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

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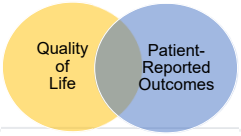
What are Patient-Reported Outcomes (PROs)?

- Direct self-report by a study patient/participant
- Status of health, quality of life, 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)



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 participant health can be quantified by clinical observation or through testing
  - PROs provide a more complete picture
- PROs reflect the participant perspective (subjective data)
  - Symptoms, concerns, functioning
- Reporting by participants may lead to improved communication, satisfaction and symptom management

PRO Data Collection

- Instruments/Questionnaires
  - Incorporated in some treatment and most cancer control studies
  - Evaluate health outcomes from the study particpant's perspective
    - Quality of life, functional status, behaviors
    - Without interpretation by a clinician or anyone else
- Instrument types
  - Validated: A process to establish that an instrument is measuring what it is intended to
  - Other, study-specific: Monitor participant satisfaction and feasibility
- Balance
  - Collect necessary data, limit burden, and conduct a feasible study

PRO Oversight: The SWOG PRO Core

- Scientific oversight and input to PRO design
  - A group of SWOG clinicians, statisticians, data and protocol staff
  - Develop a process for PROs
  - Review new PRO proposals
  - Provide guidance to study chairs on PRO objectives, instruments, timepoints
  - 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
  - Monitor data submitted

What types of studies are PROs in?

- PROs may be **integral** (inherent to the design from the onset) or **non-integral** (added information but not informing primary inference)
- Included in many treatment studies as secondary, PRO or additional objectives

Breast: S2206, S2212	Lung: S1827, S2414
Gastrointestinal: S2303	Lymphoma: S1918, S2207
Genitourinary: S1802	Myeloma: S1803, S2209, S2213
Leukemia: S1925	

- PROs are primary outcomes in some cancer control studies
  - Bowel Function Instrument – S1820
  - EORTC QLQ-CIPN 20 – S2205

Some Studies Have Unique PROs

- Not just for study participants
  - Physicians, caregivers and family members may complete instruments specific to themselves
- 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)

The Protocol as a Resource

- Study-specific details about PRO administration
  - Where to find questionnaires
    - On CTSU.org → Protocol → Documents → CIRB Approved Documents
  - 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)

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
  - Participant completed form
  - Site staff enters responses in Rave

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.

Your Role in PRO Research is Critical

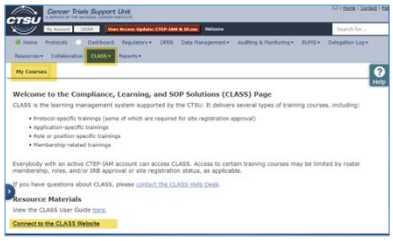
- You are the primary for quality PRO data collection and submission
- Complete training before administering questionnaires
  - SWOG PRO Training module (in CLASS in CTSU learning management system)
  - Medidata ePRO Training module (S2013 only)
- Be familiar with the PROs for each study
  - Explain/review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

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

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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Questions?

Contact: cancercontrolquestion@crab.org

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

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