[1]*Leeds University, Leeds, UK,* [2]*Johns Hopkins University, Baltimore, MD, USA,*
[3]*Universitätsmedizin Berlin, Berlin, Germany,* [4]*Hospital for Special Surgery, New York, NY, USA,*
[5]*UCLA, Los Angeles, CA, USA,* [6]*Paris-Sud University, Paris, France,* [7]*UCB Pharma, Brussels,
Belgium,* [8]*UCB Pharma, Durham, NC, USA,* [9]*Brigham and Women's Hospital, Boston, MA, USA*
OBJECTIVES: To assess effects of CZP+MTX vs placebo (PBO)+MTX on patient reported outcomes in DMARD-naïve patients with severe, active and progressive RA. **METHODS:** Patients in this double-blind randomized study (NCT01519791) were DMARD-naïve with active RA<1yr diagnosis at baseline (BL), fulfilling 2010 ACR/EULAR criteria; ≥4 swollen and ≥4 tender joints; DAS28[ESR]≥3.2; CRP≥10mg/L and/or ESR≥28mm/hr, rheumatoid factor/ACPA positive. Patients were randomized 3:1 to CZP (400mg Wks 0,2,4 then 200mg Q2W to Wk52)+MTX or PBO+MTX. MTX was initiated at 10mg/wk, increased up to 25mg/wk by Wk8, maximum tolerated dose maintained to Wk52. HAQ-DI, PtGADA, Pain VAS, %pts achieving normative physical function (HAQ-DI≤0.5), health-related QoL (SF-36, EQ-5D-3L) were assessed. At Wk52 changes from baseline (CFB) were analyzed using ANCOVA (LOCF imputation); categorical variables were analyzed using logistic regression (non-responder imputation). Data are LS mean CFB (SE) unless otherwise specified. **RESULTS:** 660 (CZP+MTX) and 219 (PBO+MTX) patients were randomized; 655 vs 213 in the full analysis set (patients with baseline and post-baselineL DAS28[ESR]). Baseline characteristics were balanced between study arms; mean (SD) HAQ-DI=1.6 (0.6), Pain VAS=66.1 (22.4), PtGADA=65.3 (22.0). At Wk52, greater improvements from baseline were observed with CZP+MTX vs PBO+MTX in HAQ-DI (-1.0 [0.0] vs -0.8 [0.0], p<0.001; 48.1% vs 35.7% patients reached normative function), pain (-48.5 [1.0] vs -44.0 [1.7], p<0.05), PtGADA (-46.7 [1.0] vs -42.0 [12.5], p<0.05) and health-related QoL measured by SF-36 (physical component summary score=12.4 [0.4] vs 10.7 [0.6], p<0.01; mental component summary score=8.2 [0.5] vs 6.8 [0.7]). Numerically higher proportions of CZP+MTX patients reported no problems in domains of the EQ-5D-3L vs PBO+MTX patients, including mobility, self-care, usual activities, pain/discomfort and anxiety/depression. **CONCLUSIONS:** In DMARD-naïve patients with severe, active and progressive RA, CZP+MTX showed greater improvements at 1-year in physical function, pain, disease activity and health-related QoL compared to PBO+MTX.

PRM144

CULTURAL ADAPTATION INTO SPANISH (SPAIN) OF THE QUESTIONNAIRE "OVERACTIVE BLADDER - FAMILY IMPACT MEASURE (OAB-FIM)"

Arlandis-Guzmán S[1], Martínez-Cuenca E[1], Martínez-García R[2], Bonillo-García M[1], Broseta-Rico E[2], Rejas J[3]
[1]*Hospital Universitario La Fé, Valencia, Spain,* [2]*Hospital Universitario Clínico Valencia, Valencia, Spain,* [3]*Pfizer, Alcobendas, Spain*
OBJECTIVES: To carry-out the cultural adaptation into Spanish (for Spain) of the questionnaire "Overactive Bladder - Family Impact Measure (OAB-FIM)". **METHODS:** The adaptation included linguistic validation through forward and back translations in duplicate, reviewed by a panel experts and a debriefing with relatives of OAB patients, and a phase of preliminary measurement of psychometric properties in OAB patients and their relatives of habitual coexistence, of both genders, ≥18 years of age, newly diagnosed and on-therapy for their symptoms of OAB. Conceptual and linguistic equivalences, internal consistency (α-Cronbach), content validity (the inter-rater Rovinelli-Hambleton index of item congruence) and construct validity were measured. Construct validity included concurrent validity (with scales ZARIT and OABq-SF), and validity of known groups according to the benefit of treatment with TBS scale. Feasibility and burden of administration were also measured. **RESULTS:** 25 couples of patients [mean (SD): 57.2 (16.0) years, 60% women] and relatives [63.0 (14.3) years, 44% women] were enrolled. The OAB-FIM was equivalent conceptually and linguistically to the original, remaining the six initial domains: activities, travel, concern, irritation, sleep and sex. Missing items was low (2.95%). Floor and ceiling effects varied, respectively, between 20%-28%, and 0%-16%. The average time of completion was 5.2 (2.8) minutes. 24.0% needed some help to complete the questionnaire. The Rovinelli-Hambleton index ranked correctly all items in its domain, except for the item 10 which ranked in domains irritation and concern. α-Cronbach varied between 0.948-0.839. Correlations of OAB-FIM with ZARIT were high-to-moderate (0.407-0.753) and moderate-to-small with the OABq-SF (0.004-0.423). Relatives whose patients showed treatment benefit showed scores lower on the scale (lowest impact). **CONCLUSIONS:** A Spanish version of the OAB-FIM conceptually and linguistically equivalent to the original has been obtained. The questionnaire has shown good internal consistency, content validity and construct validity, together with feasibility in the Spanish culture.

PRM145

DEVELOPMENT AND VALIDATION OF A QUESTIONNAIRE ASSESSING THE FEARS AND BELIEFS OF PATIENTS SUFFERING FROM CHRONIC RHEUMATIC DISEASES

Gossec L[1], Saraux A[2], Hudry C[3], Mathoret-Philibert F[3], Poussière M[4], de Chalus T[5], Russo-Marie F[6], Joubert J[7], Chauvin P[8], Berenbaum F[9]
[1]*Sorbonne Universités, Université Pierre et Marie Curie, AP-HP, Hôpital Pitié Salpêtrière, Paris, France,* [2]*CHU de la Cavale-Blanche, Brest Cedex, France,* [3]*AP-HP Hôpital Cochin, Paris, France,* [4]*Independent Researcher, Paris, France,* [5]*UCB Pharma, Colombes, France,* [6]*Arthritis Fondation Courtin, Neuilly-sur-Seine, France,* [7]*UCB Pharma, Paris, France,* [8]*French National Institute of Health and Medical Research (INSERM), Paris, France,* [9]*Sorbonne Universités, Université Pierre et Marie Curie, AP-HP, Hôpital Saint-Antoine, Paris, France*
OBJECTIVES: To develop and validate a patient-reported questionnaire assessing the fears and beliefs of patients suffering from rheumatoid arthritis (RA) or spondyloarthritis (SpA), that could improve educational programs. **METHODS:** Step 1: Qualitative research (individual patient interviews: 25 RA, 25 axial SpA [axSpA]). Step 2: All fears and beliefs appearing in more than 10% of interviews rephrased as questions by an expert group including a patient-partner. Each question scored 0–10 (10= higher fears/stronger beliefs). Step 3: Preliminary questionnaire tested by cognitive debriefing (5 RA, 5 axSpA patients), and reproducibility through a test-retest procedure among 28 patients (13 RA, 15 axSpA). Step 4: Psychometric validation through a cross-sectional study of 226 patients. Internal consistency assessed by Cronbach's alpha,

principal components analysis and descending hierarchical classification. **RESULTS:** Steps 1–3: Development and adaptation of a self-reported 44-item questionnaire on a 0–10 scale of fears and beliefs. 5 domains established a priori: origin of the disease, flares, treatments, disease progression and consequences of disease. Step 4: In the study of 226 patients (161 RA, 65 axSpA), all dimensions were ≥0.79 and ≤0.93, apart from the domain "origin of the disease" (0.67). Principal component analysis identified 6 axes (63.7% of variance explained) and the descending hierarchical analysis identified 9 clusters (63.7% of variance). 2 clusters were highly correlated (r2=0.80) and combined into a single cluster. Based on the psychometric validation, the following domains were identified: fears of the disease progression/consequences (18 items) and fears about treatment (5); beliefs related to: psychological influence (2), genetic influence (2), physical influence (4), diet influence (4), lifestyle (3) and diverse opinions (4). **CONCLUSIONS:** This analysis confirms the internal consistency of the questionnaire developed. The scoring results should help physicians to understand their patients' perceptions of their disease better and eventually lead to improved adherence to treatment.

PRM146

A VALIDITY AND RELIABILITY STUDY OF THE POVERTY RELATED QUALITY OF LIFE QUESTIONNAIRE IN A TURKISH PATIENT POPULATION

Yilmaz F[1], Numanoglu Tekin R[1], Malhan S[2]
[1]*Baskent University, ankara, Turkey,* [2]*Baskent University, Ankara, Turkey*
OBJECTIVES: Measuring poverty in health care settings may contribute to identifying patients in poverty and subsequently getting appropriate management. Although many scales are available to measure poverty in health, less attention has been paid to the poverty related quality of life. The purpose of this methodological study was to adapt the Poverty Related Quality of Life Questionnaire developed by Boyer and others (2014) into Turkish and to evaluate its psychometric properties for a Turkish patient population. **METHODS:** The scale was adapted into Turkish through a translation and back-translation process. The content validity of the scale was assessed using expert approval. The psychometric properties of the scale were investigated by collecting data from 300 patients in 3 emergency departments from random selected hospitals in Ankara during the period of 1 April–30 May 2015. **RESULTS:** An exploratory factor analysis identified that the seven-factor structure accounted for 80.1% of the total variance. A confirmatory factor analysis indicated a sufficient model fit for the construct validity of the scale: root mean square error of approximation, 0.041; comparative fit index, 0.93; general fit index, 0.97; standardized root mean square residual, 0.050. Cronbach's alpha for the total scale was 0.83 and each item achieved the 0.40 standard for item internal consistency. Significant associations with socioeconomic and clinical indicators showed good discriminant validity. **CONCLUSIONS:** This study supports the validity and reliability of the Turkish version of Poverty Related Quality of Life Questionnaire. This instrument can be used to measure multiple aspects of poverty in the health care settings; however, as poverty and quality of life are contextual facts, further work is needed to test the psychometric properties of this scale both in Turkish and different cultures.

PRM147

DEVELOPMENT OF A PREDICTION MODEL OF DISEASE ACTIVITY IN SUPPORT OF CLINICAL PRACTICE – THE ACRODAT EXPERIENCE

Pleil A[1], van der Lely AJ[2], Badia X[3], Brue T[4], Buchfelder M[5], Burman P[6], Ghigo E[7], Gomez R[8], Jorgensen JO[9], Luger A[10], van der Lans-Bussemaker J[8], Webb S[11], Strasburger C[12]
[1]*Pfizer, Inc, San Diego, CA, USA,* [2]*Erasmus University Medical Center, Rotterdam, The Netherlands,* [3]*University of Barcelona, Barcelona, Spain,* [4]*Centre de Recherche Neurobiologie Neurophysiologie, Marseille, France,* [5]*Universitatsklinikum Erlangen, Erlangen, Germany,* [6]*Skåne University Hospital, Malmo, Sweden,* [7]*Univ Degli Studi Di Torino, Torino, Italy,* [8]*Pfizer, Inc, Tadworth/Surrey, UK,* [9]*Aarhus University, Aarhus, Denmark,* [10]*Medical University of Vienna, Vienna, Austria,* [11]*Hospital Sant Pau, Barcelona, Spain,* [12]*Charité Universitätsmedizin, Berlin, Germany*
OBJECTIVES: The objective of this study was to develop and validate a decision algorithm that replicates expert opinion regarding the level of disease activity in patients with acromegaly. **METHODS:** A panel of key experts in endocrinology and outcomes research provided input as to what parameters are critical to assess disease activity. The top five parameters where then subsequently defined at three levels of severity. A final set of 243 unique health states were developed. A group of 21 expert endocrinologists from 5 European countries and Canada was recruited to participate in a discrete choice experiment. Each participant was presented with 10 common scenarios and 42 additional scenarios selected at random and asked to indicate whether the hypothetical patient was stable, having mild disease activity needing further evaluation, or having significant disease activity requiring clinical action. Concordance in decisions based on the 10 common scenarios was tested using Fleiss Kappa and a set of linear prediction models tested to predict outcome. **RESULTS:** The five parameters included: 1) IGF-I level (SDS score); 2) tumor status (change on MRI); 3) comorbidities (number and severity); 4) signs and symptoms (Patient Acromegaly Symptom Questionnaire score); and 5) health-related quality of life (scored on a disease specific measure). The inter-rater reliability was adequate (Kappa = 0.52). Based on a CART analysis, the decision model of best fit was disjunctive with IGF-1 and Tumor status primarily predicting the health status. The remaining three parameters were instructive but not deterministic. **CONCLUSIONS:** Biochemical and tumor status are the primary predictors of disease activity, with the patient's perceived disease state playing a secondary role. This may highlight the need for a more patient-centered approach to acromegaly disease management. To enable clinical use of the model, a disease specific tool named ACRODAT (ACROmegaly Disease Activity Tool) is currently in further development.

PRM148

PHYSICAL FUNCTIONING AND PAIN IN CHRONIC LOW BACK PAIN: A SYSTEMATIC REVIEW OF PSYCHOMETRIC PROPERTIES OF VARIOUS OUTCOMES MEASURES

Kanukula R[1], Vsn M[1], Ganji K[2], Likhar N[1], Dang A[1]