

# Clinician Users' Guide for Evaluating Studies with PROs

Consideration	Explanation	Notes/ comments
<b>1. Was the PRO assessment strategy appropriate?</b>		
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?	Investigators measured aspects of patients' lives that patients consider important  PRO domains correspond to anticipated effects of disease and treatment  All important aspects of patient-reported outcomes included	
<b>2. Did they measure PRO effectively?</b>		
a. Evidence for reliability and validity?	The PRO instruments appear to work as intended: evidence of internal consistency and/or test retest reliability, and construct validity are cited or 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	
<b>3. Should I believe the results?</b>		
a. Internal validity	Findings established; observed effects likely to be caused by intervention  If nontreatment factors affect PRO, risk adjustment used	
<b>4. Were the results placed in clinical context?</b>		
a. Was clinical meaning of results explained?	Magnitude of effect on PROs described  Clinical importance of observed differences in PRO scores demonstrated	
b. Will the results help me in caring for my patients?	Benefits and harms recognized and reconciled, including potential trade-offs between quality and quantity of life  Description of what a clinician should do with the results; study information helps clinician communicate with patients about treatment options; applicability of group results to an individual patient.	
<b>5. Do the results apply to my patients?</b>		
a. External validity to clinician's practice	Study population is similar enough to clinician's patient population to apply to practice	