SWOG Quality Assurance Webinar: Patient-Reported Outcomes

Bringing the Patient Voice into SWOG Clinical Trials: Best Practices for Patient-Reported Outcomes

Presenters:
– Katie Arnold, MS, Statistical Research Associate, Fred Hutchinson Cancer Center
– Salene Jones, PhD, MA, LP, Associate Professor, Fred Hutchinson Cancer Center
– Monica Yee, CCRP, Program Director, Data Management, Cancer Research And Biostatistics

Disclosure to Webinar Participants

- To participate in the Live Webinar CEU course, participants must have:
  - Already enrolled to the Quality Assurance Webinar September 11, 2026 – Patient-Reported Outcomes course in ExpertusOne.
  - Joined the webinar via their individual login. If you are attending as a group in a conference room, only the person that logged into the ExpertusOne system can obtain CEUs for participation in the live webinar.
- To receive 1.0 CEU contact hour the participant must:
  - **Attend the entire educational activity and then complete and submit the post-activity evaluation via the Survey Monkey link that will be provided via Teams chat message at the end of the webinar.**
  - CEU certificates for webinar participation will be batch-issued, approximately 1 week after the webinar, to all attendees who completed the post-activity evaluation.

    Note: For site staff who were unable to attend the entire webinar: 1 hour CEU will also be offered via review of the webinar recording and completion of the post-course evaluation within a forthcoming SWOG: Patient-Reported Outcomes course posted in the CTSU CLASS learning management system. When available in CLASS, the link to the post-meeting enduring course will be accessible from: SWOG Quality Assurance Live Webinar Series and the online CTSU CLASS catalog. The Disclosure for Enduring Course Participants will be posted under the "Resources" tab of the forthcoming course in CLASS.
- There is no relevant financial relationships with ineligible companies for those with the ability to control content of this activity exist.
- This nursing continuing professional development activity was approved by the Georgia Nurses Association, an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation.
- Georgia Nurses Association Approval Code: Webinar: 203750220 | Enduring Posting (in CLASS): 203750223.
- The expiration date of this activity is September 1, 2028.

Agenda / Overview

- Part 1: The Science of PROs

  Presented by:

  – Salene Jones, PhD, MA, LP, Associate Professor, Fred Hutchinson Cancer Center

- Part 2: Best Practices for Collecting PRO Data

  Presented by:

  – Monica Yee, CCRP, Program Director, Data Management, Cancer Research And Biostatistics

- Part 3: Survey feedback

  Presented by:

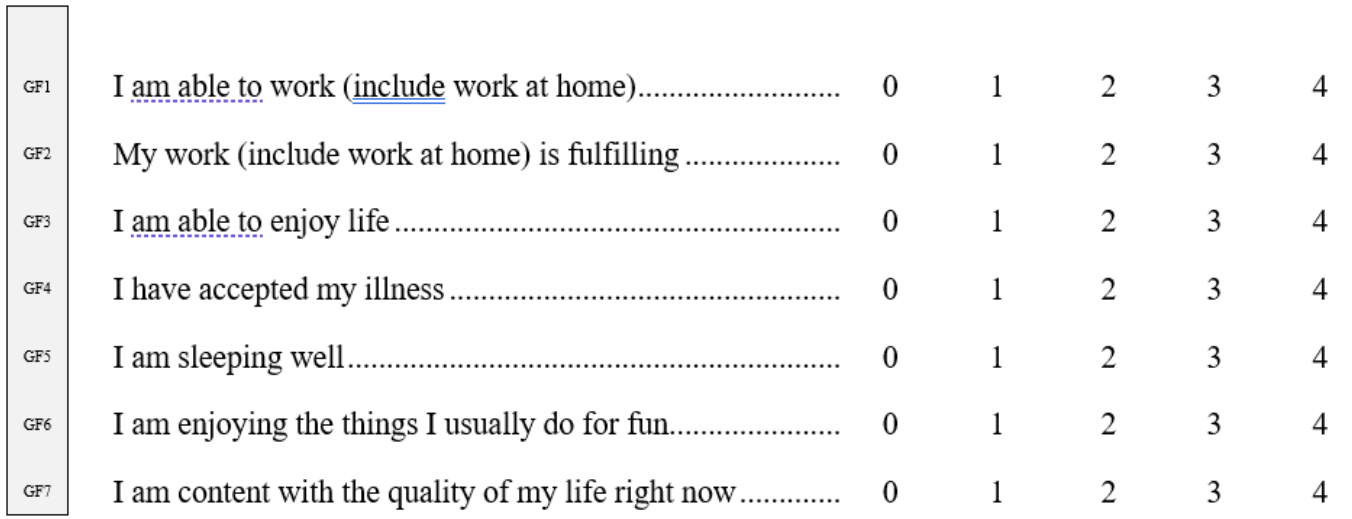
  – Katie Arnold, MS, Statistical Research Associate, Fred Hutchinson Cancer Center

Learning Goals

- How PROs support SWOG research
- Best practices for assessing and documenting PROs
- Problems to avoid

What is a PRO?

- Patient-reported outcome
- Report of the patient's symptoms, function or other aspect of health directly from the patient without interpretation by another person



	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GF1	I am able to work (include work at home).....	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well.....	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun.....	0	1	2	3	4
GF7	I am content with the quality of my life right now.....	0	1	2	3	4

Types of PRO Instruments

- Different populations, different PROs
  - General
    - Tells us how patients are doing compared to people without cancer
    - PROMIS Global Health
  - Cancer-specific
    - Tells us how patients are doing compared to other people with cancer
    - FACT-G (general cancer population) or FACT-Lymphoma (non-Hodgkin lymphoma patients)

Types of PRO Assessments (1)

- Single item
  - One question characterizes a symptom, type of function or aspect of health
  - Example: PRO-CTCAE

- Multi-item
  - Multiple questions characterize the same symptom, type of function or aspect of health
  - More reliable than single item measures
  - Example: FACT-G

Types of PRO Assessments (2)

- Using multiple PROs for the same symptom or aspect of health
  - Usually measuring the primary outcome of the study
  - Need to fully describe all dimensions of the symptom / aspect of health
  - Example: Pain
    - Pain intensity versus pain interference versus pain behaviors

The patient perspective in cancer research (1)

Patient quality of life can inform studies whose objectives are assessing the similarity of two therapies

- Study designs: equivalence, non-inferiority or de-escalation
- Do the treatments or doses have the same effect on cancer progression, recurrence or mortality?
- Are the patients' experiences (PROs) better or worse between treatments or doses?

The bottom line:
PROs can show whether a reduced dose or a different treatment could mean better quality of life for patients without compromising cancer control

The patient perspective in cancer research (2)

PROs capture treatment symptoms/side effects

- Characterize type (e.g. GI, fatigue, pain), frequency and severity
- Allows for development of treatments for specific side effects
- Gives opportunity to learn how to prevent side effects

The bottom line:
Through PROs, past patients help future patients know what side effects to expect, empowering them to prepare ahead of time.

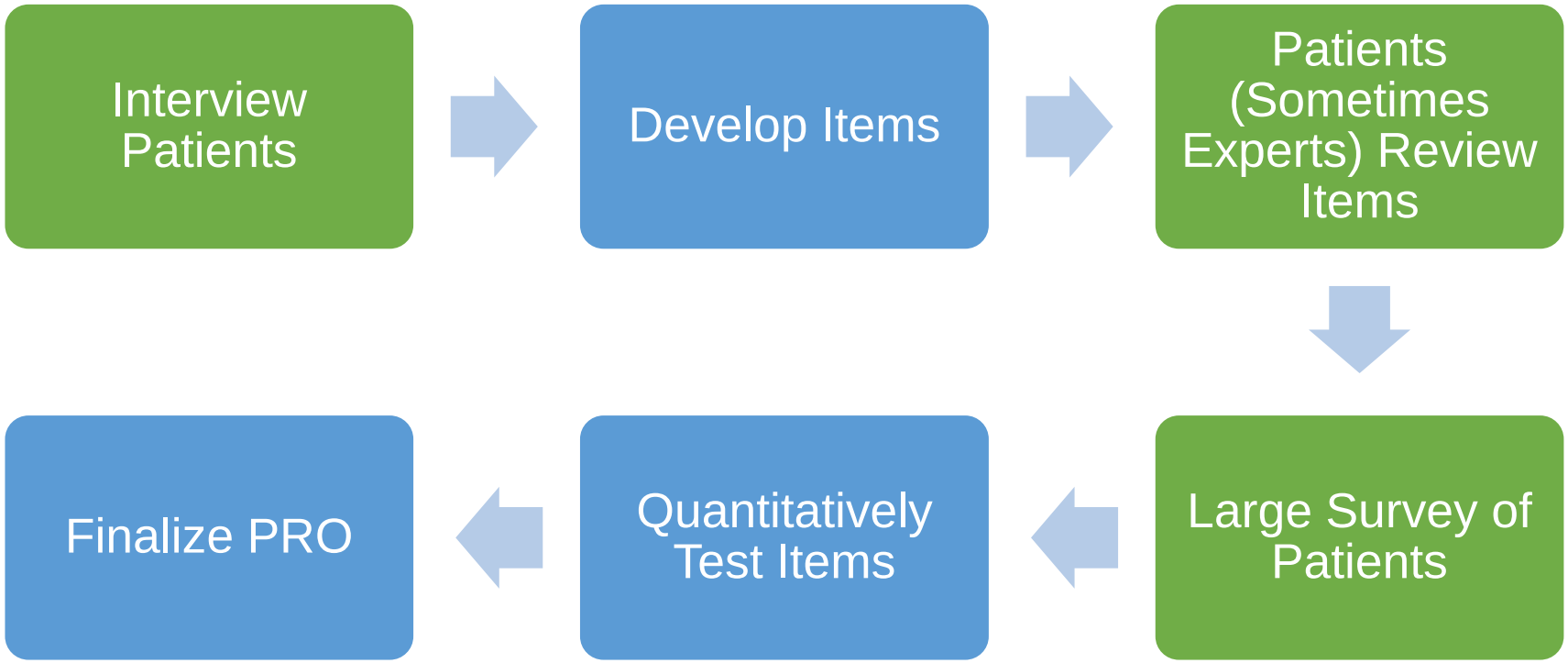
The patient perspective in cancer research (3)

Sometimes the lack of a symptom is the point

- PROs measure differences in symptoms (or lack of symptoms) between treatments → Need an unbiased comparison
- Baseline: shows which symptoms aren't (yet) present
- Follow-up: shows who develops symptoms while on treatment (or not)
- This is why patients without symptoms should complete PROs

The bottom line:
Patients who have no or minimal side effects are critical contributors to PRO-related research.

PRO validation process



How validated PROs are developed

- Validation:
  - Tries to capture as many patients' perspectives as possible
  - Is usually for a specific patient group
  - Is iterative; measures can be updated
  - Validated for each individual language
- Different patients use different words to describe their experience
  - Example: fatigue vs. tired vs. sleepy vs. exhausted
  - Need to capture as many patients' experiences as possible
  - This is why questions might seem similar

PRO Translations

- Validated PROs must use validated translations – long process
- SWOG obtains a language-specific license for each PRO
- License terms generally cover future translations
- PROs must have CIRB approval, including translations

What this means for you:

- PROs may not be translated, formally or using a translator or family member
- Participants who cannot read or write in one of the translations provided for the specific protocol cannot participate in PROs
- Verify eligibility criteria for allowed PRO languages (Protocol Section 5)

Question #1

Which of the following is <u>not</u> 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

Question #1 answer

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Best practices: PRO study development

- Use appropriate instruments
- Choose appropriate assessment times
  - Clinical vs PRO objectives may differ
- Select best format (paper vs electronic)
- Reduce patient and site burden
- Incorporate feedback from key players:
  - Study Chair
  - PRO Core
  - Patient Advocate
  - ORP representative

Best practices: With the patient (1)

- Verify correct instrument(s) / time point before the visit
- Choose the optimal time to administer (during the visit, before, after, at home and mailed back)
- Review instructions for completion of each form with patient
- Review the questionnaire responses before the patient leaves

Best practices: With the patient (2)

- Providing assistance

Do

- Allow another person to read the items and responses to the patient, if appropriate
- Provide special pens for patients with neuropathy
- Use answer/response cards if the patient has trouble speaking

Don’t

- Define the items in a lot of detail
- Allow others to answer for the patient

Best practices: Documentation

- Indicate study time point and/or Date of Completion on questionnaires
- Record how it was administered (in person, telephone interview, telehealth, etc.)
- Retain an original record of responses (e.g., a record from a telephone interview)
  - Do not enter directly into Rave (e.g., if giving a telephone interview), as there will be no documentation

Question #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 the 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 participant's answers from the last time
d) Both a and b

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Common problems: Time

Challenge	Potential Solution
Administration timing	Refer to the windows specified in the protocol
Time needed during the visit	Plan ahead so participant has time to complete PROs during the visit.
Pre-registration time point done after registration **QA**	Pre-registration must be done after consent and before registration
Not following protocol time points due to: **QA** • Delayed cycles • Progression • Off treatment	Check the protocol for specified time points - if in doubt, contact the Data Coordinator

Common problems: Completion

Challenge	Potential Solution
Incomplete questionnaires	Check the PROs before the patient leaves - it can be easy to miss a question (or more)
Missed assessment **QA**	Check the protocol
Participant reluctance Too many questionnaires or pages Questionnaires are too long Questions seem redundant	Need to read the situation for the best way to mitigate this. Sharing how patient perspective helps future patients may be useful.

Common problems: Documentation

Challenge	Potential Solution
Not checking the time point box or not filling out the Date of Completion **QA**	Fill those two parts out before handing the questionnaire to the patient
Missing documentation of how it was completed if not by patient directly **QA**	Note how patient completed the PRO if not totally self-administered: • Was it administered via telephone interview? • Did someone read the answers to patient and record them? • Any other situation where the patient didn't read and mark their own answers?

Question #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 minutes to complete the remaining questions
c) Mark the remaining PROs as missing
d) Either a or c

Question #3 answer

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You have spoken!

Survey feedback!

Survey audience

- Who: Lead ORPs (138) and the ORP Listserv (~1100)
  - 123 respondents, mostly from site staff
- Why: we wanted to address topics and questions that are important to you
- When: survey distributed 6/23/26 – 7/10/26

Survey questions

- What challenges do you encounter when collecting PRO data from patients on SWOG trials?
- What aspects of PRO data collection in SWOG trials would you like to learn more about?
- Please let us know anything that works well when you are collecting PRO data for SWOG trials.

Top challenges you reported

The challenge…	% Respondents
Patients do not want to complete PROs	41%
Protocol is unclear about administering PROs*	36%
Collecting PRO data takes too much time	26%
Patients are often too sick to complete PROs	22%
Entering PRO data takes too much time	21%
PROs are a lower priority than other parts of the trial	21%

* SWOG will consider changes based on this feedback

What you said about: Paper vs ePRO

- Paper is overwhelmingly preferred over Medidata ePRO
- Electronic administration (app, email) is a valuable tool that helps avoid the pitfalls of scheduling an in-person visit for PROs

- SWOG is considering REDCap for future studies
- Preferences may change with use of REDCap

What you said about: Resources

- Lack of time to administer PROs
  - Requires advance planning and coordination
  - Unique considerations for each site
- Lack of adequate funding
  - Impacts staffing volume and available staff time
- Lack of training

PRO training available on SWOG's learning management system at https://swog.expertusone.cloud/learner/swog/:

- Patient Reported Outcomes-Part of the SWOG Clinical Trials Training Course-CTTC
- Comprehensive Overview of Patient Reported Outcomes

What you said about:
Reasons participants may not complete PROs

- Burdened by treatment and side effects
- May not have the time to complete the questionnaires
- May be hesitant to say how poorly they feel
- May not see the value in completing PROs if they feel good
- May experience paperwork fatigue

What you said about:
How you manage PROs

- When you administer PROs in relation to the study visit
- How you manage PRO administration
- How you communicate with the participant about PROs
- Helpful things to share with the participant

A summary of your feedback will be posted with the webinar materials

What you said about: PROs in the protocol

- Make Section 15 the primary site-centric PRO resource in the protocol
- Add a specific PRO calendar to Section 15
- When appropriate, align PRO administration with clinical visits
- Make PRO administration windows wider
- Organize the PRO packets on CTSU by language and time point, as appropriate

A summary of the possible changes SWOG may make will be posted with the webinar materials

Resources

Handouts:

- Survey Feedback on PROs in SWOG Trials: Peer-to-peer Feedback
- Survey Feedback on PROs in SWOG Trials: Potential changes SWOG will consider

Training Courses:

- Patient Reported Outcomes-Part of the SWOG Clinical Trials Training Course-CTTC
- Comprehensive Overview of Patient Reported Outcomes

Open Forum Discussion – Questions and Answers

We want your input!

1. What are your ideas for reports to enhance timely PRO administration?
2. Should the paper questionnaires completed by the participants have a place for participant initials and date?
    - If so, where should that be located on the page (header, footer, lower right corner, etc.)?
    - How does your site manage this currently?
3. Have you noticed PRO-related issues for a specific study?
    - If so, please provide the study ID and describe the problem.

Please email your responses to cancercontrolquestion@crab.org

Post-Course Evaluation

- To receive 1.0 CEU contact hour participants must:
  - **Have attended the entire educational activity and**
  - **Complete and submit the post activity-evaluation via the Survey Monkey link below (and in the Teams chat screen)**
- We will keep the webinar open, so that you may complete the survey after a few brief announcements.
- CEU certificates for webinar participation will be batch-issued, approximately 1 week after the webinar (by 9/21/2026), to all attendees who have **completed the post-activity evaluation by next Friday 9/18/2026.**

  https://www.surveymonkey.com/r/TMP6ZZK

Prior QA Webinars Accessible for Review

Previous Webinars and Upcoming Webinar Information is posted at:

SWOG Quality Assurance Live Webinar Series | SWOG

All enduring courses are posted via CTSU CLASS

CEU Courses:

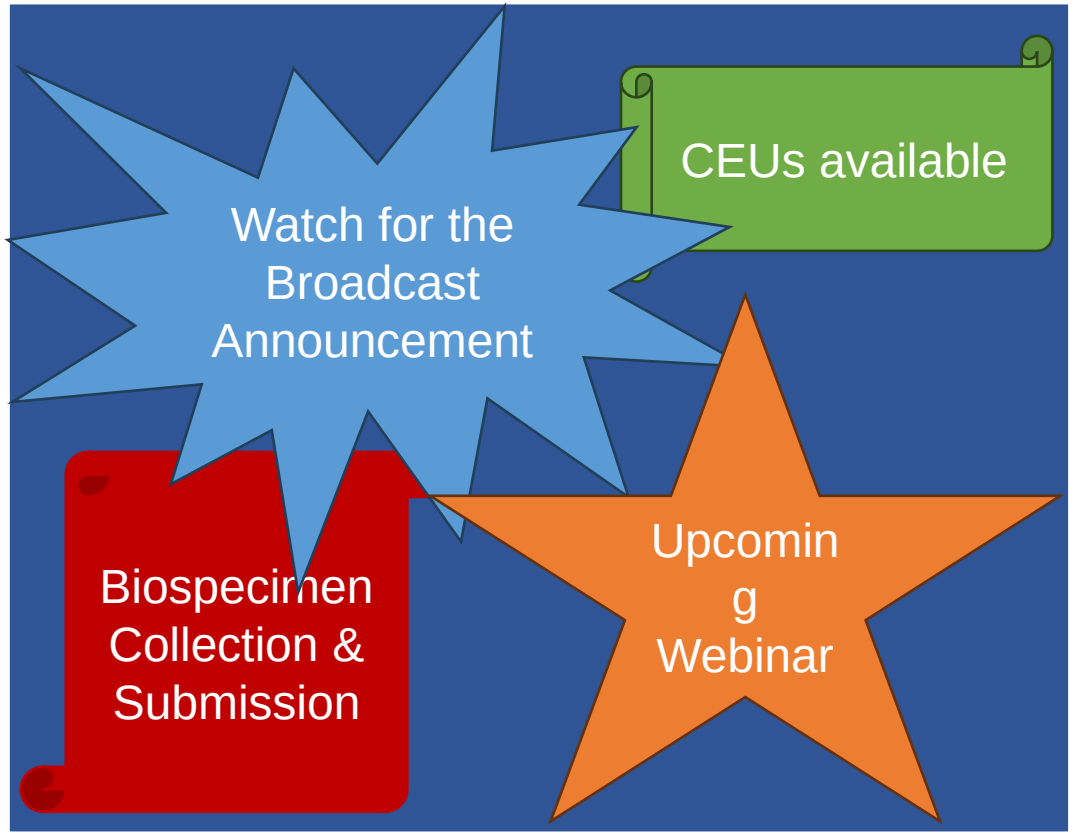
- **Safeguarding the Science: Best Practices for Investigational Drug Documentation and Management** (1 contact hour)
- **From the Ground Up: Implementing QA at the Site Level** (1 contact hour)
- **Navigating Adverse Events: What's New in CTCAE v6** (1 contact hour)
- **Biospecimen Collection and Submission** (1 contact hour)
- **Cytogenetics** (1 contact hour)
- **Serious Adverse Event Reporting & Updates** (1 contact hour)

CEU Courses Expiring Soon:

- **Disease Assessment in Solid Tumors**
  1.0 contact hour; CEU Expiration: 12/6/26.
  Last Day to Enroll to CLASS course: 12/5/26;
  Last day to Complete for CEU credit: 12/6/26

Non-CEU Courses posted in CLASS:

- **Research Protocol Deviations vs Deficiencies**
- **Best Practices for Informed Consent**
- **Adverse Event Reporting**
- **SWOG Audits: Preparing for Success and Audit Process**
- **How to Develop a CAPA Plan**



Upcoming QA Live Webinar

Informed Consent Process Considerations

~Presented by:

To be Announced

Tentatively

Friday, December 11, 2026

12:00 PM Eastern Time

Registration information will be distributed via:

- SWOG Broadcast Emails,
- CTSU Broadcast Emails, and
- Posted at: **SWOG Quality Assurance Live Webinar Series**

This activity will be submitted to the Georgia Nurses Association for approval to award contact hours. Georgia Nurses Association is accredited as an approver of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation.

Thank you

Post-Course Evaluation, accessible from:

https://www.surveymonkey.com/r/TMP6ZZK