



Psychometrics: Validating Patient-Reported Outcomes

*Psychometrics to support
your labeling and claims*

Trust Our Capabilities

Our psychometricians provide a variety of services to meet your needs throughout your product's life cycle. In addition to providing psychometric consulting, we:

- Evaluate psychometric data to identify optimal measurement strategies
- Provide psychometric evidence for existing instruments
- Develop and validate new instruments and short forms

State-of-the-Art Psychometrics

In collaboration with our clinical and survey experts, our team routinely validates outcome measures both within and independent of clinical trials. Our team is formally trained and provides expertise in both classical methods and modern psychometric techniques, including:

- Item response theory, including differential item functioning (DIF)
- Factor analysis
- Structural equation modeling

We Can Help You:

- Identify optimal measurement strategies in support of product approval, label claims, and publications
- Synthesize and compare psychometric data on existing PRO measures
- Evaluate and document the dimensionality, reliability, validity, and responsiveness of new and existing PRO measures
- Identify and evaluate responder definitions in support of regulatory submissions
- Establish clinically meaningful change scores for PRO instruments
- Develop PRO scoring algorithms and short forms
- Adapt and validate instruments for use in different cultures and patient populations or across multiple modes of administration
- Create item banks and computer-adaptive instruments

Receive Quality Deliverables

You'll benefit from our quality-assured deliverables, including:

- PRO strategy documents
- Validated PRO instruments
- Regulatory submission documents
- In-person participation during regulatory reviews
- Instrument reviews and study reports
- Presentations at professional meetings
- Peer-reviewed journal articles and abstracts
- Training courses, seminars, and workshops

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See How We've Helped Others

Psychometric Evaluation of PRO Endpoints Used in IBS-C Trials

RTI-HS collaborated with two pharmaceutical clients to evaluate a set of PRO items used as endpoints in constipation-predominant irritable bowel syndrome (IBS-C). The items addressed a variety of constructs, including bowel habits and abdominal symptoms. RTI-HS conducted the psychometric evaluation, analyzing phase 2 clinical data to assess their reliability, validity, and utility. RTI-HS staff developed a PRO dossier and also supported negotiations with the FDA. This work has been presented and a manuscript is in development.

Psychometric Evaluation of the Negative Symptoms Assessment in Schizophrenia

RTI-HS collaborated with a pharmaceutical client on an evaluation of the Negative Symptoms Assessment (NSA) used in schizophrenia. RTI-HS evaluated the construct validity of the 16-item NSA, examined the items and scoring using item response theory, and compared the psychometric properties and predictive power of the 4-item NSA to the 16-item version. The ability of mental health experts to reliably score the 4-item version after training was also assessed. This work has been presented at a meeting of the American Psychiatric Association and in *Psychiatry* (Edgemont) 2010;7(7):26-32.

Lung Function Questionnaire (LFQ)

RTI-HS conducted a study to assess the usability and validity of alternate methods of administering the lung function questionnaire (LFQ), including web-based as well as interviewing methods to identify patients at risk for airflow obstruction. Study results supported the use of the alternate forms and were published in the *International Journal of Chronic Obstructive Pulmonary Disease* 2010;5:425-434.

Selected Publications By Our Staff

Bell C, **McLeod LD**, Nelson LM, Fehnel SE, **Zografos LJ**, Bowers B. Development and psychometric evaluation of a new patient-reported outcome instrument measuring the functional impact of insomnia. *Qual Life Res.* In press. 2011 Apr 20. [Epub ahead of print]

Dalal A, **Nelson L**, Gilligan T, **McLeod L**, **Lewis S**, DeMuro-Mercon C. Evaluating patient-reported outcome measurement comparability between paper and alternate versions – using the lung function questionnaire as an example. *Value Health.* 2011;14(5):712-20.

Deal LS, **Williams VS**, DiBenedetti DB, **Fehnel SE**. Development and psychometric evaluation of the Endometriosis Treatment Satisfaction Questionnaire. *Qual Life Res.* 2010 Aug;19(6):899-905.

Gold DT, Horne R, **Coon CD**, **Price MA**, Borenstein J, Varon SF, Satram-Hoang S, Macarios D. Development, reliability, and validity of a new preference and satisfaction questionnaire. In press. *Value Health.* 2011 Oct 3.

Goldberg JF, **McLeod LD**, **Fehnel SE**, **Williams VSL**, **Hamm LR**, Gilchrist K. Development and psychometric evaluation of the Bipolar Functional Status Questionnaire (BFSQ). *Bipolar Disord.* 2010;12:32-44.

McLeod LD, **Coon CD**, **Martin S**, **Fehnel SF**, Hays RD. Interpreting patient-reported outcome results: US FDA guidance and emerging methods. *Expert Rev Pharmacoecon Outcomes Res.* 2011;11(2):163-9.

Let RTI-HS Help You

To learn more about our capabilities, please visit us online at www.rti.org, e-mail us at rtihealthsolutions@rti.org, or contact one of our experts.