terms of choice of treatment strategy for longterm treatment of gastroesophageal reflux disease and the associated costs. **METHODS:** This study is a follow-up study to the Nexium One study and is an open observational study in a general practice setting with 1206 patients. This study was designed as a naturalistic study to emulate a real-life situation as closely as possible. The observational period was six-months. Three groups of patients were included in to this study: 1) patients who participated in the Nexium One trial and were included by general practionernes (GPs), who participated in the Nexium One trial; 2) patients who did not participate in the Nexium One trial and were included by GPs, who participated in the Nexium One trial; and 3) patients who did not participate in the Nexium One trial and were included by GPs, who did not participate in the Nexium One trial. As to whether the randomised Nexium One study reflected real-life in terms of treatment and associated costs, this was investigated by comparing direct medical costs, total costs for the following patients: A) all patients from the Nexium One study and B) group three patients (see above). **RESULTS/CONCLUSIONS:** A significant difference was found in total costs between group three and all the patients in the Nexium One study. However, there was no significant difference in direct medical costs. In other words, the Nexium One study reflects real-life costs as there is no difference in the costs of treatment between all patients in the Nexium One study and the patients, who did not participate in the Nexium One study and were included by GPs who did not participate in the Nexium One study.

PGI15

VALIDATION OF EDC VERSIONS OF IBS-QOL, EQ-5D AND WPAI-IBS QUESTIONNAIRES

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OBJECTIVES: To assess the validity and subject acceptability of electronic data capture (EDC) versions of Irritable Bowel Syndrome Quality of Life(IBS-QOL), EuroQoL(EQ-5D) and Work Productivity and Activity Impairment (WPAI:IBS) questionnaires. **METHODS:** Comparability of EDC and paper questionnaires was evaluated in 72 subjects with IBS who completed a baseline EDC or paper questionnaire, a crossover questionnaire 24 hours later, and a retest of the crossover version at week-one. The EDC version was presented on a hand-held device. Comparability was assessed using paired t-test statistics, intraclass correlation coefficients (ICC) and tests for internal consistency (Cronbach's alpha). **RESULTS:** No significant differences were found between scores obtained by paper questionnaire and EDC at the baseline and crossover assessments. ICCs between baseline and crossover assessments ranged from 0.83 to 0.96 for the IBS-QOL scores, 0.82 to 0.96 for the WPAI:IBS scores, and 0.77 to 0.82 for the EQ-5D. Internal consistency was comparable for the two data collection methods for the IBS-QOL overall score (0.96) and subscales and the EQ-5D Index (0.70 vs. 0.74). Retest statistics (ICC) were generally comparable between the EDC and paper versions for all scores, as was the relationship between scores and levels of IBS symptom severity. Ease of use was comparable for the two modes of administration, but more patients preferred EDC (47.2%) than the paper questionnaire (23.6%). **CONCLUSIONS:** EDC versions of the IBS-QOL, EQ-5D, and WPAI:IBS are comparable to paper questionnaires in terms of internal consistency, test-retest reliability, and discriminant validity and have greater patient acceptability.

PGI16

HEALTH RELATED QUALITY OF LIFE CHANGES IN LAMIVUDINE REFRACTORY CHRONIC HEPATITIS B (CHB) PATIENTS AFTER ENTECAVIR (ETV) OR LAMIVUDINE (LAM) TREATMENT¡V BMS STUDY 026

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The impact of treatment on health related quality of life (HRQoL) in CHB patients is unclear. **OBJECTIVE:** The objective of this study was to compare the changes in HRQoL from baseline, as measured by changes in health status using the EuroQoL 5 Dimensions (EQ-5D) questionnaire, in patients receiving ETV or LAM treatment. Utility scores are anchored between full health (1) and death (0). **METHODS:** This was a randomized double blind, double dummy, active controlled trial. Questionnaires were administered prior to the physician visit at baseline, Weeks 24 and 48. Mean changes in health index score (HIS) and visual analog scale (VAS) score from baseline were calculated in all treated patients. Proportions of patients who had improvement or no change in health dimensions were compared between the two treatment groups, and patients with missing Week-48 data were considered failures (NC = F). **RESULTS:** A total of 116 of 141 (82%) ETV and 114 of 145 (79%) LAM patients completed the questionnaires at baseline. Though ETV patients demonstrated a clinically meaningful improvement in HIS (0.03) and LAM patients did not (0.01), the difference (0.02) was not statistically significant (p = 0.12). ETV patients had a trend towards better change in VAS at Week-48 (ETV = 4.13; LAM = 0.91; mean difference estimate ETV-LAM = 2.11; p = 0.21). A larger proportion of ETV patients had improvement or no change in all five health dimensions at Week-48. ETV treatment was superior to LAM in the following dimensions: mobility; self care; pain or discomfort (94% vs. 82%, p = 0.007; 94% vs. 85%, p = 0.03; and 90% vs. 77%, p = 0.01, respectively). **CONCLUSION:** ETV therapy was associated with greater proportions of patients with improvement or no change in mobility, self care, and pain or discomfort after 48-weeks of treatment. ETV patients demonstrated a clinically meaningful improvement in HIS, and greater improvement in VAS from baseline compared to LAM.

PGI17

TEGASEROD SIGNIFICANTLY IMPROVES QUALITY OF LIFE IN PATIENTS WITH IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C)

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OBJECTIVES: To evaluate the impact of tegaserod 6 mg b.i.d. on the quality of life (QoL) of men and women with IBS-C, as defined by Rome II criteria. **METHODS:** A multicenter, open-label, prospective, single-cohort study was conducted in Spain. Patients entered a one-month, treatment-free, baseline period followed by three months' treatment with tegaserod 6 mg b.i.d. and subsequently, a one-month withdrawal period (no treatment). QoL was assessed at the end of baseline, treatment and withdrawal periods using the IBS-QOL; a validated modified disease-specific instrument and the SF-36; a validated generic instrument. Patients recorded their level of IBS symptom relief in a weekly diary. Patients were considered responders (R) if ≥two-weeks' satisfactory relief of global IBS-C symptoms was experienced