ment by day one in shoulder and back pain when compared to a lower dose of the same drug. Patients also reported statistically significant (p < 0.05) reduced pain while awake by day three, improved overall pain by day two, global emotional improvement by day three, and global physical improvement by day seven. This improvement data was collected electronically using a verbally administered numeric scale. **RESULTS:** In both cases, these data would have been difficult, if not impossible, to collect reliably at the study site or via paper. Sponsor acceptance of ePRO data is shown by a recent survey of 156 webinar registrants that found that 36% indicated that they have included, or intend to include, ePRO data in a regulatory submission as a primary (22%) or secondary (14%) endpoint. **CONCLUSIONS:** This session reviews the methods and associated research for verbally orienting a study subject and verbally administering analog scales in clinical trials. Additionially, regulatory acceptance of electronic patient reported outcomes in clinical trials is explored through real world case studies.

PMH40

ASSESSING SELECTION BIAS ON TREATMENT EFFECTS IN OBSERVATIONAL STUDIES WITH REPEATED OUTCOME MEASURES: REGRESSION, PROPENSITY SCORING, FIXED-EFFECTS MODELS, AND BAYESIAN ESTIMATION METHODS
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OBJECTIVES: Prospective observational studies, which inform on the effectiveness of interventions in natural settings, may complement results from randomised clinical trials in the evaluation of health technologies. However, observational studies are subject to a number of potential methodological weaknesses, mainly selection and observer bias. This analysis applies various methods to control selection bias in the estimation of treatment effects. We also address the issues of estimation and inference in a multilevel setting. **METHODS:** We describe and compare the use of regression methods, propensity score matching, fixed-effects models incorporating investigator characteristics, and a multilevel, hierarchical model using Bayesian estimation techniques in the control of selection bias. To illustrate these methods, we have used data from the Schizophrenia Outpatient Health Outcomes (SOHO) study, a large, prospective, observational study of health outcomes associated with the treatment of schizophrenia. **RESULTS:** The methods used to adjust for differences between treatment groups that could cause selection bias yielded comparable results and reinforces the validity of the findings. **CONCLUSIONS:** Observational studies, when properly conducted and when using adequate statistical methods, can provide valid information on the evaluation of health technologies.

PMH41

ANXIETY DISORDERS: THE PATIENTS' PERSPECTIVE
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OBJECTIVES: Anxiety disorders like Social Anxiety Disorder (SAD) or Generalised Anxiety Disorder (GAD) are severe, chronic psychiatric disorders defined in DSM-IV-TR needing long-term treatment. However, they have been challenged as being created by physicians and pharmaceutical companies. Studies have shown that less than one-half received past year mental health treatment. Patient Reported Outcome evaluation is a useful way to evaluate the impairment caused by the diseases from the patient's perspective. **METHODS:** Two relapse prevention randomised clinical trials in SAD and GAD were used,

excluding patients with other comorbidities. Quality of life was assessed using the SF-36, consisting of eight dimensions: Physical Functioning (PF), Role-physical Limitations (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Mental Health (MH), Role-emotional Limitations (RE) and Social Functioning (SF). Baseline SF-36 evaluations of patients with SAD or GAD were compared to the published general population norms. **RESULTS:** A total of 372 SAD patients and 333 GAD patients filled the SF-36 at baseline. The SAD population was mostly impaired on the mental dimensions compared to the general population norms, with differences up to three times the Minimal Clinical Important Difference (MCID): 50.4 ± 18.6 vs. 60.9 ± 21.0 (VT); 56.2 ± 18.1 vs. 74.7 ± 18.1 (MH); 56.6 ± 40.1 vs. 81.3 ± 33.0 (RE); 50.4 ± 26.6 vs. 83.3 ± 22.7 (SF). In the GAD population, all dimensions except PF were significantly impaired. For RP, GH, VT, MH, RE and SF the differences were up to 3 times the MCID: 53.4 ± 41.3 vs. 82.0 ± 34.0; 56.4 ± 20.7 vs. 72.0 ± 20.3; 35.3 ± 18.6 vs. 60.9 ± 21.0; 42.4 ± 16.9 vs. 74.7 ± 18.1; 29.9 ± 36.0 vs. 81.3 ± 33.0; 48.6 ± 24.4 vs. 83.3 ± 22.7, respectively. **CONCLUSIONS:** From the patient's perspective the impairment is severe, and differences with general population norms are comparable with other diseases such as Major Depressive Disorder or Diabetes. These results suggest the substantial unmet need for care should be considered seriously, especially in view of available effective treatments for SAD and GAD.

PMH42

QUALITY OF LIFE IN PATIENTS WITH BIPOLAR DISORDER IN 5 EUROPEAN COUNTRIES
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OBJECTIVES: To provide information on patient-reported quality of life for patients with bipolar disorder in five European countries. **METHODS:** Physicians in France, Germany, Italy, Spain, and the UK who managed at least ten patients with bipolar disorder within the preceding six months were invited to complete a questionnaire concerning their patients' clinical status and therapy. Patients of these physicians were also invited to complete a questionnaire that included the Euroqol EQ-5D, a 5-item questionnaire assessing quality of life in five key areas: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Patient responses to the 5 EQ-5D items were used to generate EQ-5D utility scores. The patients were also asked to rate their current health on a Visual Analog Scale (EQ-5D VAS). These data were collected in 2005. **RESULTS:** Data on self-reported quality of life were collected from 1335 patients from France (n = 304), Germany (n = 247), Italy (n = 156), Spain (n = 492), and the UK (n = 136). Most were outpatients (85%) and most were aged 25–64 (87%); 57% were women. The most commonly reported reason for the physician visit was maintenance (44%), followed by depressed (23%), manic (13%), hypomanic (9%), and mixed (8%) health states. Mean (±standard deviation) EQ-5D utility scores (76.0 ± 26.7) were greater than EQ-5D VAS scores (63.2 ± 20.4). This relationship held across all countries. EQ-5D utility and VAS scores were significantly higher for Germany (P < 0.01) and significantly lower for Spain (P < 0.05). Patients reporting depressed health state as the reason for their visit had the lowest reported EQ-5D utility (64.2 ± 33.5) and EQ-5D VAS (52.7 ± 21.3) scores. **CONCLUSIONS:** In this large, multinational, cross-sectional survey of physicians and their patients with bipolar disorder, patient-reported quality of life varied by country and current phase of illness.