

Appendix 1 (Online Material). - Cognitive interview probes administered to patients to evaluate content validity of PRO-CTCAE items

Comprehension

Symptom Terms

For all endorsed and randomly selected unendorsed items

Example: What does "BRUISING EASILY" mean to you as it is used in this question?

Issues raised by Experts during Item Development - Asked to all Patients - Round 1 Only

Does lightheadedness mean the same thing to you as DIZZINESS, or is this a different concept in your mind?

What does URINATE mean to you? Are there any other words that you would use to describe to URINATE?

What does INJECTION mean to you?

Have you experienced any sort of mental symptoms or challenges?

Issues raised by Experts during Item Development - Asked to all Patients - Round 1 and Round 2 Only

What does BLOATING mean to you? Are there any other words that you would use to describe BLOATING?

Issues raised by Experts during Item Development - Asked to all Patients - Round 1, Round 2, and Round 3

What does the term WHEEZING mean to you? Are there other terms you might use to describe it?

Asked to all Male Patients - Round 1 Only

What does EJACULATION PROBLEMS mean to you as it is used in this question? Are there other terms that you might use for this symptom?

Asked to all Female Patients - Round 1 Only

What is your understanding of the term VAGINAL SEX?

Issues raised during Round 1 and Round 2 - Asked to all Patients - Round 3

What does TREMORS mean to you? Are there any other terms that you would use to describe TREMORS?

What does CONSTIPATION mean to you? Are there any other words that you would use to describe CONSTIPATION?

What does DIARRHEA mean to you? Are there any other words that you would use to describe DIARRHEA?

Attribute Terms

For all endorsed and randomly selected unendorsed items

What does HOW OFTEN mean to you as it is used in this question?

What does HOW SEVERE mean to you as it is used in this question?

What does INTERFERENCE mean to you?

What does INTERFERE WITH DAILY ACTIVITIES mean to you as it is used in this question?

Would INTERFERE WITH USUAL ACTIVITIES be a better way to phrase this? Why or why not?

Did you consider nighttime when you considered interference with daily activities?

Which activities did you actually think about to evaluate interference?

What does DID YOU HAVE mean to you as it is used in this question?

Response Scale

Asked to all Patients

Overall, how difficult was it to select an answer for questions about never, rarely, occasionally, frequently, or almost constantly?

For all endorsed and randomly selected unendorsed items

Did you find it easy or difficult to choose an answer?

You said (x). How did you come up with that answer?

You answered (x). What makes that a better answer than (x+1)? What makes (x) a better answer than (x-1)?

Were there any other words in the response choices that were confusing or hard for you to understand? If so, which ones?

What would you recommend to make this question easier for patients to answer?

Memory Retrieval

Seven-day recall period

For endorsed and randomly selected unendorsed items

- What did you need to recall in order to answer this question?
- How easy or difficult was it to think back over the last seven days?
- If it was difficult, what made it so?
- Was there anything else that came to mind while you were answering this question?

Judgment

Symptom Terms

Issues raised by Experts During Item Development - Asked to all Patients - Round 1 Only

- Would you have answered the FELT THAT NOTHING COULD CHEER YOU UP question any differently if we had used the word SAD? How about UNHAPPY?
- If we had asked about BREAST AREA TENDERNESS, would you have had a different answer? What would that be?
- Would you have answered differently if we had asked about HAVING ORGASM rather than FEELING ORGASM? Would you have answered differently if we had asked about DIFFICULTY WITH ORGASM instead of PROBLEMS WITH ORGASM?

Issues raised by Experts during Item Development - Asked to all Patients - Round 1 and Round 2 Only

- In answering the SWEATS (EXCESSIVE SWEATING) question, did you consider more than normal sweating with activities, or normal sweating as well?

Asked to all Male Patients - Round 1

- If we had asked separately about your DIFFICULTIES GETTING AN ERECTION, and KEEPING AN ERECTION, would your answers have been different?

Response Mapping

Symptom Terms

Issues raised by Experts during Item Development - Asked to all Patients - Round 1 Only

- In reporting the frequency of your hiccups, is that a separate consideration than the severity of your hiccups, or are these similar concepts in your mind?
- Aside from the SEVERITY of your PAIN, how would you describe your PAIN FREQUENCY? Does this relate to how severe the symptom was, or not?
- Did BLURRED VISION interfere with your daily activities? Does this relate to how severe the symptom was, or not?
- Did DIFFICULTY SLEEPING/INSOMNIA interfere with your daily activities? Does this relate to how severe the symptom was, or not?
- What specific problems did you have from NUMBNESS OR TINGLING IN YOUR HANDS OR FEET? How did it interfere with your daily activities?
- Does the frequency of your HOT FLASHES relate to how severe they are? Or, is it enough for you to report on only the severity of your hot flashes regardless of the frequency?
- Does the frequency of your pain in the abdomen relate to how severe it is? Does the frequency of your pain relate to how much it interferes with your daily activities?
- Or, is it enough for you to report on only the severity of your pain in the abdomen regardless of the frequency of this symptom? Regardless of how much it interferes with your daily activities?

Issues raised by Experts during Item Development - Asked to all Patients - Round 1 and Round 2 Only

- Did ITCHY SKIN interfere with your daily activities? Does this include sleep or only daily activities?

Issues raised during Round 1 and Round 2 - Asked to all Patients - Round 3

- If participant prioritizes FREQUENCY of DIARRHEA, probe on whether consistency of DIARRHEA is relevant to their understanding of the term.
- If participant prioritizes CONSISTENCY of DIARRHEA, probe on whether FREQUENCY of DIARRHEA is relevant to their understanding of the term.

General Summary Questions

Asked to all Patients - All Rounds

- Did you find this interview difficult?
 - Was the interview okay in terms of the length, or was it too long?
 - Does any one question stick in your mind as being particularly difficult for you?
 - Is there anything else you would like us to know about this questionnaire? Do you have any suggestions for improving it for other patients?
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