NRG ONCOLOGY

Advancing Research. Improving Lives.™

Incorporating PROs Into Clinical Practice

NRG CRA and CTN Protocol Committee & NRG Quality Assurance

October 2025

NCI National Clinical Trials Network
a National Cancer Institute program

NCI Community Oncology Research Program
A program of the National Cancer Institute of the National Institutes of Health

Learning Objectives

- Definition of Patient Reported Outcomes (PRO)
- Significance of PROs within NRG Research
- Applying PROs to Practice

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Interactive Question

What are Patient Reported Outcomes (PROs)?

a) Measure of patient's health status directly from the patient

b) Measure of disease progression

c) Measure of disease metastasis

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What are Patient Reported Outcomes (PROs)?

- Patient reported outcomes (PROs) are measures of a patient's health status as reported directly from the patient without added interpretation by a healthcare worker or a pain scale.
- Quality of Life (QOL) assessments are a common type of PRO assessment.
- Popular PROs that are collected in research include:
    - Symptoms
    - Physical Functioning
    - Mental and Emotional Well-Being
    - Satisfaction With Care

What do PROs look like?

Support Documents		
1	Screening Script (version 05/01/25)	12-Jun-2025
2	Screening Script (version 05/01/25): Tracked	12-Jun-2025
3	Background Questionnaires Packet (version 05/01/25)	12-Jun-2025
4	Background Questionnaires Packet (version 05/01/25): Tracked	12-Jun-2025
5	QOL and Psychological Measures Questionnaire Packet	12-Jun-2025
6	QOL and Psychological Measures Questionnaire Packet: Tracked	12-Jun-2025
7	Work Productivity and Health Care Utilization Questionnaires Packet	12-Jun-2025
8	Work Productivity and Health Care Utilization Questionnaires Packet: Tracked	12-Jun-2025

medidata
PATIENT CLOUD

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Why Are PROs Important in Oncology Research?

- Cancer treatments may result in patients experiencing physical and psychosocial consequences that impact quality of health. Oncology patients verbally report **moderate** to **severe** symptoms to their clinicians **less than 5%** of the time.
- A health professional's assessments of outcomes are often assessed days or weeks **after** the patients have experienced their symptoms. As a result, clinicians may underestimate symptom severity and symptom impact on quality of health, daily functioning, and QOL.
- Utilizing PROs to meet study endpoints provides patient-centered and subjective data

Interactive Question

At your practice, do you notice that subjects are more compliant with:

a) Paper-based PROs
b) Electronic PROs (ePROs)
c) Equally Compliant

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Locating PROs in an NRG Protocol

PROs are usually listed in:

- Section 1, “**Objectives**”
- Section 4, “**Requirements for Study Entry, Treatment, and Follow-up**”
- Section 7, only if the only PRO is **PRO-CTCAE**
- Section 11, "**Special Studies"** (Non-Tissue)

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Interactive Question

Which of the following promotes PRO assessment compliance?

a) Provide calendar of expected assessment dates to the patient

b) Explain PROs and their importance to the health care team

c) Explain PROs and their importance to the patient during the consenting process

d) All the above

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Applying PROs to Clinic Practice

- Ensuring PRO compliance is an essential part of on study activities; non-compliance can significantly affect study outcomes
- PRO compliance is the responsibility of **everyone** on the research team, not just the patient
- The NRG Patient Centered Outcomes Research Committee (PCOR) and NRG Compliance Officers monitor PRO compliance
- Most NRG trials include PROs in study analysis even if the patients:
  - Do not initiate protocol therapy
  - Stop therapy early
  - Experience a cancer event on trial

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Interactive Question

My study subject is overdue to complete PROs electronically, but is on active hospice care, what should I do?

a) Submit a deviation for non-completion of PROs, document "not completed"

b) Call the patient or caregiver and have them complete the PROs as soon as possible

c) This is a nuanced issue that depends on several factors and requires thorough documentation to support PRO completion outcome

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PROs in the Hospice Setting

- If you're able to discuss a patient's wishes regarding PRO contact in advance it's ideal, but not always feasible or appropriate
- If a patient status is declining **before** hospice admission:
    - You can discuss options: complete study withdrawal, remaining on study for data collection requesting not to be contacted for PROs
    - In the hospital setting, you can follow records and see what their course of care outcome is to determine if it's appropriate/feasible to contact about due PROs; if you have a window, wait until patient is discharged as acute issues occurring can also cause significant changes in PRO answers that may be outliers or not best representations of patient status
    - If a patient cannot come into the clinic but is willing to have paper PROs mailed for mail-back or completion over the phone, this is a potential option
    - **Document the process and show supporting records**

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PROs in the Hospice Setting

- If a patient's status declines and they are **enrolled onto hospice**:
  - Follow your institutional guidelines; if your institution does not have guidelines, determine the best plan to maintain patient quality of life while also supporting integrity of data
- Always include supporting documentation about PRO completion or non-completion with supporting events and evidence if the patient is unable to complete them; DO NOT have a family member complete the PROs on behalf of the patient if they are of questionable cognitive status
- When a patient passes, remember to notify the study appropriately or document the appropriate forms that will cause the electronic alerts to complete PROs to cease

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Interactive Question

If a patient self-reports **fatigue** interfering with usual/daily activities **"VERY MUCH"** on the PRO-CTCAE and then during their physician's physical assessment, the patient reports they have a grade 1 fatigue, how should you address the discrepancy?

a) Use the in-person assessment (the investigator has the final decision)

b) Use the completed PRO-CTCAE answers (the subject's perception is the most important)

c) A combination of both in-person assessment and completed PROs with follow-up on discrepancies in reporting; may require further investigation/conversation with the patient, especially if it's related to a potential dose-limiting adverse event

PRO Tips

Clinics that utilize non-research clinical PROs for patient care:

- Ensure the patient understands the reasoning for completion of multiple research/non-research PROs, especially if there is overlap
- Encourage research PRO completion electronically (at home before visit if applicable) to decrease perceived "paperwork" burden
- Have the patient complete research PROs **before** clinic PROs to decrease potential for survey fatigue and non-compliance of research PROs by saving them until the end

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PRO Tips

- Protocols specify when PROs should be completed in relation to on study activities
- Ensure documentation of PRO completion timing in supporting documentation; if it's an ePRO, they will be time stamped.
- If a subject is non-compliant or completing ePROs out of window, you could utilize a tablet (some studies provide these) or patient phone to have them pull up and complete the ePROs at the clinic visit; research staff are also available to answer questions. Some patients may request contact in advance as a reminder (if allowable per protocol design).

Interactive Question

At your practice, what are the most common barriers to accurate PRO completion?

a) Patient non-compliance (overdue/non-completion)
b) Leaving questions blank/answering illegibly
c) IT issues - not receiving emails, can't locate PROs, losing their paper forms
d) Patients not understanding the questions (require explanations from staff)
e) Patients unable to complete without assistance (research staff/caregiver assistance required)
f) All the above

PRO Non-Compliance Issues

- Patient refused due to illness/symptom burden
- Patient refused for other reason
- Unable to contact patient
- Patient completing PRO out of study allowed window/timeframe
- Institutional error
- Tool not available in participant’s language
- Patient death
- Patient consent withdrawal

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Trials to Highlight: NRG-CC015

Table 1 for assessment timepoints

Section 7.4 PROS collected using VisionTree (VTOC) and study provided tablet to help increase compliance (participants can utilize their personal device)

Section 8 Primary endpoint: monitoring depressive symptoms

$25 electronic gift card per timepoint (4 total)

Table 1. Study overview and requirements for NRG-CC015

Required Steps/Assessments	Registration (Step 0)	Baseline assessment prior to intervention (T1)	Randomization (Step 1)	Intervention Delivery	Within 2 weeks post-intervention (T2)	3 months post-intervention (T3)	6 months post-intervention (T4)
Medical chart review for eligibility[a]	X						
Eligibility screening, requires verbal consent with screening assessment	X						
Written consent of eligible participants	X						
Participant Contact Information Form[b]	X						
Participant Completion of PROs[c]		X			X	X	X
Depression safety monitoring with PHQ-8[d]					X	X	X
Clinical Site notified to randomize participant			X				
Randomization: NRG SDMC notifies UCLA research staff about treatment assignment			X				
UCLA: Intervention Assignment Implemented				X			

a Demographic and medical and information including: age, diagnosis date and stage of disease, and cancer treatment (surgery, chemotherapy and/or radiation) and current endocrine therapy (yes/no) and other clinically relevant information will be collected by the site.
b The form will collect the participant's e-mail account, mailing address to send study information, and phone numbers.

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NRG Resources

Links to NRG resources

- NRG-PSC e-mail is the best way to contact us for more information about this presentation or other topics. NRG-PSC@nrgoncology.org
- PSC Newsletters written by the QC&C Subcommittees NRG > Home > News > Newsletters
- NRG is working really hard to make ourselves present on CLASS. We have about a dozen topics/modules in the works currently. The first round should be uploaded soon. Catalog | CLASS (Compliance, Learning, and SOP Solutions)

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THANK YOU!

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