A385

95% CI: 0.53-2.07) and psoriasis (OR: 1.07; 95% CI: 0.56-2.03). CONCLUSIONS: More than half of the PsA patients were persistent with the index subcutaneous biologic over a 12-month period with similar persistence rates observed among those with and without psoriasis and DMARD use.

### PMS69

IMPACT OF MEDICATION ADHERENCE BY USING INDIAN VERSION COMPLIANCE QUESTIONNAIRE RHEUMATOLOGY (CQR) AND MEDICATION ADHERENCE REPORT SCALE (MARS) TOOLS ON QUALITY OF LIFE OF PATIENTS WITH RHEUMATOID ARTHRITIS

<u>Shetty R<sup>1</sup>, Reddy K<sup>2</sup>, Inam S<sup>2</sup>, Khera K<sup>1</sup></u> <sup>1</sup>Manipal College of Pharmaceutical Sciences, Manipal, India, <sup>2</sup>Manipal Univiersity, Manipal, India OBJECTIVES: To assess medication adherence to DMARD in patients with Rheumatoid Arthritis using CQR and MARS tools, identification of factors affecting adherence and its effect on quality of life. METHODS: A randomly selected sample of 110 adult patients with RA on DMARDs admitted to hospital were asked about their medication adherence, through self-report questionnaire [CQR and MARS] and quality of life was assessed by HAQ (Health Assessment Questionnaire). Additionally, various factors affecting adherence were identified. **RESULTS:** According to the tools used, 86.4% (CQR), 74.29% (MARS -mean cut point) and 95.45% (MARS -prior study cut point) of patients showed adherence towards DMARD. Better adherence was seen in patients with primary education (COR- 94%) or secondary education (MARS -83%). Patients who suffered from RA for more than 2yrs showed better adherence (CQR- 93%) compared to those with recent disease (<2yrs) (CQR- 89%). Non adherence was seen in patients having co-morbidities compared to patients with only RA (CQR- 91% vs 94%; MARS- 62% vs 82%). Mean HAQ of adherent patients was better (2.83±1.05) than non-adherent patients (3.23±0.74). Adherent patients showed mod-erately active disease state (Mean DAS – 5.96±1.67) whereas, non-adherent patients showed highly active disease state (Mean DAS –  $6.70 \pm 0.84$ ). CONCLUSIONS: Patient reported questionnaires showed disease duration of less of 2yrs, and patients with co-morbidities lead to Non-adherence which worsened disease activity which lead to decreased quality of life.

### PMS70

# QUALITY OF LIFE IN PSORIATIC ARTHRITIS: CONSISTENT AND STABLE ACROSS DATASETS

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OBJECTIVES: Psoriatic arthritis (PsA) is a multi-factorial disease that affects the skin, joints and soft tissues. Two of the commonly used measures for PsA are the Psoriasis Area and Severity Index (PASI, 0-100 scale) and the Health Assessment Questionnaire (HAQ, 0-3 scale) for skin and joints symptoms, respectively. Previous work in the area has estimated a relationship between these patient-reported instruments and utility (SF-36 mapped to the EQ-5D). The objectives of this study were to calculate patient-reported utility and investigate the consistency of the relationship between PASI, HAQ and utility with previously published estimates, based on the PSUMMIT trials of ustekinumab versus placebo. METHODS: Patient level data from PSUMMIT1 (anti-TNF $\alpha$  naïve) and PSUMMIT2 (both anti-TNF $\alpha$  naïve and experienced) were analysed in Stata 11. SF-36 data were converted to EQ-5D using the mapping by Rowen et al., with regression analysis used to estimate the relationship between PASI, HAQ and the resulting utility (including multiplicative terms). Goodness of fit was determined by the adjusted  $R^2$  and Root Mean Squared Error (RMSE). **RESULTS:** Anti-TNFα naïve and experienced patients had a baseline utility of 0.50 and 0.48, respectively. Utility improved over the 24-week blinded period by 0.04/0.06 in the placebo arms for anti-TNF $\alpha$  naïve and experienced, and 0.11/0.13 in the treatment arms. In regression analysis utility was predicted as 0.897 - 0.004xPASI - 0.298xHAQ (adjusted R<sup>2</sup> 0.60, RMSE 0.12), similar to previously published estimates. Adding a multiplicative term for PASI and HAQ did not improve goodness of fit statistics, although baseline methotrexate use was linked to a lower utility. CONCLUSIONS: Patients with PsA have a low level of health-related quality of life that improves with treatment. The determinants of utility in the PSUMMIT trials were the skin and joint symptoms faced by patients, in keeping with previous estimates.

#### **PMS71**

PATIENT PREFERENCES IN THE CHOICE OF DISEASE MODIFYING ANTI-RHEUMATIC DRUGS

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OBJECTIVES: There is a variety of biologic and non-biologic disease modifying antirheumatic drugs (DMARDs) available for the treatment of rheumatoid arthritis (RA). These DMARDs are associated with different characteristics in key attributes such as mode of administration, side effects, etc. The current study assessed the importance of treatment characteristics for RA patients' preferences. METHODS: In a discrete choice experiment (DCE), 1570 RA patients are asked to choose the most and the least preferred DMARD (best-worst-scaling) among hypothetical multi-attribute treatment alternatives with varying levels of key attributes, as defined in focus groups: mode of administration, frequency of administration, time till onset of drug effect, necessity of combination therapy with methotrexate, and side effects. The multi-profile case design simulates a real choice situation between different hypothetical treatment alternatives. Interim analysis was conducted after half the sample size had been reached. RESULTS: Interim analysis included 836 patients from 33 office based rheumatologists across Germany. Majority of patients were female (74%), 50 to 64 years of age (46%), with <10 years of disease duration (54%), and reported experience with injectable DMARDs (63%). Mode of administration appeared the most important attribute guiding patients' preferences, with 'oral application' being most desired (selected as best option in 51% of the cases) and

infusion being least preferred (worst option in 45% of the cases). The second most relevant attribute was "necessity of combination therapy with methotrexate", with DMARDs not requiring such combination being most preferred (in 43% of the cases). CONCLUSIONS: Our data indicate that, of the included attributes, the most important ones are route of administration (oral being the number one choice by majority) and combination therapy with methotrexate (with DMARDs not requiring such combination being the most preferred) for RA patients' choice. This research was funded by Pfizer GmbH.

#### **PMS72**

# ARE PATIENTS' PREFERENCES TRANSFERABLE BETWEEN COUNTRIES? A CROSS-EUROPEAN DISCRETE-CHOICE EXPERIMENT TO ELICIT PATIENTS' PREFERENCES FOR OSTEOPOROSIS DRUG TREATMENT

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#### PMS73

# 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: 96-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 96 weeks (wks) of the RAPID-axSpA trial. METHODS: The RAPID-axSpA trial (NCT01087762) is double-blind and placebo-controlled to Wk24, dose-blind to Wk28, and open-label to Wk204. Patients fulfilled ASAS criteria and had active axSpA. Patients originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose at Wks 0, 2, 4) continued on their assigned dose in the dose-blind phase and OLE. Here we report PRO data for the CZP-treated randomized set, including mean change from baseline and the proportion of patients achieving a Minimal Clinically Important Difference (MCID). Missing data were imputed by LOCF. Correlations between clinical and patient-reported outcomes were also investigated. **RESULTS:** Of 218 patients randomized to CZP, 203 (93%) completed Wk24, 191 (88%) Wk48, and 174 (80%) Wk96. Rapid improvements from baseline to Wk24 were maintained to Wk96 in all patient subpopulations (overall ax5pA, AS, nr-ax5pA) in pain (Wk24: -3.2, -3.2, -3.3; Wk96: -3.6, -3.7); fatigue (Wk24: -2.7, -2.5, -2.9; Wk96: -2.9, -2.8, -3.1); BASFI (Wk24: -2.4, -2.3, -2.4; Wk96: -2.6, -2.6, -2.6); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1) and sleep (Wk24: -2.4, -2.3, -2.4; Wk96: -3.6, -3.6); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1) and sleep (Wk24: -2.4, -2.3, -2.4; Wk96: -3.6, -3.6); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQOL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQUL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQUL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQUL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5, -6.1); ASQUL (Wk24: -5.1, -4.8, -5.5; Wk96: -5.7, -5.5; Wk96; -5.7; -5.5; Wk96; -5.7, -5.5; Wk96; -5.7; -5.5; -5.5; Wk96; -5.7; -5.5; -5.5; Wk96; -5.7; -5.5; -5 -12.8, -10.5, -15.7; Wk96: -13.9, -11.6, -16.7). CZP-treated patients also maintained improvements in SF-36 components and domains. Sustained improvements in the proportion of patients (overall axSpA, AS, nr-axSpA) achieving MCID (%) were observed in fatigue (Wk24: 78.4, 76.0, 81.4; Wk96: 67.0, 70.2, 62.9); BASFI (Wk24: 67.4, 68.6, 66.0; Wk96: 64.2, 68.6, 58.8) and ASQoL (Wk24: 69.3, 71.1, 67.0; Wk96: 65.6, 66.9, 63.9). Similar outcomes were seen with both dosing regimens. Correlations were observed between improvements in PROs (pain/fatigue/SF-36) and clinical outcomes (ASDAS) (data not shown). CONCLUSIONS: Improvements in PROs (including pain, fatigue and ASQoL) were maintained over 96 wks in both the AS and nr-axSpA subpopulations. Sustained improvements in the proportion of patients achieving MCID were also reported.

#### PMS74

# INADEQUATE PAIN RELIEF AMONG PATIENTS WITH PRIMARY KNEE OSTEOARTHRITIS - ANALYSIS FROM THE PORTUGUESE SAMPLE OF THE SURVEY OF OSTEOARTHRITIS REAL WORLD THERAPIES (SORT)

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#### PMS75

# QUALITATIVE EQUIVALENCE BETWEEN A PAPER AND ELECTRONIC TABLET VERSION OF THE WOMAC®NRS3.1 AND PATIENT GLOBAL ASSESSMENT Eremenco S<sup>1</sup>, Fleming S<sup>2</sup>, Riordan D<sup>3</sup>, Stringer S<sup>1</sup>, Gleeson S<sup>1</sup>, Sanga P<sup>4</sup>, Kelly K<sup>5</sup>

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**OBJECTIVES:** Prior equivalence work with the WOMAC® scale was published for the VAS scale and older touchscreen computer technology. Additional equivalence evaluation of the WOMAC®NRS3.1 and the Patient Global Assessment (PGA) in a newer tablet with stylus was needed to document suitability of this mode of data collection for these instruments in upcoming clinical trials. METHODS: A cross-sectional qualitative study was conducted involving cognitive and usability interviews with patients diagnosed with osteoarthritis of the hip or knee who were taking pain medication for their condition. Interviews were conducted in two waves of 10 participants each, with revisions to the PGA made in between the rounds, which allowed for changes to the electronic version to be evaluated. RESULTS: Mean age of the sample (N=20) was 66 years, (range 43-78), 90% over 60 years old; 60% were female; 95% were white; 75% were retired; 70% had completed secondary school or some college, while 30% had completed college or a post-graduate degree. In wave 1, minor issues were found with completing the WOMAC®, mainly with using the stylus to select responses and glare on the screen. There were no issues identified in interpreting the response scale. For the PGA, 50% (5/10) used the wrong recall period (48 hours or longer). The PGA recall period was revised from "at this time" to "over the past 24 hours" and bolded for emphasis. In wave 2, similar issues with glare and stylus response were found, while 80% used the correct recall period on the PGA, with 20% using 48 hours. CONCLUSIONS: The study showed excellent qualitative equivalence between the paper and electronic WOMAC® with only minor usability issues. The two wave study design provided the opportunity to detect and make changes to the PGA recall period and formatting that showed improvement in the second wave.

#### PMS76

# LONG-TERM MAINTENANCE OF IMPROVEMENTS IN MULTIPLE FACETS OF PSORIATIC ARTHRITIS WITH CERTOLIZUMAB PEGOL: 96-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 96 weeks (wks) of the RAPID-PsA trial. **METHODS:** The RAPID-PsA trial (NCT01087788) is double-blind and placebo-controlled to Wk24, dose-blind to Wk48 and open-label to Wk216. Patients had active PsA and had failed ≥1 DMARD. Patients originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose at Wk0, Wk2, Wk4) continued on their assigned dose in the dose-blind phase and OLE. Here we present PRO data for the CZP-treated randomized set, including mean change from baseline (CFB) and Minimal Clinically Important Differences (MCIDs). Data were also analysed for CZP-randomized patients with (19.8%) or without (80.2%) prior anti-TNF exposure. Missing data were imputed by LOCF. Correlations between clinical outcomes and PROs were also investigated. **RESULTS:** Of 273 patients randomized to CZP at Wk0, 91% completed Wk24, 87% Wk48, and 80% Wk96. Rapid improvements observed to Wk24 were maintained to Wk96 for pain (Wk24 and Wk96; CFB: -28.5 and -31.3; MCID: 69.2% and 66.3%), fatigue (Wk24 and Wk96; CFB: -2.0 and -2.4; MCID: 64.1% and 60.4%), HAQ-DI (Wk24 and Wk96; CFB: -0.48 and -0.52; MCID: 48.7% and 48.0%), SF-36 PCS (Wk24 and Wk96; CFB: 8.01 and 9.01; MCID: 67.4% and 60.1%), SF-36 MCS (Wk24 and Wk96; CFB: 4.50 and 3.92; MCID: 50.9% and 43.6%), PsAQoL (Wk24 and Wk96; CFB: -3.87 and -4.50), and DLQI (Wk24 and Wk96; CFB: -5.8 and -6.0; MCID: 40.7% and 41.0%). Similar improvements were observed with both dosing regimens and in patients with or without prior anti-TNF exposure. Correlations were observed between improvements in PROs and DAS28 (data not shown). **CONCLUSIONS:** Improvements observed to Wk24 in generic and disease-specific PROs were sustained to Wk96 of the RAPID-PsA trial for both CZP dosing regimens.

# PMS77

# USABILITY TESTING OF A NOVEL PAIN MEDICATION DIARY ADMINISTERED ELECTRONICALLY

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**OBJECTIVES:** Pain medication diaries have traditionally been collected via paper due to challenges of patients entering unlimited medications, units, dosages, and administration schedules. This study developed an electronic diary that permits site staff to enter medications that patients are taking, enables the patient to update medication taken and to enter new medications within the reporting period, and reduces the possibility of cheating behaviors during the study. Usability of this electronic diary was evaluated to ensure that patients in a clinical trial setting could successfully update their diaries in real-time to accurately track pain medication intake. METHODS: A cross-sectional qualitative study was conducted involving usability interviews with patients diagnosed with osteoarthritis of the hip or knee who were taking pain medication. Interviews were conducted in two waves of 10 participants each, allowing for evaluation of findings and revisions to the eDiary between waves. **RESULTS:** Mean age of the sample (N=20) was 66 years (range 43-78), 90% over 60 years old; 60% were female; 95% were white; 70% completed secondary school or some college. In wave 1, issues were noted with training, selecting responses, exiting to send data, and some wording. For wave 2, the training module was revised to more closely match the diary, wording was revised, and a screen added to facilitate exiting the diary. No issues were noted with training, 4 had trouble selecting responses, and 3 suggested additional instructions on the new screen. No additional changes were made following wave 2. CONCLUSIONS: The study showed it is possible to develop an electronic pain medication diary that allows patients to update their medications during a study. Extensive training was critical to the usability of the electronic version. The two wave study design provided the opportunity to detect and make changes to the eDiary with marked improvement in wave 2.

# PMS78

QUALITY OF LIFE IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS IN CLINICAL PRACTICE IN SWEDEN: BASELINE RESULTS FROM A LONGITUDINAL STUDY Jacobsson L<sup>T1</sup>, Husmark T<sup>2</sup>, Theander E<sup>3</sup>, Henriksson K<sup>4</sup>, Johansson M<sup>5</sup>, <u>Büsch K<sup>5</sup></u> <sup>1</sup>Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden, <sup>2</sup>Falu Hospital, Falun, Sweden, <sup>3</sup>Lund University, Malmo, Sweden, <sup>4</sup>Rheumatology city clinic, Stockholm, Sweden, <sup>5</sup>AbbVie AB. Sohna. Sweden

OBJECTIVES: Spondyloarthritis (SpA) is a group of diseases that share common clinical, radiographic and genetic features. Axial SpA is one major subgroup including patients with radiographic (rad-axSpA) and non-radiographic axSpA (nr-axSpA). There has been limited research on axSpA patients in clinical practice and the impact of the disease on patient's health-related quality of life (HrQoL). The aim of this study was to characterize patients with axSpA in clinical practice and to investigate similarities/differences between rad-axSpA and nr-axSpA with respect to their HrQoL. METHODS: This is a longitudinal, multi-center cohort study where patients were consecutively recruited from Swedish clinical practice and followed for 3 months. At baseline, the rheumatologists registered information on disease history, extra articular manifestations and treatments. The patients answered online questionnaires capturing patient demographics, disease activity, function and HrQoL. HrQoL was measured using the EQ-SD and the Ankylosing Spondylitis Quality of Life Questionnaire (ASQoL). While higher scores in the EQ-5D indicate better HrQoL, the opposite is true for the ASQoL. RESULTS: 251 patients were included of whom 197 (78%) were classified as axial SpA. Of those, 125 (63%) were classified as rad-axSpA and 72 (37%) as nr-axSpA according to the ASAS axSpA criteria. There were more women in the nr-axSpA group (50%) compared with the rad-axSpA group (38%). The nr-axSpA patients had a shorter time between symptom onset and diagnosis than the rad-axSpA patients (6.7 vs. 9.0 years) and a significantly higher disease activity (BASDAI=4.1 vs 2.7, p<0.001). Mean EQ-5D score at baseline was 0.66 for rad-axSpA and 0.61 for nr-axSpA, lower than the Swedish general population (0.84). ASQoL scores was significantly higher in the nr-axSpA group (8.8 vs 6.4, p=0.016). CONCLUSIONS: HRQoL is poorer in axial SpA patients compared to the general population and patients with nr-axSpA reported a higher impact on HRQoL than patients with rad-axSpA.

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# FUNCTIONAL STATUS, QUALITY OF LIFE AND WORK DISABILITY FOR PATIENTS WITH RHEUMATIC DISEASES IN GREECE

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**OBJECTIVES:** Rheumatic diseases (RD) have been associated with functional and work-related disability due to the deliberating and progressive nature of these diseases and have many deleterious consequences on patients' life. *The aim of the*