

## Capturing the Patient's Perspective: Patient-Reported Outcomes

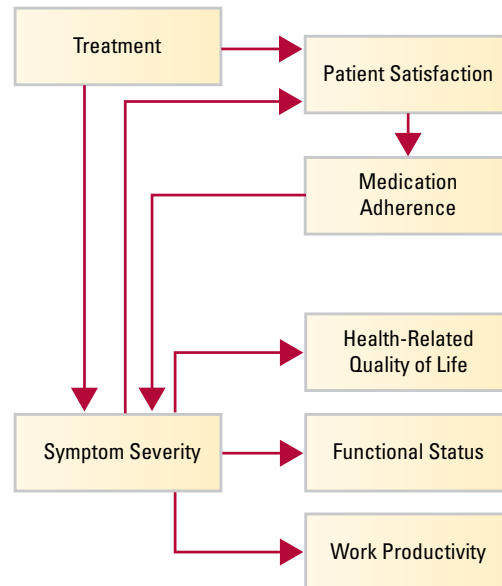
*Providing patient-reported outcomes data to support your products*

### Communicate the Patient's Perspective

Payers, providers, and regulatory agencies are increasingly interested in understanding patient-reported outcomes (PROs). We can help you by collecting, assessing, and strategically communicating PRO information.

### Trust Our Capabilities

Our clients rely on our large and experienced team of psychometricians and health outcomes and survey research experts to implement effective PRO studies. We have worked with a wide variety of pharmaceutical companies to collect and analyze PRO data to support both product development and post-marketing strategies.



Our team of PRO experts:

- Develop and validate instruments for patient-reported outcomes, such as quality of life, patient satisfaction, and medication adherence
- Conduct patient, caregiver, and physician surveys using a broad array of data collection techniques, including mail, telephone, and web-based methods
- Design case report forms for measurement of PROs in clinical trials
- Demonstrate the reliability, validity, responsiveness, and dimensionality of PRO assessment instruments
- Evaluate psychometric data to identify optimal measurement strategies
- Adapt and validate instruments for use in different cultures and patient populations
- Conduct focus groups and in-depth interviews to identify constructs and value messages important to specific populations
- Analyze patient- and physician-reported outcomes data
- Author manuscripts on the development and validation of PROs and surveys

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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. The clinical trial 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 minimally clinically important different (MCID) values for the MEI. A manuscript describing the development and psychometric evaluation of the MEI was published in *Quality of Life Research*.

### Prevalence and Impact of Antidepressant-Induced Sexual Dysfunction in Europe

RTI-HS conducted a cross-sectional survey to assess the prevalence and impact of antidepressant-induced sexual dysfunction (ADSD) in Europe, which included more than 500 individuals being treated for depression across several European countries. Inclusion criteria for the study required that patients be over the age of 18 and taking a selective serotonin re-uptake inhibitor (SSRI) that had been newly prescribed within the past three months. RTI-HS developed the survey questionnaire, which gathered information about patients' current treatments for depression, other medications and conditions that could impair their sexual functioning, changes in sexual functioning since beginning SSRI therapy, the impact of any such changes, and demographic information. A combination of validated and established scales and *de novo* questions were utilized. Working with European collaborators, RTI-HS obtained appropriate translations of the questionnaires, consent forms, and instructions for use in each country. Along with a confirmatory indicator and "positive signal" that ADSD is quite prevalent in Europe, we found evidence of negative impacts on patient quality of life arising directly from this SSRI side effect. RTI-HS presented the results of this study at the Annual International Meeting of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR).

## Let RTI-HS Help You

To learn more about our capabilities, please visit us online at [www.rtihs.org](http://www.rtihs.org), email us at [rtihealthsolutions@rti.org](mailto:rtihealthsolutions@rti.org), or call one of our international offices listed on the front.