

# Applying the PRO Findings in Practice: Guidance for Clinicians

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*Funded by the Patient-Centered Outcomes  
Research Institute and Genentech*

**PROTEUS**  
Patient-Reported Outcomes Tools:  
Engaging Users and Stakeholders

# The PROTEUS Consortium

Patient-Reported Outcome Tools:  
Engaging Users & Stakeholders

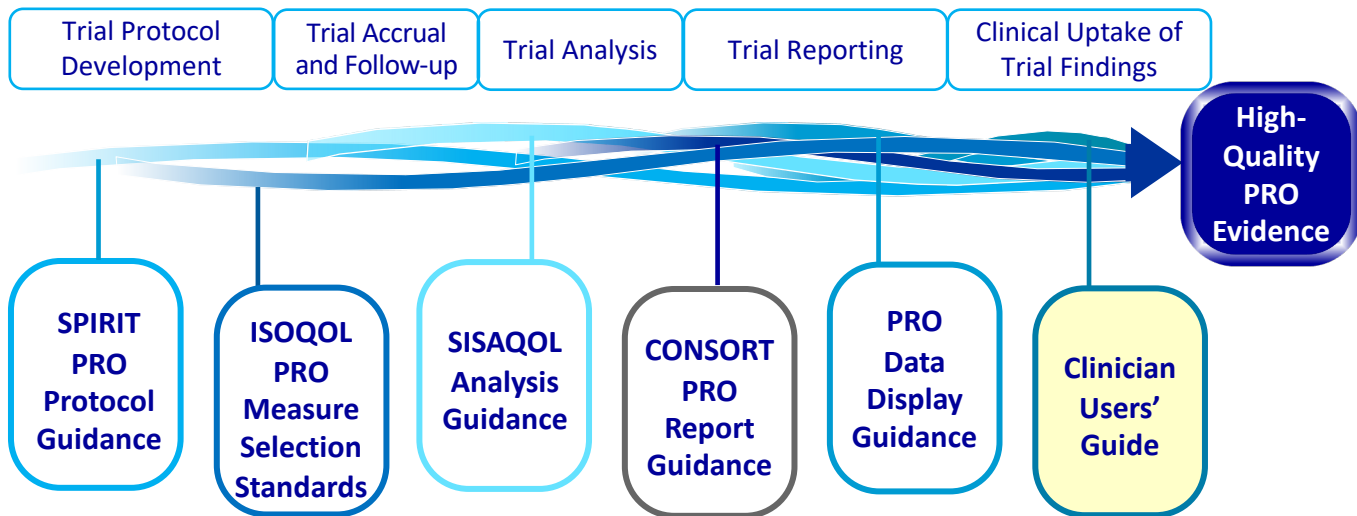
The logo for the PROTEUS Consortium. The word "PROTEUS" is written in a bold, dark blue, sans-serif font. The letters "T", "E", and "U" are partially overlaid by a graphic element consisting of several horizontal, wavy lines in shades of light blue and white, creating a sense of motion or a stylized wave. The entire logo is contained within a thin white rectangular border.

[TheProteusConsortium.org](http://TheProteusConsortium.org)

# Overview of Presentations

Introduction to PROs and PROTEUS

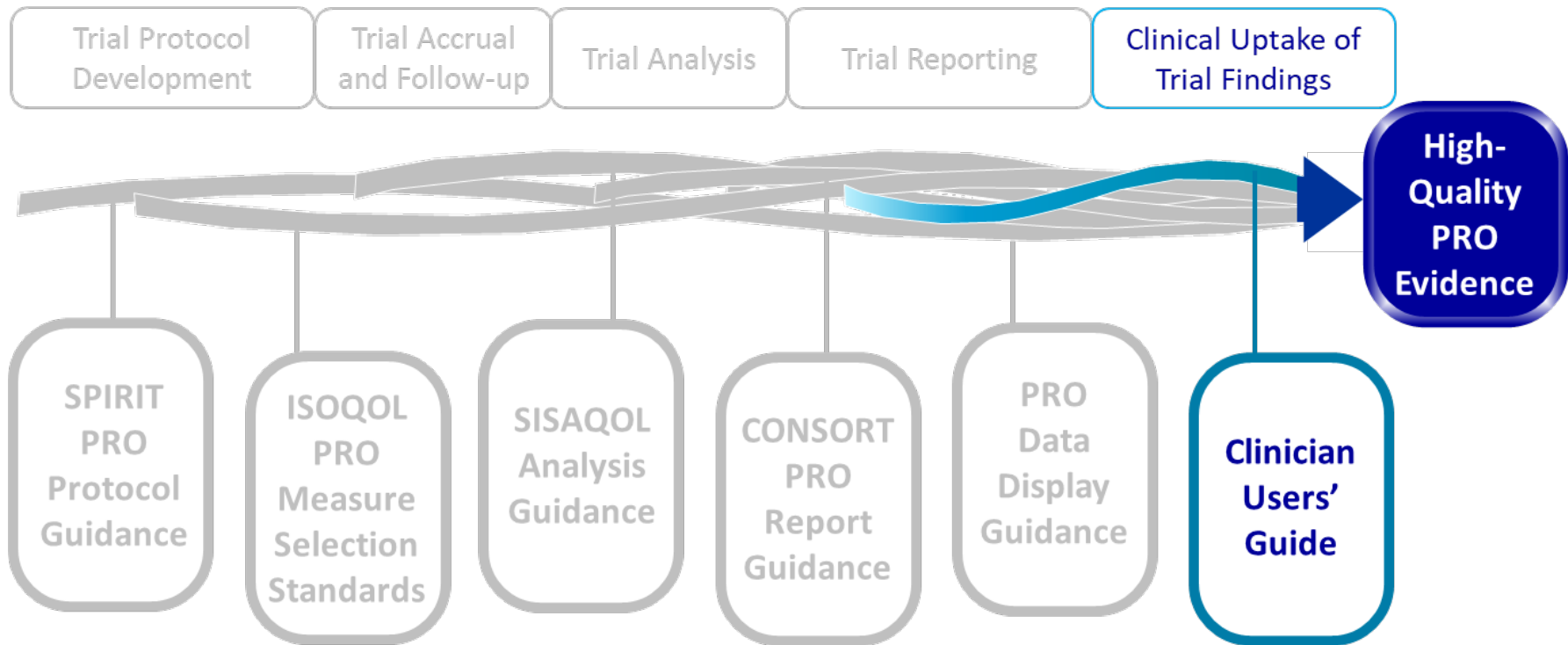
Introduction to the PROTEUS Tools



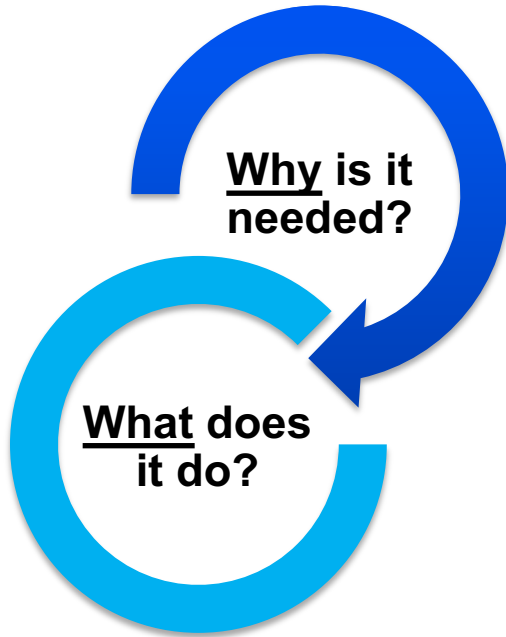
Overview of Tool Recommendations

How to Apply the Tools

# Applying the PRO Findings in Practice



# Applying PRO Findings in Practice



To help clinicians assess the quality of PRO research studies and determine whether findings are useful for clinical practice

Provides a checklist to evaluate the quality of studies that use PROs

# Applying the PRO Findings in Practice

## Clinician's Checklist for Reading and Using an Article About Patient-Reported Outcomes

Albert W. Wu, MD, MPH, FACP; Anna N. Bradford, PhD, MSW, LCSW;  
Vic Velanovich, MD; Mirjam A.G. Sprangers, PhD; Michael Brundage, MD, FRCP, MSc;  
and Claire Snyder, PhD

### Abstract

Clinicians need evidence-based medicine to help them make clinical decisions with their patients. For many health problems, the goal of treatment is to help the patient to function and feel better. To measure patient functioning, well-being, and symptoms, questionnaires referred to as patient-reported outcome (PRO) measures are often used. Clinicians are generally not trained in survey design, scale development, and questionnaire administration, making it difficult for them to interpret and effectively use PROs as clinical evidence. It is increasingly important that clinicians be able to understand and use outcomes measured from both the clinical and patient perspectives to inform their practice. We aim to provide a "Clinician's Checklist" to help practicing clinicians understand clinical research articles that include PROs so that the information can be used for decision making. This checklist provides an itemization of important areas for the reader to consider in evaluating research articles. We propose that clinicians consider 5 elements when reading a study using PROs: study design and PRO assessment strategy, PRO measure performance, validity of results, context of the findings, and generalizability to their own patient population. Patient-reported outcomes play an increasingly prominent role in clinical research and practice, and this trend has the potential to improve the patient-centeredness of care. Clinicians will need to understand how to use PROs to partner with patients and help them function and feel better. The proposed Clinician's Checklist can help clinicians systematically evaluate PRO studies by determining whether the study design was appropriate and whether the measurement approach was adequate and properly executed as well as by assisting in the interpretation and application of the results to a specific patient population.

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**Collaborators:** Albert W. WU, MD, FACP; Anna N. Bradford, PhD, MSW, LCSW; Vic Velanovich, MD; Mirjam A.G. Sprangers, PhD; Michael Brundage, MD, FRCP, MSc; and Claire Snyder, PhD

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# Why Is This Resource Needed?

- In order to use PRO results to inform patient care, clinicians need to be able to evaluate published literature that includes PROs
- Barriers to clinicians applying PRO findings in clinical practice include:
  - lack of education and training on measurement and interpretation of PROs
  - wide variety of PRO measures
  - variation in how PRO findings are reported in the literature



# Objective of this Resource

- **Purpose:** To help practicing clinicians apply results of clinical research studies that include PROs in their patient care
- **How?** By providing a brief **checklist** to help clinicians review published research studies that include PROs



# Methods

- Builds on guidelines published by Guyatt et al 1997
- Wu et al 2014, propose 5 key elements to consider when reading a published study using PROs:
  1. Assessment strategy & study design
  2. Performance of the PRO tool
  3. Validity of results
  4. Context of results
  5. Generalizability to one's own patient population
- Questions were formulated into a Clinician's Checklist to address each key element

## The Medical Literature

### Users' Guides to the Medical Literature

#### XII. How to Use Articles About Health-Related Quality of Life

Gordon H. Guyatt, MD, MSc; C. David Naylor, MD, MSc, DPhil; Elizabeth Juniper, MCSP, MSc; Daren K. Heyland, MD; Roman Jaeschke, MD, MSc; Deborah J. Cook, MD, MSc; for the Evidence-Based Medicine Working Group

##### CLINICAL SCENARIO

You are a physician following a 35-year-old man who has had active Crohn disease for 8 years. The symptoms were severe enough to require resectional surgery 4 years ago, and despite treatment with sulfasalazine and metronidazole, the patient has had active disease requiring oral steroids for the last 2 years. Repeated attempts to decrease the prednisone have failed, and the patient has required doses of greater than 15 mg per day to control symptoms. You are impressed by both the methods and re-

cent future morbidity, or make patients feel better. The first 2 of these 3 end points are relatively easy to measure. At least in part because of difficulty in measurement, clinicians have for many years been ready to substitute physiological or laboratory tests for the direct measurement of the third. In the last 20 years, however, clinicians have recognized the importance of direct measurement of how people are feeling and how they are able to function in daily activities. Investigators have developed increasingly sophisticated methods of

how the relative values of items and domains need to be established and how these values should be determined. Is it enough to know that both dyspnea and fatigue are important to people with lung disease, or does one need to establish their relative importance? If establishing their relative importance is necessary, which of the many available approaches should one use?

In this article, we take a simple approach. We use HRQL to refer to the health aspects of their lives that people, in general, value, and we are ready to

# Clinician's Checklist to Evaluate Studies Using PROs

## 1. Was the PRO assessment strategy appropriate?

a. PRO hypothesis stated?	A priori hypothesis explicit for PROs
b. PRO measures described?	PRO measures used, and timing/follow-up of subjects
c. PRO content appropriate?	<ul style="list-style-type: none"><li>• Investigators measured aspects of patients' lives that patients consider important</li><li>• PRO domains correspond to anticipated effects of disease and treatment</li><li>• All important aspects of patient-reported outcomes included</li></ul>

# Clinician's Checklist to Evaluate Studies Using PROs

## 2. Did they measure PROs effectively?

a. Evidence for reliability, validity?

The PRO instruments appear to work as intended; evidence of internal consistency and/or test-retest reliability, and construct validity are well established

b. Were missing data handled appropriately?

- Similar number of questionnaires completed by respondents in all treatment groups at every time point
- Missing data management strategy described
- Presence of data analysis plan for handling death, if frequent

# Clinician's Checklist to Evaluate Studies Using PROs

## 3. Should I believe the results?

### a. Internal validity

- Findings established; observed effects likely to be caused by intervention
- If non-treatment factors affect PRO, risk adjustment needed

# Clinician's Checklist to Evaluate Studies Using PROs

## 4. Were the results placed in a clinical context?

- |  |  |
|--|--|
| a. Was the clinical meaning of results explained?      | <ul style="list-style-type: none"><li>• Magnitude of effect on PROs described</li><li>• Clinical importance of observed differences in PRO scores demonstrated</li></ul>   |
| b. Will the results help me in caring for my patients? | <ul style="list-style-type: none"><li>• Benefits and harms recognized and reconciled, including potential trade-offs between quality and quantity of life</li><li>• Description of what a clinician should do with the results; study information helps clinicians communicate with patients about treatment options; applicability of group results to individual patient</li></ul> |

# Clinician's Checklist to Evaluate Studies Using PROs

## 5. Do the results apply to my patients?

a. External validity to clinician's practice

- Study population is similar enough to clinician's patient population to apply to practice

# Recap

- The quality of PRO research studies affects the usefulness of the resulting PRO findings for clinical decision making
  - The Clinician's Checklist can help clinicians to:
    - determine whether a PRO study was conducted with sufficient rigor for the results to be applied in practice
    - evaluate the relevance of PRO findings for their own patients and practice
  - If
    - ✓ PRO results are believable
    - ✓ PRO endpoints are relevant to the specific patient population
    - ✓ The magnitude of the results is clear
- The clinician will be in a stronger position to apply PRO findings in practice





# Further Reading

Wu A, Bradford A, Velanovich V, Sprangers M, Brundage M & Snyder C. Clinician's checklist for reading and using an article about patient-reported outcomes. *Mayo Clinic Proc.*89(5):653-661; 2014

Guyatt GH, Naylor CD, Juniper E, Heyland DK, Jaeschke R, Cook DJ. Users' guides to the medical literature, XII: how to use articles about health-related quality of life. Evidence-based Medicine Working Group. *JAMA.* 277(15):1232-1237; 1997

