ESTABLISHING THE RELATIONSHIP BETWEEN THE ULCERATIVE COLITIS DISEASE ACTIVITY INSTRUMENT (UCDAI) AND PATIENT HEALTH RELATED QUALITY OF LIFE FROM A LARGE RANDOMISED CONTROLLED TRIAL
Poole CD1, Nielsen SK2, Currie CJ1, Connolly M4
1Pharmatelligence, Cardiff, South Glamorgan, UK; 2Ferring International Center, Saint-Prex, Switzerland; 3Cardiff University, Cardiff, UK; 4Global Market Access Solutions, St Prex, Switzerland
OBJECTIVES: The purpose of this study was to conduct a statistical mapping between standard assessments of disease severity in ulcerative colitis (UC) using the ulcerative colitis disease activity index (UCDAI) and a patient reported generic health-related quality of life instrument to estimate patient preference-based health utility. METHODS: Multinomial logistic regression was used to estimate response probabilities to each of the five domains of the EuroQol-5D instrument (EQ-5D) from assessments of UC severity using the original UCDAI and an abbreviated (ie. No endoscopy) UCDAI instrument in patients enrolled into a clinical trial studying the use of oral/rectal mesalazine combination maintenance therapy. Predicted EQ-5D health utility was estimated by Monte Carlo bootstrap simulation. The predictive ability of the response mapping was assessed by comparing estimated and directly measured utility derived from the UK tariff (Dolan, 1999). RESULTS: Evaluable data were available for 128 patients, 59% of whom were male, and for which the median age at screening was 43.5 years (IQR 30 to 54). Using UCDAI item responses as predictor variables, the percentage of variance in domain response attributable to predictor variable change ranged from 20.4% (ANXIETY/DEPRESSION) to 42.5% (SELF CARE). Summary attributable to predictor variable change ranged from 20.4% to 38.0% (ANXIETY/DEPRESSION) to 42.5% (SELF CARE). Summary attributable to predictor variable change ranged from 20.4% to 38.0% (ANXIETY/DEPRESSION) to 42.5% (SELF CARE). The results from this study will enable future investigators to generate health-related utility from the UCDAI in trials where this data was not prospectively collected.

METHODS: The sample consisted of Spanish IBD patients completing the Spanish versions of IBDQ and EQ-5D. EQ-5D scores were estimated using the Spanish tariffs. Algorithms for estimating utilities based on responses to IBDQ were derived for combined IBD population and then separately for CD and UC patients using a stepwise forward OLS regression. The algorithms consisted of a combination of important patient characteristics and significant IBDQ domains. Adjusted R-square and root mean-squared error (RMSE) were used to select the most appropriate algorithm. The ability of the algorithm based on IBD patients to predict the utilities for CD and UC patients was assessed. RESULTS: The sample consisted of 424 IBD patients with a mean age of 35 years and median disease duration of 4.33 years. Disease severity (Harvey-Bradshaw/Rachmilewitz index) was correlated with IBDQ ($r = -0.75$) and EQ-5D ($r = -0.38$). CONCLUSIONS: This regression approach enables clinicians and decision makers to estimate preference based utilities from IBDQ in IBD patients. The algorithm appears to be fairly robust based on the explanatory power of the algorithm and validation results.

PGI25
PSYCHOMETRIC VALIDATION OF TRANSLATION TO SPANISH OF THE REFLUX DISEASE QUESTIONNAIRE (RDQ) AND GASTROINTESTINAL IMPACT SCALE IN PATIENTS WITH GASTROESOPHAGEAL REFLUX DISEASE (GERD)
Tafalla M1, Nuevo J2, Muñoz M3, Zapardiel J4
AstraZeneca, Madrid, Spain
OBJECTIVES: The study aims to document the psychometric characteristics of the Spanish translation of two questionnaires: RDQ to evaluate GERD symptoms and GIS to evaluate impact of symptoms in patients’ daily life. METHODS: A psychometric validation study to evaluate two self-administered questionnaires in 300 patients with reflux symptoms. Each investigator conducted the study on two consultations (basal/2 weeks visits) in one patient with GERD diagnosis and no predictable changes in their health status in the following 16 days (reliability group) and 4 new patients to be treated with a known efficient treatment (sensibility group). RESULTS: A total of 281 evaluable patients were analysed; mean age was 55.6 years (95%CI: 53.9–57.3) and 48% were male. Facticity: More than 80% of patients completed the RDQ (100% Visit 1 and 99.6% Visit 2) and 99.3% GIS questionnaire (both visits). Only 0.71% patients left one missing item in the RDQ and 1.07% in the GIS questionnaire. Validity: RDQ and GIS questionnaires are able to discriminate frequency and intensity of symptoms (p < 0.0001). Reliability of internal consistence: Both questionnaires have a good internal consistence. RDQ showed an alpha value (Cronbach) of 0.70 and CCI of 0.60 in all domains. GIS questionnaire had an alpha value of 0.69 and CCI of 0.45 in all domains. Sensibility to change (sensibility group): Both questionnaires show a high sensitivity to the patient recovery. When the either the physician or the patient found an improvement in the health at two weeks, the differences in the scores were always statistically significant (p < 0.0001). CONCLUSIONS: RDQ and GIS questionnaires have satisfactory reliability, validity and sensibility to change. Both tools are easy to use and suitable to evaluate the impact and the severity of reflux symptoms in GERD patients.

PGI26
DERIVING PREFERENCE BASED UTILITIES FOR CD AND UC PATIENTS: CONVERTING IBDQ INTO EQ-5D UTILITIES
Punjekar YS1, Casellas F2
1Schering-Plough Ltd, Welwyn Garden City, Hertfordshire, UK; 2Mapi Values, Lyon, France
BACKGROUND: Inflammatory Bowel Disease Questionnaire (IBDQ) is a disease specific instrument widely used to assess quality of life (QoL) of patients with inflammatory bowel disease (IBD) particularly patients with Crohn’s Disease (CD) and Ulcerative Colitis (UC). However, decision makers require preference based utilities to allocate health care resources when only QoL data estimated using IBDQ is available. OBJECTIVES: To derive an algorithm capable of generating preference based utilities for IBD patients based on their QoL assessed using IBDQ and to estimate its applicability to CD and UC patients separately.

METHODS: The sample consisted of Spanish IBD patients completing the Spanish versions of IBDQ and EQ-5D. EQ-5D scores were estimated using the Spanish tariffs. Algorithms for estimating utilities based on responses to IBDQ were derived for combined IBD population and then separately for CD and UC patients using a stepwise forward OLS regression. The algorithms consisted of a combination of important patient characteristics and significant IBDQ domains. Adjusted R-square and root mean-squared error (RMSE) were used to select the most appropriate algorithm. The ability of the algorithm based on IBD patients to predict the utilities for CD and UC patients was assessed. RESULTS: The sample consisted of 424 IBD patients with a mean age of 35 years and median disease duration of 4.33 years. Disease severity (Harvey-Bradshaw/Rachmilewitz index) was correlated with IBDQ ($r = -0.75$) and EQ-5D ($r = -0.38$). CONCLUSIONS: This regression approach enables clinicians and decision makers to estimate preference based utilities from IBDQ in IBD patients. The algorithm appears to be fairly robust based on the explanatory power of the algorithm and validation results.

PGI27
DEVELOPMENT AND PSYCHOMETRIC VALIDATION OF A NEW QUESTIONNAIRE MEASURING THE IMPACT OF CHILD GASTROENTERITIS ON PARENTS
Viala-Danten M1, Meunier J2, Arnold B3
1Mapi Values France, Lyon, France; 2Mapi Values, Lyon, France
OBJECTIVES: To define the scoring and assess the psychometric properties of a newly developed questionnaire measuring the
A EUROPEAN CROSS-SECTIONAL STUDY TO EVALUATE SYMPTOM BURDEN AND CLINICAL MANAGEMENT OF GASTROESOPHAGEAL REFLUX DISEASE (RANGE-GREECE)
Karagiannis D1, Vaskantiras V1, Yourgioti G2, Daskos G2, Nikas N2
1Athens Medical Center, Athens, Greece, 2AstraZeneca SA, Athens, Greece

OBJECTIVES: Limited epidemiological data are available concerning gastroesophageal reflux disease (GERD). The aims of this study were to estimate the proportion of patients with GERD-related symptoms in primary care, and to describe the symptom burden and clinical management of the disease.

METHODS: RANGE-Greece was part of a European programme, which was conducted in six countries and comprised similar cross-sectional studies run in parallel. RANGE-Greece recruited retrospectively identified patients who visited an office-based gastroenterologist for a GERD-related reason during a 4-month period (index visit). Consenting subjects were invited to attend a study visit. Data collection was performed for both the index and study visits. Patient-reported outcomes were collected by means of validated questionnaires (RDQ, XQS, GIS, WPAI-GERD).

RESULTS: From the 29,903 patients identified by 23 gastroenterologists, 2116 (7.1%) had GERD-related reasons for the index visit. 505 randomly selected patients, who consented to participation, comprised the analysed population. Mean (±SD) age was 52 (14) years; 52.5% were women. The main reasons for the index visit were: recurrent symptoms after a remission period (41.8%), new reflux symptoms in a treatment-naive patient (35.6%), persistence of previous reflux symptoms (10.9%), and follow-up visit in an asymptomatic patient (5.5%). 57.4% of patients had an endoscopic diagnosis. At the index visit, 99.8% of patients were prescribed a proton pump inhibitor. The study visit was performed after a median of 6.5 months. A total of 40.6% of patients had not changed treatment, whereas 23.6% and 21.0% were still suffering from heartburn and acid regurgitation, respectively (frequency ≥2 days the previous week). Symptom severity was moderate in 29.3% and 22.8% and severe in 3.2% and 4.2% of patients with heartburn and acid regurgitation, respectively. CONCLUSIONS: Despite medical attention and treatment a considerable proportion of patients did not achieve an acceptable control of GERD-related symptoms.

GENDER, AGE AND BODY MASS-RELATED DIFFERENCES IN THE IMPACT OF GASTRO-ESOPHAGEAL REFLUX DISEASE (GERD) SYMPTOMS IN PRIMARY CARE PATIENTS ASSESSED BY THE GASTROINTESTINAL IMPACT SCALE (GIS)
Ferrus J1, Zapardiel J1, Sobreviela E1
1IMAS-CS, Santa Mónica, Madrid, Spain, 2AstraZeneca Spain, Madrid, Spain, 3Quintiles Iberia, Madrid, Spain

OBJECTIVES: GERD is associated with obesity, age and gender in several studies. The GERD impact scale is a validated one-page self-administered questionnaire that asks patients about GERD symptoms.