their routine clinical management. METHODS: e-STAR is an ongoing, long-term, multinational, non-interventional observational study designed to evaluate the clinical and economic outcomes of patients who require a change in antipsychotic treatment. Data are prospectively collected over 2 years and recorded via a secure website. Data are also recorded retrospectively for a 1 year period to enable a mirror-image design in which patients act as their own control for appropriate outcome parameters. These include changes from baseline (time of initiation of new treatment in Clinical Global Impression of Illness-Severity (CGI-S) and Global Assessment of Functioning (GAF), hospitalisations and adverse events. RESULTS: Presently in the study 1107 Spanish patients have commenced treatment with RLAI and have 6 months of follow-up. Demographics: 62.8% male, mean (SD) age of 39.1 (11.2) years, and time since diagnosis 13.3 (9.7) years. Mean (SD) CGI-S score of 4.7 (1.0) at baseline (n = 712) reflected marked–extremely severe illness in 57.8% and moderate illness in 32% of patients. Mean (SD) baseline GAF score was 46.9 (16.3) n = 713), and 28.1% patients had been hospitalised during the 6 months before RLAI. After 6 months on RLAI, mean (SD) CGI-S score had decreased to 3.9 (0.9) reflecting a significant reduction from baseline and significantly fewer patients had marked–extremely severe illness (23.7%; p < 0.001). Mean (SD) GAF score significantly improved to 57.2 (16.1) (p < 0.001) and significantly fewer patients were hospitalized (19.2%) compared with the corresponding 6 month retrospective period (p < 0.001). CONCLUSIONS: Patients switched to RLAI during routine clinical management are significantly more likely to exhibit improvements at six months in illness severity and functioning, and are less likely to require hospitalisation. Follow-up of patients is continuing.

PMH37

BURDEN OF ILLNESS OF PATIENTS WITH ANXIETY IN THE UK

Makinson G, Konz T, Lister S
Pfizer Limited, Tadworth, Surrey, UK

OBJECTIVES: Anxiety results in physical and psychological burdens for patients, and increased health care costs. The objective was to compare resource utilisation by patients, with and without anxiety, in the UK. METHODS: A primary care database, representative of the UK population (DIN-LINK), covering 100 practices (400 GPs), containing the records of over 800,000 registered patients was used. A cohort presenting to General Practitioners with anxiety during the three years to August 2005 was identified. A control cohort was identified comprising randomly selected patients with no history of anxiety; this cohort was matched by age, sex, GP practice and ACORN socio-economic classification. Patient demographics and resource utilisation data (including prescribed medications, number and type of prescriptions, GP consultations, out-patient referrals, hospital admissions, and medical certificates issued by GPs) were reported in total, and for anxiety-related encounters. The aggregate number of follow-up days for each cohort was reported to facilitate comparison. RESULTS: The database identified 1,569 patients diagnosed with anxiety. There were similar numbers of matched control subjects, with the same number of follow-up days. The anxiety cohort utilised the following resources during the follow-up period compared to the matched cohort: There were: 105% more prescriptions (n = 1,859,000) –26% related to anxiety; 86% more GP consultations (n = 769,000) –25% related to anxiety; 94% more outpatient referrals (n = 92,800) –23% related to anxiety; 83% more hospital admissions (n = 12,100) –14% related to anxiety; 324% more medical certificates issued (n = 38,000) –64% related to anxiety.

CONCLUSIONS: Patients with anxiety were prescribed many more medications, and consumed many more primary and secondary care resources, than the matched patient cohort. The fact that much of the additional resource use was not entirely related to anxiety also suggests that extensive co-morbidity exists alongside anxiety.

PMH38

A MODEL TO ASSESS THE COST-EFFECTIVENESS OF NEW TREATMENTS FOR DEPRESSION

Soboci P1, Ekman M1, Ågren H2, Jonsson B1

OBJECTIVES: To develop a model to assess the cost-effectiveness of a new treatment for patients with depression. METHODS: A Markov simulation model was constructed to evaluate standard care for depression as performed in clinical practice compared to a new treatment for depression. Costs and effects were estimated for time horizons of six months to five years. A naturalistic longitudinal observational study provided data on costs, quality of life and transition probabilities. Data on long-term consequences of depression and mortality risks were collected from the literature. Cost-effectiveness was quantified as quality-adjusted life years (QALYs) gained from the new treatment compared to standard care and the societal perspective was taken. Probabilistic analyses were conducted in order to present the uncertainty in the results and sensitivity analyses were conducted on key parameters employed in the model. RESULTS: Compared with standard care, the new hypothetical therapy was predicted to substantially decrease costs and was also associated with gains in QALYs. With an improved treatment effect of 50% on achieving full remission the net cost savings were 20,000 Swedish kronor (SEK) over a follow-up time of 5 years, given equal costs of treatments. Patients gained 0.073 QALYs over 5 years. The results are sensitive to changes in assigned treatment effects. CONCLUSIONS: The present paper provides a new approach for assessing the cost-effectiveness of treatments for depression by incorporating full remission as treatment goal and QALYs as primary outcome measure. Moreover, we show the usefulness of naturalistic real-life data on costs and quality of life and transition probabilities when modelling the disease over time.

PMH39

USE OF VERBALLY ADMINISTERED AND VERBALLY ORIENTING SCALES TO IMPROVE DATA COLLECTION

Wood A1, Wenzel KW2
1ClinPhone, Nottingham, UK, 2ClinPhone, Oregon, WI, USA

OBJECTIVES: Several new research reports coupled with state-ments by regulatory authorities indicate that the penetration, models for use, and acceptance of patient reported outcomes (PRO) collected electronically (ePRO) is rapidly evolving for clinical drug trials. METHODS: In one recent study, the Patient Global Impression of Improvement was modified to include a verbal recording of the subject’s health status at the beginning of treatment. This recording was then subsequently used to orient the subject at every subsequent rating and resulted in a 16% difference in effect size (0.0526 vs. 0.612) when compared to the standard PGI-I. For compounds with a fast onset-of-action profile, it is critical that data be collected outside of the office setting. In a separate study (n = 137), patients started at higher doses of the study drug (duloxetine) reported greater improve-