



# NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

# Patient-Centered Outcomes Core Toolkit

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## Background and Purpose

### BACKGROUND

[Patient-reported outcome](#) (PROs) measures provide an important means of gathering information directly from ePCT participants. PRO measures typically include information about symptoms, functioning, satisfaction with care or symptoms, adherence to prescribed medications or other therapy, and perceived value of treatment. As such, PROs can provide critical information about the patient experience, but they must be culturally and linguistically appropriate to be valid. The use of culturally and linguistically adapted PROs can also facilitate enrollment of a broad and diverse study population, ultimately leading to more generalizable results. Therefore, in collaboration with the [Health Equity Core](#), the [Patient-Centered Outcomes Core](#) developed this toolkit to help investigators incorporate health equity considerations into the process of selecting and implementing PRO measures, and to leverage existing resources available to facilitate appropriate adaptations. Ultimately the goal is to enhance validity of PRO measure data and to improve diversity, equity, and inclusion in pragmatic research.

### PURPOSE

The purpose of this toolkit is to provide resources to support the capture of patient-reported outcome measures in diverse study populations participating in the NIH Pragmatic Trials Collaboratory [Demonstration Projects](#) and other pragmatic clinical trials. This toolkit contains a Checklist focused on health equity considerations and PROs, along with Additional Resources.

The Collaboratory's Patient-Centered Outcome Core leadership developed the adapted checklist from the Center for Nursing Research at Duke University School of Nursing (DUSON) [INFusE \(Implementing a New Focus on Equity in Research\) Checklist](#). The Adapted DUSON Checklist provides a starting point for study teams to consider how to best support the collection of valid data from diverse study populations in the context of an ePCT.

The Additional Resources document provides links to virtual libraries containing a range of existing translated and/or culturally adapted PRO measures; links to relevant peer-reviewed literature focused on PRO collection in PCTs; and other toolkits to support equity in the collection of patient-centered outcomes and conduct of pragmatic research.



## Adapted DUSON Checklist

The following checklist was adapted by Patient-Centered Outcome core leadership from the Center for Nursing Research at Duke University School of Nursing (DUSON) [INFusE \(Implementing a New Focus on Equity in Research\) Checklist](#) in order to focus on patient-reported outcome measures and health equity. The Adapted DUSON Checklist provides a starting point for study teams to consider how to best support the collection of valid data from diverse study populations in the context of an ePCT.

### PATIENT-CENTERED OUTCOME (PCO) PLANNING

- Be intentional about selecting PCOs with a diverse research team inclusive of multiple perspectives that offer an accurate representation of the study population and context
- Plan to engage the Community Advisory Board as part of the research team to
  - Review planned PCOs for community-level acceptability and feasibility
  - Pretest PCOs externally with representatives from the participant group of interest if not already validated in this population
- Consider whether selected PCOs could be completed by understudied subgroups
- Anticipate whether language restrictions for PCO measures could unintentionally worsen health disparities between groups by excluding marginalized populations from the study
- Provide a glossary of specific terms and abbreviations used in your PCOs
- Develop a budget including funds or appropriate compensation associated with cultural and linguistic adaptation/translation of PCOs

### PCO DATA COLLECTION

- Consider community preferences regarding data collection methods (qualitative vs. quantitative)
- Ensure that PCO measures are reliable and valid for the study population
- Limit the Flesch-Kincaid readability (to between 3rd and 4th grade level) of PCO measures if possible
- Present all study-related materials (e.g., consent forms, flyers, websites, proposals) in participant-identified chosen language
- Provide at a minimum the opportunity for end-user testing before finalizing participant-facing data collection tools
- Use a comprehensive categorization for race, ethnicity, sex, and other identities (e.g., CDISC CDASH)
- Collect data and conduct advanced analysis on (qualitative and quantitative) participant-reported social drivers of health



## Additional Resources

RESOURCE	DESCRIPTION
The Center for Nursing Research at Duke University School of Nursing (DUSON) INFusE (Implementing a New Focus on Equity in Research) Checklist	<a href="#">DUSON-INFUSE</a> is a checklist designed to help researchers embed an equity lens throughout the research lifecycle.
The Miami Measures Library	The <a href="#">Miami Measures Library</a> at the Center of Excellence for Health Disparities Research: El Centro at the University of Miami aims to advance capacity for research with non-English speaking participants through this collection of measures with Spanish translations. By facilitating access to translated measures, we aim to encourage investigators to include non-English speaking participants in their studies.
Peer-reviewed literature	<p><a href="#">Cultural and linguistic adaptation of psychosocial measurements for latinx participants —Leveraging community-engaged research methods</a></p> <p><a href="#">Good practices for the translation, cultural adaptation, and linguistic validation of clinician-reported outcome, observer-reported outcome, and performance outcome measures</a></p> <p><a href="#">Person-Centered Outcome Measures- NCQA</a></p> <p><a href="#">Patient and Family Engaged Care: An Essential Element of Health Equity</a></p> <p><a href="#">NIA IMPACT Collaboratory- Health Equity and ePCTs</a></p> <p><a href="#">Planning for patient-reported outcome implementation: Development of decision tools and practical experience across four clinics</a></p>
PhenX Toolkit	The <a href="#">PhenX toolkit</a> (consensus measures for Phenotypes and eXposures) provides detailed protocols for collecting data and tools to help investigators incorporate these protocols into their studies. A collection of measures with a shared characteristic, target population or topic. The measures included in a Collection may cut across research domains.
Living Textbook Chapter	The <a href="#">Patient-Reported Outcomes</a> chapter in the Living Textbook contains sections on how PROs are used in PCTs, NIH, HEAL, FDA and other core outcome sets, choosing PRO measures, incorporating PRO data into the EHR, cultural and linguistic translation, patient-focused drug development, and case studies.
Community engagement/ community consultation studios	<a href="#">Duke University Community Consultation Studio</a> (Check your institution's CTSA for similar resources)