PRO Instruments

EXACT® + E-RS™ ePRO information

The EXAcerbations of Chronic pulmonary disease Tool (EXACT) and Evaluating Respiratory Symptoms (E-RS) are patient-reported outcome (PRO) instruments used to measure treatment effects on patients with COPD. The EXACT was designed as an eDiary for use in clinical studies of COPD.

The EXACT eDiary is completed by study participants on a handheld electronic platform similar in size to a smartphone.

- Although validation studies were conducted using the Palm® Tungsten E2, the instrument is transferable to other electronic handheld platforms.
- Specifications for formatting and layout are available to assure ease of patient use and consistency across studies.

A paper-pen booklet is available; however, this method of administration is not recommended.

- Paper-pen daily diaries are bulky, cannot be tracked for daily compliance, and require manual data entry with associated error risk, among other limitations.
- All performance evaluations of the EXACT and E-RS are based on data from ePRO devices.

Selecting an eDiary device

Physical features

Device size

- Larger devices may be less portable.
- Smaller devices may be more difficult to handle and use.

Screen size

- For the EXACT, screen sizes smaller than 2.75 in x 1.5 in may not be sufficient to display each question and responses on the same screen.
- Smaller screens provide less real estate to display text and may be problematic for longer questions and responses.
- Consider the impact of translations which may run 25% longer than the English source. Modification of existing translations to fit screen size is not permitted.

Font size

- Consider the age of your target population; Font should be large enough to be easily readable.
- Will fonts have to be reduced to accommodate translations?

Font resolution

The clearer and sharper the font, the easier it is to read when smaller. Large fonts that are not sharp can be more difficult to read than smaller clearer fonts.

Response area or buttons

- Consider the size of the response area. If the response area is too small, patients may have difficulty getting their responses to register which could cause frustration and lower compliance.
- The response area should be large enough to be selected without choosing the wrong answer. Consider how much pressure must be applied to a response area for the device to register a selection.

Navigation

How easy is it to move from screen to screen? Is it intuitive?

Changing responses

How easy is it to change an answer when completing the diary?

Data transmission

- Does data transmission take place at the clinical site or is it transmitted by the patients?
- Is transmission wireless or analog?
- Is the device capable of automatic transmission to the central server?
- If patients are required to upload data nightly and the transmission requires additional hardware, this could cause frustration and lower compliance.

- Do you need immediate access to the data? Access within one day? One week? Monthly?
- How closely will the patients be monitored for compliance by sites, i.e., do they need to view data daily or will data uploads at scheduled clinic visits suffice?

Usability

Completion time

How long does it take to answer a question and move to the next screen? The more clicks or taps needed, the more frustrated the patient may become when answering over a long period of time, resulting in reduced compliance.

Touchscreen

- Can answers be selected by touching the screen and is using one's finger possible as well as a stylus?
- Consider older populations or those with conditions like arthritis for whom holding a stylus may be more difficult than tapping with a finger.

Ease of use

- Is the device easy to use for patients who are not technology savvy? If difficult to use, compliance may decrease.
- Consider older populations or those with conditions like arthritis for whom pressing buttons may be more difficult than using a touchscreen.
- Consider whether the device can be laid flat on a table and continue to be legible so that patients who do have trouble holding a device steady can still answer the questions using a touchscreen or buttons.

Integrated device

If using a device that integrates a diary with other functionality but sacrifices usability, is the extra functionality truly necessary for your study?

Other considerations

Compliance program

- Does the vendor have processes to enhance compliance, such as reminder alarms, positive reinforcement messages on the device, patient take-home instructions, and an available help desk?
- Consider whether the vendor can tailor compliance features like alarms and diary completion windows to be patient-specific (alarms 1 hour prior to bedtime, at bedtime, 1 hour post bedtime; study window + 3 hours from bedtime), or if the alarms and/or diary will follow 1 study-wide guideline (i.e. alarm goes off at 8PM every evening regardless of bedtime; study completion window 3PM-3AM).

Web portal

How easy is it for the sites to view patient data and for study monitors to view overall site compliance data?

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