

IMPLEMENTING NEW COA INSTRUMENTS ON ALTERNATIVE DATA COLLECTION MODES: THE ELECTRONIC IMPLEMENTATION ASSESSMENT

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Abstract

Objectives:

The Critical Path Institute's (C-Path) ePRO Consortium, consisting of seven ePRO 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 all currently available electronic platforms.

Methods:

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

Results:

The instruments that have emerged from C-Path's PRO Consortium's Depression and Irritable Bowel Syndrome Working Groups have undergone the electronic implementation assessment process. Some assessment findings common to both instruments include: suggestions to modify the recall period or the way the recall period is expressed to subjects; identifying the translated character length of some items that may pose a concern for small-screen devices; and highlighting that bold and underlined text are rendered differently on various operating systems and cannot be rendered on an IVR platform. Issues unique to each of the instruments were also detected.

Conclusions:

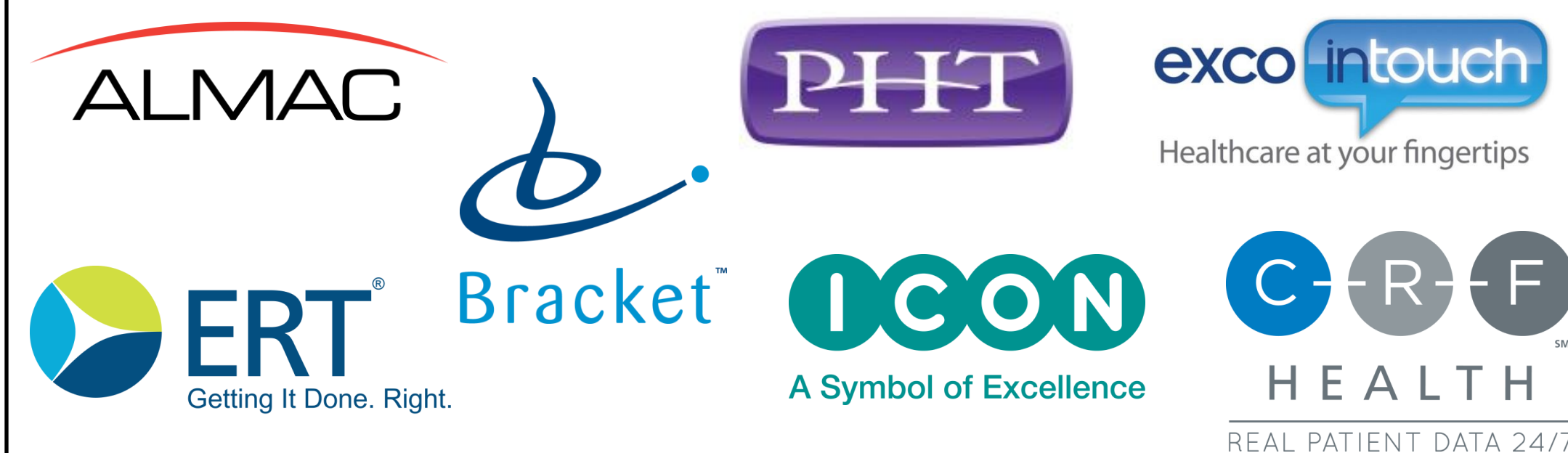
The PRO Consortium Working Groups have taken into account the feedback included in the electronic implementation assessments and have made changes to the draft COA instruments prior to additional instrument testing. The electronic implementation assessment has shown the ability to identify elements of COA instruments that should be modified to allow for easier implementation on a variety of electronic data collection platforms which is important for enhancing the quality of data collected with these instruments in future 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



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. The table below contains the results of the Electronic Implementation Assessment for the PRO instruments being developed by the Depression and IBS WGs.

Results

| Issue | Proposed Changes to Instrument from Electronic Implementation Assessment | Resulting Changes |
|---------------------------------------|---|--|
| Depression WG | | |
| Length of Instrument, Length of Items | <ul style="list-style-type: none"> The overall length of the questionnaire (35 items) does not lend itself to administration on an IVR platform due to the subject burden. <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> The bold text included in the items is a concern for the handheld and IVR platforms; the subcommittee suggests removing bold text. <ul style="list-style-type: none"> 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: <ol style="list-style-type: none"> 1) Over the past 7 days; 2) Overall, in the past 7 days; 3) Overall, during the past 7 days. <ul style="list-style-type: none"> '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 | <ul style="list-style-type: none"> The subcommittee suggests including instructions to alert the subject when the response set transitions from intensity to frequency <ul style="list-style-type: none"> A transitional screen informing the respondent of the change in response set is suggested for visual devices. Verbal instructions informing the respondent of the change in response set is suggested for the IVR platform. | No change made |
| IBS WG | | |
| Recall Period | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> 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 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 was recommended |
| Item Format | <ul style="list-style-type: none"> 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 | <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> The subcommittee suggests considering shortening the text for the anchors. 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 | <ul style="list-style-type: none"> The translated character length of some items is a concern for implementation on a handheld device. <ul style="list-style-type: none"> 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. <ul style="list-style-type: none"> 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 |

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.