



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

Monica Yee, CCRP  
Program Director, Data Management  
Cancer Control and Prevention Studies  
SWOG Statistics and Data Management Center (SDMC)



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## Agenda

- What?
- Why?
- Your role
- Resources
- Training



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## What are PROs?

- **Instruments**
  - Evaluate functioning and health outcomes
  - From the patient's perspective
- **Incorporated**
  - In some treatment and cancer control studies
- **Reported by the patient**
  - Health and overall status
  - Without interpretation by a clinician



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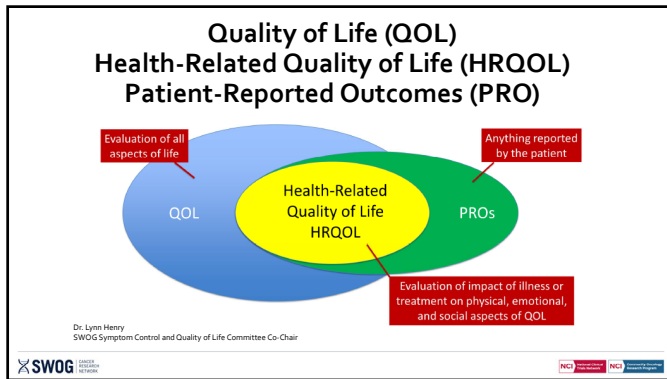
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### Why PROs?

- Captures **critical information** for SWOG trials
- Outcomes **reported by patients** can be different than those reported by clinicians and researchers
- Evidence that **side effects are underestimated** by clinicians (Basch, 2006)
- Reporting by patients may lead to **improved communication, satisfaction and symptom management**

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### Your Role in PRO Research is Critical

- You are the primary for quality PRO data collection and submission
- **Be prepared**
- Complete the online SWOG PRO Training module before administering questionnaires on any trial
- Familiarize yourself with the PROs and process for each study
  - Perform quality control of data after patient completion and prior to submission
    - Avoid "garbage in, garbage out"
  - Submit data in a timely fashion
- Consider how you would navigate any potential patient issues or barriers
  - Refer to the protocol for options

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## The Protocol as a Resource



- **Study-specific details about PRO administration**
  - Data collection forms
    - Locate the forms in CTSU → CIRB Approved Documents
  - Target timepoints and windows for administration
  - Study-specific details and instructions
  - Mode of collection
    - Hard copy forms completed by patient in person then submitted by site staff in Rave
    - Electronic completion by patients via ePRO app on personal device (an option on S2013)
    - Collection of data by study collaborator by phone (e.g. Cancer Control studies)

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## The SWOG Protocol as Your PRO Resource



- **Section 5** – Eligibility
- **Section 7** – Treatment Plan
  - Follow-up duration defined
- **Section 9** – Study Calendar
  - Timepoints for administration
- **Section 14** – Data Submission
  - What forms are due when
- **Section 15** – Special Instructions
  - Instructions for administration of instruments
- **Section 18** – Appendix
  - Description of objectives, background, instruments, etc.

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## SWOG PRO Training Module



- For all research staff involved in PRO data collection and submission
- Describes the "what," "why" and details of the "how" of PRO administration to patients
- 20 minutes
- Located at [www.swog.org](http://www.swog.org)
- Clinical Trials → Protocol Workbench → Training → Patient-Reported Outcome Questionnaires Training Program
- Review training as many times as you like; great for a refresher

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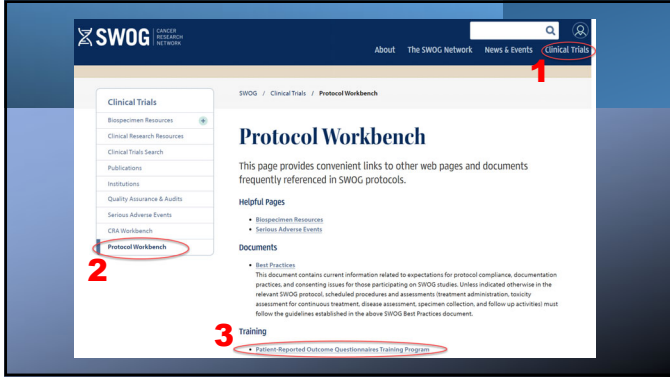
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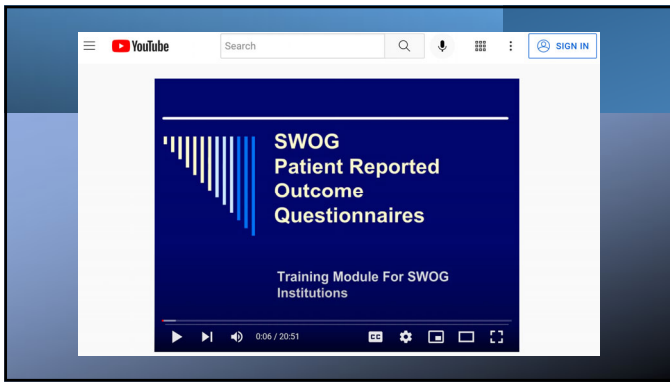
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**Questions?**

Contact:  
[cancercontrolquestion@crab.org](mailto:cancercontrolquestion@crab.org)

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

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