OBJECTIVES: To evaluate the preferences of osteoporotic patients for medication attributes in Belgium and Ireland, and to assess whether preferences are transferable across these jurisdictions. **METHODS:** A discrete-choice experiment was designed in which patients were asked to choose between two unlabelled drug alternatives (and an opt-out option), which vary in five attributes: efficacy in reducing the risk of fracture, type of potential common side-effects, mode and frequency of administration and out-of-pocket costs. An efficient experimental design was used to construct the sets of treatment options and a mixed logit panel data model was employed to estimate patients' preferences. To assess the significance of the differences between countries, a joint model was estimated using interaction terms. **RESULTS:** A total of 257 Belgian and 200 Irish osteoporotic patients completed the experiment. In both countries, patients preferred a drug treatment with a higher risk reduction and a lower cost. They disliked more being at risk of gastro-intestinal disorders than at risk of skin reactions and flu-like symptoms and preferred 6-month subcutaneous injection compared with weekly oral tablets. In Belgium, patients also preferred oral monthly tablet over weekly tablets, while Irish patients preferred yearly intravenous over weekly tablets. Some differences between countries were significant. Irish patients attached higher value to being at risk for skin reactions or flu-like symptoms, and the parameter of yearly intravenous was higher (and significant) in Ireland. In addition, higher costs are more acceptable for Irish patients. These differences were generally robust in subgroups analyses including patients over 65 years, with prior fracture, high income or high education. **CONCLUSIONS:** In this study, the preferences of osteoporosis patients for drug therapy did not substantially differ between two European countries. Only for levels of some attributes significant differences were observed, which could not only be related to health and socio-demographic factors.

PMS80

LONG-TERM MAINTENANCE OF IMPROVEMENTS IN PATIENT-REPORTED OUTCOMES WITH CERTOLIZUMAB PEGOL IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS, INCLUDING ANKYLOSING SPONDYLITIS AND NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS: 48-WEEK RESULTS OF THE RAPID-AXSPA STUDY

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OBJECTIVES: To report the effect of certolizumab pegol (CZP), a PEGylated Fc-free anti-TNF, on patient-reported outcomes (PROs) in axial spondyloarthritis (axSpA), including ankylosing spondylitis (AS) and non-radiographic axSpA (nr-axSpA), over 48 weeks (wks) in the RAPID-axSpA trial. **METHODS:** The ongoing RAPID-axSpA trial (NCT01087762) is double-blind and placebo (PBO)-controlled to Wk24 and dose-blind to Wk48. Patient (pts) fulfilled ASAS criteria and had active axSpA. Pts originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose at Wks 0, 2, 4) continued on their assigned dose in dose-blind phase; PBO pts entering dose-blind phase were re-randomized to CZP loading dose followed by CZP 200mg Q2W or 400mg Q4W. We report efficacy data for the full analysis set (FAS) originally randomized to CZP. PRO endpoints included physical function (BASFI), total spinal pain, fatigue (from BASDAI), ASQoL, Sleep Problems Index II domain of MOS Sleep scale, and SF-36. Missing data were imputed by LOCF. **RESULTS:** Of 111 and 107 pts randomized to CZP 200mg Q2W and 400mg Q4W, 105(94.6%) and 98(91.6%) completed the double-blind period, and 98(88.3%) and 93(86.9%) completed the dose-blind period. Rapid improvements from baseline to Wk24 were maintained to Wk48, for both CZP 200mg Q2W and 400mg Q2W, in total spinal pain (Wk24: -3.3 and -3.2; Wk48: -3.6 and -3.5), fatigue (Wk24: -2.6 and -2.8; Wk48: -2.8 and -2.9), BASFI (Wk24: -2.4 and -2.3; Wk48: -2.6 and -2.4), ASQoL (Wk24: -5.1 and -5.1; Wk48: -6.0 and -5.6) and sleep (Wk24: -12.7 and -12.9; Wk48: -14.7 and -14.2). CZP-treated pts also maintained improvements in SF-36 components and domains. Similar outcomes were seen in AS and nr-axSpA populations. **CONCLUSIONS:** Improvements in PROs observed with both CZP dosing regimens were maintained over 48 wks, including those in pain, fatigue, physical function and HRQoL. Maintenance was observed in both AS and nr-axSpA pts.

PMS81

LONG-TERM MAINTENANCE OF IMPROVEMENTS IN MULTIPLE FACETS OF PSORIATIC ARTHRITIS WITH CERTOLIZUMAB PEGOL: 48-WEEK PATIENT-REPORTED OUTCOME RESULTS OF THE RAPID-PSA STUDY

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OBJECTIVES: To report the effect of certolizumab pegol (CZP), a PEGylated Fc-free anti-TNF, on patient-reported outcomes (PROs) in psoriatic arthritis (PsA) over 48 weeks (wks) in the RAPID-PsA trial. **METHODS:** The ongoing RAPID-PsA trial (NCT01087788) is double-blind and placebo-controlled to Wk24 and dose-blind to Wk48. Patients (pts) had active PsA and had failed ≥1 DMARD. Pts originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose at Wks 0, 2, 4) continued on their assigned dose in dose-blind phase; placebo pts entering dose-blind phase were re-randomized to CZP loading dose followed by CZP 200mg Q2W or 400mg Q4W. We report efficacy data for the randomised set (RS) of pts originally randomized to CZP. Mean changes from baseline in patient assessment of pain (VAS), fatigue assessment scale (NRS), HAQ-DI, SF-36, PsAQoL and Dermatology Life Quality Index (DLQI) were assessed with LOCF imputation. **RESULTS:** Of 138 and 135 pts randomized to CZP 200mg Q2W and 400mg Q4W, 128 (92.8%) and 120 (88.9%) completed the double-blind period, and 123 (89.1%) and 114 (84.4%) completed the dose-blind period, respectively. Rapid improvements from baseline to Wk24 observed in double-blind period were maintained to Wk48 for pain (Wk24: -28.6 and -28.4; Wk48: -31.6 and -29.5), fatigue (Wk24: -2.2 and -1.9; Wk48: -2.4 and -2.0), HAQ-DI (Wk24: -0.52 and -0.43; Wk48: -0.56 and -0.49), SF-36 physical component summary (Wk24: 8.4 and 7.6; Wk48: 8.6 and 8.4) and mental component summary (Wk24: 5.5 and 3.5; Wk48: 4.8 and 3.2), PsAQoL (Wk24: -4.4 and -3.3; Wk48: -4.8 and -3.5), and DLQI (Wk24: -6.3 and -5.2; Wk48: -6.2 and -5.6) for CZP 200mg Q2W and 400mg Q4W patients, respectively. **CONCLUSIONS:** Improvements in generic and disease-specific PROs observed over 24 wks were sustained over 48 wks in CZP-treated PsA pts. Improvements were observed regardless of CZP dose regimen.

PMS82

EXPANDING THE MEASUREMENT OF TREATMENT BENEFIT IN RHEUMATOID ARTHRITIS: THE ROLE OF THE PATIENT-REPORTED OUTCOME CONSORTIUM'S RA WORKING GROUP

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OBJECTIVES: To develop a patient-reported outcome (PRO) instrument that can be qualified by the Food and Drug Administration (FDA) for use in rheumatoid arthritis (RA) randomized controlled trials (RCTs) to support treatment benefit claims. **METHODS:** On August 28, 2012, a consensus development workshop was held by the RA Working Group (WG) within the Critical Path Institute's PRO Consortium to identify RA-related PRO concepts to determine their potential role in the documentation of treatment benefit in RA RCTs. Key stakeholders participated in this one-day meeting, including RA patients, representatives from the FDA (Division of Pulmonary, Allergy, and Rheumatology Products [DPARP] and Study Endpoints and Labeling Development [SEALD]), experts from the American College of Rheumatology (ACR), European League Against Rheumatism (EULAR), Outcome Measures in Rheumatology (OMERACT), National Institutes of Health (NIH, NIAMS) and the pharmaceutical industry (RA WG members). **RESULTS:** Over the course of the workshop, a consensus emerged that there are several outcomes important to RA patients not explicitly assessed by the ACR response criteria (i.e., fatigue, stiffness, and social participation). Finally, consensus amongst the various stakeholders was reached that any new measure needs to provide information over and above what is currently captured by the traditional primary composite endpoints and the priority would be to focus on FDA qualification of a PRO measure evaluating RA-related fatigue. **CONCLUSIONS:** The RA WG is initiating a collaboration with clinical experts through OMERACT to provide an operational definition of fatigue and to develop a conceptual framework to support its measurement in clinical trials. Following this preliminary step, qualitative and quantitative steps will be launched to develop the fatigue measure.

PMS83

SHORT RUN DYNAMICS OF INADEQUATE PAIN RELIEF (IPR): EVIDENCE FROM A EUROPEAN MULTINATIONAL SURVEY OF REAL WORLD THERAPIES (SORT)

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Osteoarthritis (OA) is the most prevalent musculoskeletal disorder and has been associated with poorer quality of life for patients who experience heightened pain and decreased functionality. Despite the importance of OA management in clinical practice settings, there has been limited evidence confirming the adequacy of pain relief in patients with knee OA who take analgesics to manage their symptoms. **OBJECTIVES:** To assess changes in pain relief states in the short run (30 days) and evaluate associated changes in outcome measures: SF-12, Brief Pain Inventory (BPI) and WOMAC in participants with knee OA. **METHODS:** The Survey of Real World Therapies (SORT), a 12-month prospective study across 6 EU countries (N=1,254), enrolled participants > 50 years old with knee OA who were prescribed analgesics. Patient-reported outcomes measures were collected at baseline and one month post baseline: BPI, SF-12 and WOMAC. Inadequate pain relief (IPR) was defined as BPI pain score of "moderate or greater pain" (>4). **RESULTS:** A total of 1153 participants were included: 67.3% women; mean age 68 years (SD=9.4); mean OA duration 5.9 years (SD=6.2). 54% of participants reported experiencing IPR. After 30 days, 28% of participants reported changes in pain relief, which was equally distributed (14% each) between the two baseline pain-relief states. Changes in IPR states were significantly associated with changes in SF-12 composite summary scores and WOMAC subscales. Patients who reported improvements in pain scores showed statistically significant improvements in average pain (2.7 points) and both QOL composite measures ($p<0.01$): WOMAC subscales improvement ranged from 8-11 points and the Physical and Mental Component Summaries scores decreased 1.83 and 1.79 points, respectively. Those who experienced worsening pain had an increase in average pain of 2.7 points on the BPI. These participants showed statistically significant decreases in QOL - WOMAC scores decreased between 4-9 points and PCS and MCS scores increased 2.10 and 2.27 points, respectively. **CONCLUSIONS:** Changes in pain states were significantly associated with overall quality of life and physical function.

PMS84

HEALTH OUTCOMES AND ECONOMIC BURDEN OF POST-KNEE REPLACEMENT SURGERY IN OSTEOARTHRITIS PATIENTS: COMPARISON WITH MATCHED CONTROLS

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OBJECTIVES: Osteoarthritis (OA), a degenerative condition of the articular cartilage, primarily affects the knee joint and surgery is often required for late-stage patients. The number of total knee arthroplasties (TKAs) is expected to grow to 3.48 million procedures by 2030 in the US alone. However, the devices lack an ideal safety profile. The objective of this study was to examine real-world outcomes among OA patients post-knee replacement. **METHODS:** Data from the 2012 U.S. National Health and