drug trials; 2) to identify trials that specifically examined the impact of treatment on patient-reported anxiety, depression and sleep disturbance, as these common comorbid symptoms are associated with poorer health status in people with epilepsy; and, 3) to identify which measures/domains were most responsive to change.

**METHODS:** A review of 41 adult epilepsy trials examining the impact of an oral antiepileptic drug on patient-reported assessments of anxiety, depression, well-being, sleep, function and treatment satisfaction. Studies were identified through searches in MEDLINE, the Cochrane Central Register of Controlled Trials and reference lists of published articles. **RESULTS:** The most common types of PROs comprised epilepsy-specific measures assessing multiple domains of functioning and well-being (used in 30 studies) and generic measures assessing anxiety/depression and other emotions (used in 21 studies). There was limited detection of treatment effect on scales assessing anxiety/depression and emotional well-being. Scales assessing perceptions of emotional well-being were more likely to show significant differences than measures assessing symptom severity. Patients were not required to have clinically significant anxiety/depression to participate. It is possible that patients entered trials with symptoms in the normal range, leaving no room to show improvement; that treatment did not worsen symptoms; or, that instruments were not responsive. Findings were mixed regarding other specific health status domains. Patients receiving active treatments typically reported significantly higher levels of satisfaction than those receiving placebo. Only 2 trials were identified that assessed patient-reported sleep, but both showed significant differences on specific domains. **CONCLUSION:** Anxiety and depression were among the most common PROs assessed, but there was limited detection of treatment effect. Trial selection criteria complicate interpretation of findings. Patient-reported sleep outcomes were rarely studied, but deserve more attention in adult epilepsy drug trials.

**PND38**

LONGITUDINAL PATIENT-REPORTED OUTCOMES (PRO) IN SUBJECTS WITH REFRACTORY PAIN ASSOCIATED TO TRIGEMINAL NEURALGIA: A POST-HOC ANALYSIS OF A 12-WEEK PROSPECTIVE STUDY IN PRIMARY CARE SETTING (PCS) UNDER ROUTINE MEDICAL PRACTICE

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1 Primary Care Centre "Raúles", Castillón, Asturias, Spain; 2 Hospital University La Princesa, Madrid, Spain. **OBJECTIVES:** To analyze longitudinal PRO measurements evolution after treating refractory pain due to Trigeminal Neuralgia in Primary Care Setting (PCS) during 12-weeks under routine medical practice. **METHODS:** Sub-analysis of a sample of patients above 18 years, with 6-month chronic pain due to trigeminal neuralgia refractory to, at least, one previous analgesic [previous mean (SD) number of drugs was 2.2 (1.2), with a 36.3% on one-drug only], included in a prospective, naturalistic, 12-weeks two-visit study on refractory peripheral Neuropathic pain. PRO measurements included pain severity by McGill-pain scale (included 50%-reduction responder rate and days with no/mild pain), anxiety and depression symptoms (HAD scale), sleep disturbances (MOS-sleep), disability (Sheehan scale), and quality-adjusted-life-year (QALY) gain (EQ-5D). Paired non-parametric and t-tests were applied. **RESULTS:** Ninety-one [62.2% women, 57.7% (13.9) years] patients were analyzed: 43% switched to pregabalin as a monotherapy, 37% received pregabalin as add-on therapy, and in 18% previous treatment was replaced by a regimen not including pregabalin. After 12 weeks of therapy, significant reduction in last-week mean pain severity [-35.0 (23.9) mm, p < 0.0001, 53.9% responders] and percentage of subjects declaring the pain as severe or worst from 60.5% to 10.5% (p < 0.0001), was accompanied by reductions in total disability score [-8.2 (6.0) pts, p < 0.0001], depression symptoms score [-3.8 (4.2) pts, p < 0.0001], anxiety symptoms score [-3.4 (3.3) pts, p < 0.0001], and summary-index sleep problems scoring [-16.5 (18.4), p < 0.0001], while treatment increased the quarterly mean number of days with no/mild pain [+32.3 (28.9) days, p < 0.0001], the average number of sleeping-hours per night [+0.8 (1.3), p < 0.0001], and produced a QALY gain of 0.0317 (0.0385). **CONCLUSION:** A therapy mix of painful trigeminal neuralgia mostly based on pregabalin (82% of cases) was associated with a significant longitudinal improvement in patient-reported-outcomes including severity of pain, symptoms of depression and anxiety, disability, sleep disturbance and quality-adjusted-life-year gain.

**PND39**

PATIENT-REPORTED OUTCOME (PRO) LABELING CLAIMS IN PARKINSON’S DISEASE: OVERVIEW OF US AND EUROPEAN DRUG APPROVALS

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1 Mapi Research Trust, Lyon, France; 2 Mapi Values, Boston, MA, USA. **OBJECTIVES:** To review the Parkinson’s disease products approved both in the United States (US) and in Europe with a particular focus on the PRO end-points appearing in the products’ labels. **METHODS:** Parkinson’s disease products approved in Europe since 1995 through the centralized procedure and in the US since 1998 (new molecular entities) were identified from a review of the EMEA and FDA websites. Using the PROLabels database, we then identified the products indicated for Parkinson’s disease treatment and showing evidence of PRO in labeling. PROLabels is a unique on-line tool which provides information on the drug products for which the FDA and/or the EMEA have granted PRO labeling claims. **RESULTS:** Overall, 10 different products indicated for the treatment of Parkinson’s disease was identified in this review, accounting for 7 different molecules. Of these 10 drugs, 9 demonstrated the efficacy of the treatment using PRO endpoints. We will focus here on the 3 active molecules approved both in Europe and in the US with a PRO labeling claim. All six dossiers report the use of patient diaries to record ON- and OFF-times. Other PRO endpoints assessed were health-related quality of life (HRQL) and activities of daily living (ADL) in two cases, and global functioning and levodopa dose in one case. Regarding the methods of PRO measure, 4 products used a defined instrument to capture ADL and HRQL, and one used a single item to assess functioning. **CONCLUSION:** Overall, PRO data in labeling for Parkinson’s disease products is quite frequent (in 9 out of 10 approved products), and above the average rate over all therapeutic areas (source PROLabels). PRO endpoints appeared mainly in the clinical studies section of the product label. An interesting finding is the discrepancy between the American and the European PRO claims.