

Patient-Reported Outcome (PRO) Research in SWOG Clinical Trials

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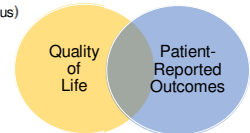
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What are Participant-Reported Outcomes (PROs)?

- Direct self-report by a study participant (patient, caregiver, physician)
 - Anything the participant reports about themselves
- Sometimes called surveys or questionnaires
- Status of health, quality of life, emotions, behaviors or functional status associated with health care, study treatment or intervention
 - Health-related quality of life (including functional status)
 - Symptoms and symptom burden (e.g., pain, fatigue)
 - Health behaviors (e.g., smoking, diet, exercise)



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Importance of PROs

- Cancer treatment or interventions can impact several aspects of life
- **Clinical data** is based on physician/clinician observations, lab tests, etc. (objective data)
 - Not all aspects of a person's health can be quantified by clinical observation or through testing
 - Clinician observation compares a patient experience to other patients while a PRO compares a patient's current experience to their prior experience or ideal state
 - PROs provide a more complete picture
- **PROs** reflect the participant perspective (subjective data as in the subject/participant is reporting)
 - Symptoms, concerns, functioning
- Reporting by participants may lead to improved communication, satisfaction and symptom management and identify treatments that maximize quantity and quality of life



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Why PROs? An example...

Randomized trial - Treatment A vs Treatment B
Participants complete PRO questionnaire measuring how bothersome treatment side effects are



Clinical Outcome Data

- Treatments equally effective
- Different side effects
- Similar toxicity grades

Patient-Reported Outcomes (PRO)

- Treatment A: more bothersome side effects
- Treatment B: **less bothersome side effects**
- Clear difference in patient experience

PROs can differentiate treatments → Treatment B likely to be the treatment of choice

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PRO Data Collection

- Instruments/Questionnaires/Surveys
 - Used in both treatment and cancer control studies
 - Evaluate outcomes from the study participant's perspective
 - Without interpretation by a clinician or anyone else
- Instrument Integrity
 - Validated: Statistically shown that an instrument is measuring what it intends to measure
 - Non-validated: For study-specific measures (a validated instrument is not always available for a measure)
- Balance
 - Collect necessary data while limiting burden on participant and site staff



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PRO Oversight: The SWOG PRO Core

- Scientific oversight and input to PRO design
 - A group of SWOG clinicians, statisticians, data and protocol staff
 - Review new PRO proposals
 - Provide guidance to study chairs on PRO objectives, instruments, timepoints and participant burden
 - Manage/advise on resources for PRO study support
- Oversee logistics of managing PRO for a study
 - Protocol development
 - Seek permissions for validated instruments
 - Study forms build
 - Oversight for data analysis



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What studies are PROs in?

- Treatment studies: Secondary, PRO or additional study objectives
 - Breast: S2206, S2212 Lung: S1827, S2414
 - Gastrointestinal: S2303, S2433 Lymphoma: S1918, S2114, S2207
 - Genitourinary: S1802, S2427 Myeloma: S1803, S2209, S2213
 - Leukemia: S1925
- Cancer control studies: Primary and secondary study objectives
 - S2408: Palliative Care
 - S1904: Prevention, Screening and Surveillance
 - S2010, S2013, S2205: Symptom Management and Survivorship
 - S1703, S1912CD, S2108CD, S2417CD: Cancer Care Delivery

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Some Studies Have Unique PROs

- Not just for study participants
 - Caregivers, family members and physicians may complete instruments specific to themselves -- sometimes called ClinPROs (clinician-reported outcomes) or ObsPROs (observer-reported outcomes)
- Not just for health
 - Can cover any aspect of the participant experience

Examples:

- Physician perspective on whether participant received genome-informed therapy, experience with genomic tumor testing (S2108CD)
- Caregiver perspective on financial situation (S1912CD)

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PRO-CTCAEs

NCI Common Terminology Criteria for Adverse Events (CTCAEs)

- Participant-reported counterpart to clinician-assessed adverse events (AEs)
- Included in many treatment studies
- PRO-CTCAE items are study-specific
- Items selected are most relevant to the study
- Participant report of AEs or symptoms
- Collected at same time points as AEs

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Your Role in PRO Research is Critical (1)

- You are the primary for quality PRO data collection and submission
- Complete training before administering questionnaires
 - SWOG PRO Training module (in CLASS in CTSU learning management system)
 - Medidata ePRO Training module (S2013 only)
- Consider how to navigate potential participant issues or challenges
 - Refer to the protocol for options

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Your Role in PRO Research is Critical (2)

- Be familiar with the PROs for each study
 - Explain/review forms and instructions with participant prior to first time completion
 - Perform quality control of form after participant completion and before submitting
 - Submit timely data per protocol timelines
 - If ePRO (S2013), understand App set up process for the site and each participant
- Know where to find questionnaires
 - On CTSU.org → Protocol → Documents → CIRB Approved Documents
 - Provide a copy of the questionnaires to each participant

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The Protocol as a Resource

- Target timepoints and windows for administration
 - Timing based on study registration date
 - Study-specific objectives, details and instructions
- Methods of PRO collection and submission
 - Paper forms completed by participant in person then submitted by site staff in Rave
 - Electronic completion by participant on ePRO app on personal device (an option on S2013)
 - Collection of data from participant by a study collaborator (e.g. on some cancer control studies)

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Slide 8

M1 Any other examples of non-ppt PROs?


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Slide 9


M1 Elevate to first level bullets

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The SWOG Protocol as Your PRO Resource



- **Section 5** – Eligibility
- **Section 7** – Treatment Plan
 - Follow-up duration and requirements for PRO defined
- **Section 9** – Study Calendar
 - Time points for PRO administration
- **Section 13** – Registration Guidelines (If applicable, S2013 ePRO information)
 - Site instructions for ePRO Patient Cloud registration for each patient after study registration
 - Patient instructions for the ePRO Patient Cloud
 - Medidata eLearning requirement described
- **Section 14** – Data Submission
 - What forms are due when
- **Section 15** – Special Instructions
 - Instructions and timing for administration of questionnaires
 - Link to PRO training in CLASS (on CTSU)
- **Section 18** – Appendix
 - Description of objectives, background, instruments, etc.

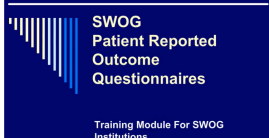



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SWOG PRO Training Module

- For research staff involved in PRO data collection and submission
- Describes the “what, why and how” of administering PROs to participants
- 20 minutes
- In CLASS in the CTSU learning management system
- Note: If ePRO is option for a trial (e.g., S2013), also complete Medidata eLearning for ePRO
 - See Section 13 of the protocol

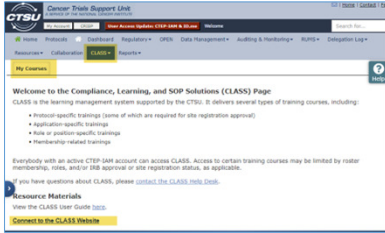




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PRO Training: CLASS on CTSU.org

- Log on to www.ctsu.org with ID.me credentials
- Go to **CLASS** in menu bar → **My Courses** → **Connect to the CLASS Website**
- Navigate to the PRO training
- Completion certificate provided
- For questions contact the Help Desk at: CLASSHelpDesk@westat.com



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Thank you!

Questions? Contact: cancercontrolquestion@crab.org

Thank you for your effort on this critical aspect of SWOG clinical trials!

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