# Translation and Cultural Adaptation Special Interest Group (TCA-SIG)

## Panel Discussion

**Translatability Assessment: How is it conducted and what is it intended to achieve during PRO instrument development?**

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# Critical Path Institute's Patient-Reported Outcome (PRO) Consortium

# A Translatability Assessment Context

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# Critical Path Institute (C-Path)

- Established in 2005 by the University of Arizona and the US Food and Drug Administration (FDA)
- An independent, non-profit organization that provides a neutral, pre-competitive venue for collaboration
- **Dedicated to implementing FDA's *Critical Path Initiative* -** A strategy for transforming the way FDA-regulated products are developed, evaluated, manufactured, and used

# PRO Consortium

- Formed in late 2008 by C-Path, in cooperation with the FDA and the pharmaceutical industry
- **Membership**
  - Only available to medical product companies
  - 25 (pharmaceutical firm) members in 2012
- **Non-member Participants**
  - Representatives of governmental agencies (e.g., FDA)
  - Clinical consultants, patients, academic researchers, and CROs partnering in the development of the PRO instruments in eight therapeutic areas

# Mission Statement

- To establish and maintain a collaborative framework with appropriate stakeholders for the development of qualified, publicly available patient-reported outcome (PRO) instruments for use in clinical trials where PRO endpoints are used to support product labeling claims.

- **An objective of the PRO Consortium is to advance the science of PRO measurement, so our interest in today's topic is both scientific and pragmatic.**

# Translatability Assessment (TA)

As addressed by Conway et al. (2012), translatability assessment is defined as "**the evaluation of the extent to which a PRO measure can be meaningfully translated into another language**."

Conway K, Patrick DL, Gauchon T, Acquadro C. Enhancing Cross-Cultural Appropriateness for Newly Developed Patient-Reported Outcome (PRO) Instruments: the Use of Translatability Assessment. *PRO Newsletter* 44 (Fall issue).

# Problem Statement

- Instruments that will emerge from the PRO Consortium will be used in clinical trials conducted in multiple nations and cultures, requiring many translations.
- Such trials are increasing in geographic scope and include more sites in Eastern and Central Europe, Asia, and Latin America.
- As a result, targeting a finite number of languages may not be the most effective approach for ensuring that the instruments can be readily translated into other languages/cultures.

# Questions for Panel

- What are the current approaches to TA?
- As opposed to focusing on individual languages in individual countries, is there a higher level of translatability assessment that could be conducted?
- What practical recommendations can be made to optimize TA to effectively avoid translation difficulties during the PRO instrument development process?