

*More than 20 staff with experience in mental health projects including*

Dana DiBenedetti, PhD  
Head, Patient-Reported Outcomes  
ddibenedetti@rti.org

Stephanie Earnshaw, PhD  
VP, Health Economics, US  
searnshaw@rti.org

Sheri Fehnel, PhD  
VP, Patient-Reported Outcomes  
sfehnel@rti.org

Lori McLeod, PhD  
Head, Psychometrics  
lmcLeod@rti.org

Valerie Williams, PhD  
Senior Director, Psychometrics  
vwilliams@rti.org

## Contact

RTI Health Solutions  
Research Triangle Park, NC, USA  
+1.800.262.3011

Ann Arbor, MI, USA  
+1.734.213.5372

Barcelona, Spain  
+34.93.241.7766

Lund, Sweden  
+46.706.58.3442

Manchester, UK  
+44(0)161.447.6000

Sheffield, UK  
+44(0)114.213.3390

Waltham, MA, USA  
+1.781.434.1700

rtihealthsolutions@rti.org  
www.rtihs.org

# Mental Health Experience

## A Wealth of Experience

At RTI Health Solutions, we have collaborated with our clients on more than 175 projects researching mental health disorders, mental health treatment studies, and burden and complications of mental health disorders. Our experience includes:

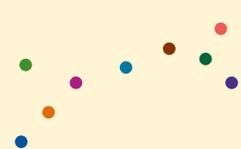
- Alcohol and drug abuse and dependence
- Anxiety disorders, including
  - Acute stress disorder
  - Generalized anxiety disorder
  - Obsessive-compulsive disorder
  - Panic disorder
  - Post-traumatic stress disorder
  - Social phobia
- Attention deficit hyperactivity disorder
- Bipolar disorder
- Communication disorders
- Dementia
- Depression
- Eating disorders
- Insomnia and other sleep disorders
- Nicotine dependence
- Schizophrenia
- Sexual dysfunction

## Types of Projects

We have implemented studies to help our clients design strategies in the mental health market and to develop and commercialize products to treat mental health illnesses and complications arising from mental health disorders and/or treatment of mental health illnesses. Recent projects have included:

- PRO instrument development, psychometric evaluation, and validation
- PRO studies to support label claims
- Survey research
- Health economic models, including
  - Cost-effectiveness models
  - Budget impact models
  - Markov models
- Retrospective analyses using health care claims and other databases
- Meta-analysis studies
- Qualitative work with patients, caregivers, and healthcare professionals, including
  - Focus groups
  - In-depth interviews
- Literature and instrument reviews
- Economic burden of illness studies
- Epidemiology of disease
- Treatment preference studies
- Preparation of Health Technology Assessment (HTA) submissions
- Stated preference studies
- Benefit-risk preference studies
- Global value dossiers
- Value communication strategies
- Gap analysis for HEOR strategy planning
- Product value and access kits
- Abstract and manuscript development
- Prospective observational studies
- Communication of key strategic non-labeled claims

*(continued)*



## See How We've Helped Others

### Refractory Generalized Anxiety Disorder (GAD), Systematic Literature Review

Using data from MEDLINE, EMBASE, and the Cochrane Library, we conducted an analysis of clinical trials that evaluated refractory GAD patients. In these trials, patients either added treatment or switched treatment because of inadequate response to at least one earlier drug. The largest trial was with pregabalin, an 8-week, 356-patient study. All other trials had fewer than 50 patients in each clinical study, suggesting a significant need for larger augmentation trials for refractory patients with GAD. Study results were published in *International Clinical Psychopharmacology* 2011;26(2):63-8.

### Bipolar, PRO Instrument Development and Evaluation

We developed and evaluated a new patient-reported outcomes instrument for use in bipolar disorder. Key aspects of the study included drafting 52 items to address each of the relevant constructs, cognitive testing, and collecting data from nearly 600 bipolar patients and their psychiatrists at 11 clinical sites across the United States. Results were published in *Bipolar Disorders* 2010;12(1):32-44.

### Antidepressant-Induced Sexual Dysfunction, Critical Support for the Communication of Key Strategic NonLabeled Claims

We conducted a set of cross-sectional surveys to assess the prevalence and impact of antidepressant-induced sexual dysfunction (ADSD) in Europe. The surveys included more than 1200 individuals being treated with an SSRI across several European countries. We 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. The studies showed that sexual dysfunction is a frequent occurrence during antidepressant treatment and is associated with reduced quality of life, and poorer self-esteem, and relationships. Study results were published in *Journal of Clinical Psychiatry* 2006;67:204-10 and in *Journal of Psychopharmacology* 2010;24(4):489-96.

### Bipolar Disorder, Stated Preference Study

We conducted a stated preference study to analyze factors that improve patient adherence to medications for bipolar disorder. As part of the study, patients completed a web survey that included a series of choice-format questions about three hypothetical medications with different attributes. The study showed that medications that reduce the severity of depressive episodes and do not cause weight gain or cognitive side effects are likely to increase patient adherence. Study results were published in *Medical Care* 2007;45(6):545-52.

## Selected Recent Publications By Our Staff

**Beard SM**, Maciver F, Clouth J, Ruther E. A decision model to compare health care costs of olanzapine and risperidone treatment for schizophrenia in Germany. *European Journal of Health Economics* 2006;7(3):165-72.

Feltner D, **Hill C**, Lenderking W, **Williams V**, Morlock R. Development of a patient report assessment to identify placebo responders in a generalized anxiety disorder trial. *Journal of Psychiatric Research* 2009;43:1223-30.

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

**Granger A**, **Fehnel SE**, **Hogue SL**, Bennett L, Edin HM. An assessment of patient preference and adherence to treatment with Wellbutrin SR: a web-based survey. *Journal of Affective Disorders* 2006;90:217-21

**Johnson FR**, Ozdemir S, Manjunath R, **Hauber AB**, Burch SP, Thompson TR. Factors that affect adherence to bipolar disorder treatments – a stated-preference approach. *Medical Care* 2007;45(6):545-52.

**Karve S**, Cleves MA, Helm M, Hudson TJ, West DS, Martin BC. Prospective validation of eight different adherence measures for use with administrative claims data among patients with schizophrenia. *Value in Health* 2009;12(6):989-95.

**Mauskopf JA**, Simon GE, Kalsekar A, Nimsch C, Dunayevich E, Cameron A. Nonresponse, partial response, and failure to achieve remission: humanistic and cost burden in major depressive disorder. *Depression and Anxiety* 2009;26(1):83-97.

Mcafee, AT, Holdridge KC, **Johannes CB**, Hornbuckle K, Walker AM. The effect of pharmacotherapy for attention deficit hyperactivity disorder on risk of seizures in pediatric patients as assessed in an insurance claims database. *Current Drug Safety* 2008;3(2):123-31.

**Price MA**, Hill CD, **Williams VSL**, Morlock RJ, Leeuwenkamp O, Patterson TL. Measures of functional status and quality of life outcomes in schizophrenia. *Current Psychiatry Reviews* 2008;4:28-38.

**Williams VS**, Morlock RJ, Feltner D. Psychometric evaluation of a visual analog scale for the assessment of anxiety. *Health and Quality of Life Outcomes* 2008;8:57.

**Zarkin GA**, **Bray JW**, **Aldridge A**, **Mitra D**, **Mills MJ**, Couper DJ, Cisler RA. Cost and cost-effectiveness of the COMBINE study in alcohol-dependent patients. *Archives of General Psychiatry* 2008;65(10):1214-21.