except for the Lupus-specific HRQoL measures, lacked SLE patient involvement during development limiting their content validity. The HADS, SF-36v2, EQ-5D-3L and WPAI:Lupus showed suitability for SLE economic models. **CONCLUSIONS:** SLE is a condition associated with clear unmet medical needs and considerable burden to patients. This review highlights the current availability and future need for both disease-specific and generic patient-reported measures of relevant domains of disease signs and symptoms, HRQoL and work productivity.

#### PRM147

MODE EQUIVALENCE OF INTERACTIVE VOICE RESPONSE (IVR) AND PAPER VERSIONS OF THE BRIEF PAIN INVENTORY (BPI) "WORST PAIN" ITEM IN METASTATIC CASTRATE RESISTANT PROSTATE CANCER (MCRPC) EVALUATED CONCEPTUALLY USING QUALITATIVE METHODS

Bennett A<sup>1</sup>, Eremenco S<sup>2</sup>, Heon N<sup>3</sup>, Scheffold C<sup>4</sup>, Schimmoller F<sup>4</sup>, Weitzman A<sup>4</sup>, Basch E<sup>1</sup> <sup>1</sup>University of North Carolina, Chapel Hill, NC, USA, <sup>2</sup>Evidera, Bethesda, MD, USA, <sup>3</sup>Memorial Sloan-Kettering Cancer Center, New York, NY, USA, <sup>4</sup>Exelixis Inc, South San Francisco, CA, USA OBJECTIVES: The BPI "pain at its worst in the last 24 hours" item is often administered as a primary or key secondary endpoint in clinical trials using an IVR daily diary. However, evidence of equivalence between the validated paper version and IVR has not been published. This study evaluated conceptual equivalence between IVR and paper version of this item using qualitative methods. METHODS: Twentysix patients with mCRPC in a non-randomized expansion cohort (N=144) of phase 2 study XL184-203 were interviewed to confirm their comprehension of the BPI "worst pain" item administered using an IVR simulation by the interviewer and presented on paper. Patient interpretation of the item's meaning in both modes was elicited and compared to identify similarities between the modes. Patients were also interviewed regarding the usability of IVR during the trial. **RESULTS**: Patients (median age = 68; range 44-81) had ECOG performance status of 0 (38%) and 1 (62%). Nearly all patients answered the IVR version of the question as intended by considering the past 24 hours (72%; 18% did not specify); including non-cancer related pain (96%); and reporting pain experienced with analgesia (100%). Patients did not interpret the paper version of the pain question differently from the IVR version; 4 patients spontaneously stated that the paper version was the same as the IVR version they had used. All patients reported that the IVR was easy to use to answer the diary. CONCLUSIONS: This study provides important qualitative support of conceptual equivalence between an IVR and paper version of the BPI "worst pain" item. These results confirm that this item is well understood by patients, and that they interpret the question similarly whether administered via IVR or on paper. The results also show good usability and acceptability of IVR administration of this important item in clinical trials.

### PRM148

## A COMPARISON OF THE RELATIVE WEIGHTS OF HEALTH DOMAINS ON GLOBAL RETROSPECTIVE AND EXPERIENCED HEALTH AND WELL-BEING

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OBJECTIVES: Are the relative weights of different dimensions of health different when determined by their impact on subjective well-being (SWB; 2 types of self-report: retrospective global evaluation, momentary experience) and health (3 types of self-report: retrospective global evaluation, future prospect, momentary experience). METHODS: The study population consisted of persons experiencing psychosomatic, psychological and somatic illness, and members from public. The experience sampling study took 6 days, during which momentary self-reports of health and SWB were obtained. In addition, participants completed retrospective global evaluations of health (EQ-5D), SWB (Life Satisfaction Scale) and preference for a future prospect of health (time trade-off). Regression analysis was used to determine relative weights of EQ-5D dimensions on the outcomes. RESULTS: A total of 139 participants were included. Some/moderate problems in usual-activities and anxiety/depression were associated with the largest drop in health for all three types of self-report. Moderate anxiety/depression had a larger impact than moderate problems in usual-activities in momentary as compared to retrospective healthreports. Moderate problems in usual-activities and anxiety/depression and selfcare were associated with a drop in retrospective and momentary SWB. Moderate problems in usual-activities was associated with the largest drop in retrospective SWB, while moderate anxiety/depression was associated with the largest drop in momentary SWB. Comparing the relative weights, it was shown that anxiety/depression was more important relative to usual-activities in momentary experiences than in retrospective evaluations. CONCLUSIONS: Relative weights of health domains are different, depending on the type of self-report (global or momentary) and concept of value (health or SWB) used. Most notably, the relative weight of anxiety/ depression is larger when using a momentary measure, and when taking SWB as the outcome of interest. This finding warrants further discussion and research on the place and value of momentary measures of experience and SWB as outcome in health (economic) evaluation.

### PRM149

### PATIENT SURVEY: INVESTIGATION ON WHAT IMPACTS PATIENT SATISFACTION, DROP-OUT AND COMPLIANCE IN PATIENT DIARIES

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**OBJECTIVES:** Patient Reported Outcomes (PROs) play an important role in patient-centered research where compliance is important. To better understand patient preferences when participating in PROs, survey research was conducted in 2013. This presentation investigates what impacts patient satisfaction, drop-out and compliance. **METHODS:** An internet-based survey was administered to a global

sample of patients who participated in at least 1 clinical trial that included patient diaries in the past 2 years. The survey asked questions about the most recent trial  $\,$ with a diary focusing on the patient's diary experience. RESULTS: A total of 398 patients provided complete responses. On a scale of 1-7 (1=Very Bad: 7=Very Good). mean satisfaction rating=5.4. Satisfaction was categorized for sub-group analysis purposes: Positive Satisfaction (75%); Ok Satisfaction (16%); Negative Satisfaction (9%). Time per diary entry had the biggest impact on satisfaction. Those whose diaries took <=30 minutes had the highest percentage of positive satisfaction (78%) and those whose diaries took >30 minutes had the lowest percentage of positive satisfaction (46%), p<0.001. Patients who were negatively satisfied had the highest percentage (44%) of reporting dropping out or considering dropping out due to diary effort, p<.0001. Patients who were negatively satisfied had the highest percentage (67%) of reporting non-compliance with completing diaries (p<0.01). Time per diary entry impacted compliance where those patients whose diaries took > 30 minutes had the highest percentage of reporting non-compliance (68%), p=0.03. CONCLUSIONS: When planning patient diaries, it is important to consider the patient population and preferences. As the results show that satisfaction is linked to drop out and compliance, it is important to keep patients satisfied. As time per diary was found to impact satisfaction, it is important to keep patient burden and their experience in mind when developing ePRO instruments and selecting mode of administration. Satisfied patients lead to higher compliance, retention and data quality.

#### PRM150

### CAN WE USE THE EQ-5D ONLY FOR ASSESSING THE QUALITY OF LIFE OF PATIENTS WITH OSTEOPOROSIS?

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OBJECTIVES: Osteoporosis is a chronic disease which has impact on specific aspects of health such as pain, physical functioning, social and mental functioning and loss of personal independence. Generic questionnaire EQ-5D explores similar dimensions and therefore is usually used as a questionnaire for assessing the concurrent validity of the specific osteoporosis questionnaires. The objective of this study was to explore for a potential correlation between the similar dimensions of the specific osteoporosis questionnaire QUALEFFO-41 and EQ-5D. METHODS: Analyzed data were a part of the study that included 50 patients with osteoporosis and vertebral fractures conducted during the period June 2010 - October 2011. The correlation between the questionnaires was assessed using the Spearman's correlation coefficient. **RESULTS:** Strong correlations were found between EQ-5D index / VAS score and QUALEFFO-41 total score ( $\rho$ =-0.73 and  $\rho$  =-0.57, p<0.001, respectively). The EQ-5D dimensions "Pain/discomfort", "Mobility", "Activities", "Anxiety/Depression" similar to QUALEFFO-41 dimensions "Pain", "Physical function", "Leisure, social activities", "Mental function" were also strongly correlated  $(\rho$ =0.42,  $\rho$  =0.76,  $\rho$  =0.46 and  $\rho$ =0.32, p<0.001, respectively). **CONCLUSIONS:** Strong correlations between similar dimensions of the compared questionnaires were notified. Negative values of the Spearman's correlation coefficient indicated that total score of the QUALEFFO-41 were scored in the reverse order. There was only one QUALEFFO-41 dimension ("General health perception") that is not similar to any of the EQ-5D dimensions. Although there was a strong correlation between the total scores of compared questionnaires, the results of the EQ-5D questionnaire should be observed with caution, because it does not contain all important dimensions that osteoporosis affects.

### PRM151

# VALIDITY, RESPONSIVENESS AND RELIABILITY OF THE ARTHRITIS-SPECIFIC WORK PRODUCTIVITY SURVEY ASSESSING WORK PRODUCTIVITY WITHIN AND OUTSIDE THE HOME IN PATIENTS WITH PSORIATIC ARTHRITIS

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<sup>1</sup>Wasatch Health Outcomes, Park City, UT, USA, <sup>2</sup>UCB Pharma, Brussels, Belgium OBJECTIVES: The arthritis-specific Work Productivity Survey (WPS) estimates arthritis-related productivity limitations at workplace and within home, and on social activities, during the preceding month. There is an unmet need for an instrument assessing similar limitations in psoriatic arthritis (PsA). Following its validation in rheumatoid arthritis, this analysis aimed to assess the psychometric properties of WPS in adult-onset active PsA. METHODS: WPS comprises 9 questions evaluating employment status, workplace and household productivity. Psychometric properties were assessed using data from RAPID-PsA (NCT01087788). The WPS was completed at baseline and every 4 weeks (wks) until Wk24. Validity was evaluated via known-groups approach, comparing patients (pts) with a worse vs better health state, defined by the 1st and 3rd quartiles cut-off of pt scores to DAS28(CRP), HAQ-DI, SF-36 and PsAQoL. The responsiveness and reliability were assessed comparing WPS mean changes in ACR20 or HAQ-DI MCID=0.3 responders vs non-responders at Wk12. Comparisons were conducted in the Randomized Set (observed cases) using a non-parametric bootstrap-t method. RESULTS: Results confirmed the discriminant validity of WPS. Compared to pts with a better health state, pts with a worse health state had significantly more days of household work lost, household work with reduced productivity, social activities missed, outside help hired and a significantly higher interference rate of arthritis. Similarly, employed pts with a worse health state had significantly more work days lost or with productivity reduced by  $\geq$ 50%, and higher interference of arthritis on work productivity. WPS was also responsive to clinical changes, with responders reporting significantly larger improvements at Wk12 in WPS scores vs non-responders. The effect sizes for changes in productivity in responders were moderate (0.5<SRM<0.8) or small. CONCLUSIONS: These analyses demonstrate that the WPS is a valid, responsive and reliable instrument for measurement of productivity within and outside the home in adult-onset PsA.