is a concern for the handheld and IVR platforms; the subcommittee suggests removing the underlined text. o The capability for bold and underlined text on handheld devices is dependent on the operating system. Further, if capable, various operating systems may render bold and underlined text differently. Bold and underlined text cannot be rendered on an IVR platform.	Underlined text removed

After electronic implementation assessment was completed, IBS instruments were migrated to a handheld device (smartphone) platform, and the following improvements were made:
- Date and time entry screen added to allow the subject to confirm the time of each episode
- History screen to remind subjects about episodes already recorded
- Option of entering episodes during the evening diary administration if not already entered

Conclusions

- The electronic implementation assessment uncovered several common issues in both instruments, such as concerns over the translated character length and suggestions to remove bold and underlining.
- The electronic implementation assessment resulted in changes being made to both of the instruments, which highlights the importance of conducting the assessment early in the instrument development process.
- Early involvement of the ePRO provider for instruments being implemented on electronic platforms is essential to avoid wasting resources testing sub-optimal instrument formats and to reduce future issues during electronic implementation.