

Comment: Regarding Poll Question #2 (Slide 21), options A & B doesn't capture the possibility of completing the survey over the phone.

Response: Yes, the question doesn't encompass everything that could happen as far as collecting the PROs. You can absolutely complete the survey over the phone.

Question: If the participant wants to leave, can we complete the rest of it over the phone?

Answer: Yes, absolutely. If you have a study participant scheduled to have an infusion next week and the PROs are due, completing the PROs over the phone is fine.

Comment: Including explicit language in the protocol that permits/forbids phone completion would be helpful.

Response: We have language about that as part of our standard template, but older studies may not have it. Katie also reviews all PRO protocols, so she will keep an eye out for that.

Question: If a patient refuses to complete all of the PROs, completes only a portion, or stops in the middle, we would expect that to be documented in the source documentation for audit purposes. From a data perspective, how is that best documented in Rave?

Answer: (Monica): There was also an accompanying cover sheet for the patient completed questionnaires that will be expected from the site. You can document and report on that form that a questionnaire was not completed and the reason why not.

(Katie): If the entire questionnaire was not completed, you can indicate that on the cover sheet, and that's the right place. If a participant refuses to answer certain questions within a questionnaire, there is always an option to select "no response" or "participant didn't response" within Rave. You can still submit the rest of the data, but for the few questions where the participant said, "I don't want to answer this" then you just mark it as they refused or they didn't respond.

Question: Are the participants expected to initial and sign all pages of the PROs?

Answer: (Katie) I did not have that expectation and was under the impression that this was a site-specific requirement, not something that SWOG requires.

(Rose) From a QA perspective, if there is no place for an initial and date, we are not going to ding the site for that during an audit. I think it would only come up if there was some kind of question about the data – for example, if it looked like the patient might not have been present and the PRO is completed without evidence within the EMR that the patient was present or contacted by phone. In that case, we might ask for documentation. The most important thing is documenting how the PRO was collected and any issues around it, so that we're not really looking for things like that because it's clearly documented.

Question: If a patient gets stuck on a question and asks for clarification, how much can we clarify? For example, the distinction between “do you have a symptom” vs “how do you feel about this symptom” [regardless of how impactful that symptom is].

Answer: This is tricky because you do want to respond and give participants clarification, but it’s important not to give too much because, at that point, it could change the meaning of the question. For that specific example, “do you have a symptom?” vs “how do you feel about it?”, it could be understood as “how impactful it is?”, “what interferes with it?” vs just have it as a “yes” or “no” response, or “how frequently it occurs?”. If you’re going into multiple sentences to explain it, that’s probably more than is needed. Try rephrasing the question slightly; that may be most that you can do. Unfortunately, the PROs are supposed to be standardized in how they are administered. Rereading the question, emphasizing it, or maybe pointing out the words that are kind of the key words are all good strategies.

Question: Can you provide a short script to explain to patients why PROs are important?

Answer: We can certainly put together something for that, but I would also encourage you to read that peer-to-peer handout that was mentioned earlier. There are some suggestions from other ORPs who have already found a way to communicate this with their participants. So, we can work on that from a SWOG perspective, but I think your peers actually already have some pretty good ideas.

Polling:

1. Which of the following is not a scientific reason PROs are included in SWOG clinical trials?
 - a. Helps identify treatments that cause fewer side effects
 - b. Ensures future patients know what to expect when they receive the same treatment.
 - c. Better reimbursement
 - d. Brings the patient voice into research without interpretation by physicians or caregivers

Answer: C. Better reimbursement

2. You have a study participant who is scheduled to have an infusion next week and PROs are due for this participant. Which of the following are good strategies for collecting PRO data in this situation?
 - a. Check PROs for this particular timepoint and print them out the day before
 - b. Have a stamped envelope ready in case the participant’s infusion is held and they have to mail back the completed PROs
 - c. Prefill out the PRO questions with participants answers from the last time
 - d. Both a & b

Answer: D. Both a & b

3. A study participant comes in for an infusion and starts to complete their PROs, which are due within the next two weeks. After seeing the physician, the infusion is held for this cycle. Which is the best way to handle this situation?
 - a. Wait until the next cycle in four weeks to collect the remaining PROs
 - b. Meet the participant before they leave, check the PROs they have completed and see if they can stay for a few more minutes to complete the remaining questions
 - c. Mark the remaining PROs as missing
 - d. Either a or c

Answer: D. Either a or c