



Validating Patient-Reported Outcomes: Psychometrics

*Psychometrics to support
your labeling and claims*

Trust Our Capabilities

Support the scientific credibility of your health outcomes data through our services. 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 independent of clinical trials. Our team is formally trained in both quantitative and qualitative analytic methods. We provide expertise in both classical methods and modern psychometric techniques, including:

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

We Can Help You By:

- Conducting focus groups and cognitive testing
- Identifying and coordinating expert panels
- Synthesizing and comparing psychometric data
- Identifying optimal measurement strategies
- Developing and validating new patient-reported outcomes (PRO) measures
- Developing PRO scoring algorithms and short forms
- Evaluating reliability, validity, and responsiveness
- Estimating minimal clinically important differences (MCIDs)
- Providing cross-cultural adaptation of PRO measures
- Creating 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

Development and Psychometric Evaluation of the Motivation and Energy Inventory (MEI)

RTI-HS developed a questionnaire for a pharmaceutical client designed to measure changes in energy and motivation among individuals being treated for depression. The constructs addressed by the MEI were identified through a combination of literature review, consultation with experts and a series of patient focus groups. The draft questionnaire was then submitted to four iterative rounds of cognitive testing and revision.

To evaluate the psychometric properties of the new instrument, the data from two clinical trials were analyzed. In general, the data collected during the first and second trial were used for exploratory and confirmatory analyses, respectively. Consistent with the measurement model of the MEI, the psychometric results confirmed that the instrument has three factors generally addressing physical energy, mental energy and social motivation. Furthermore, these results provided evidence for the internal consistency, construct validity and responsiveness of all three MEI subscales. Most recently, RTI-HS conducted a follow-up study to establish the test-retest reliability and MCID values for the MEI. A manuscript describing the development and psychometric evaluation of the MEI was published in *Quality of Life Research*.

Psychometric Evaluation of the Acne-Specific Quality-of-Life Questionnaire

In response to queries from the Food and Drug Administration (FDA), a pharmaceutical client asked RTI-HS to bolster the psychometric evidence for the Acne-Specific Quality-of-Life Questionnaire (Acne-QoL), an instrument the company had used in several clinical trials testing the ability of an oral contraceptive to improve facial acne among both adolescent and adult women. Consequently, we utilized the data from these clinical trials to evaluate the responsiveness and extend the developer's psychometric validation of the questionnaire, as well as to derive minimal clinically important difference (MCID) estimates for the four Acne-QoL subscales. A manuscript describing the responsiveness evaluation was published in *Quality of Life Research*, and the results of the MCID work have been published in *Pharmacoeconomics*.

We Provide Sound Information

We leverage our psychometric expertise to help you communicate your product's competitive advantages. We provide optimal measurement and validation of patient-reported outcomes for:

- Consumers
- Payers
- Regulatory agencies

Let RTI-HS Help You

To learn more about our capabilities, please visit us online at www.rtihs.org, email us at rtihealthsolutions@rti.org, or call one of our international offices listed on the front.