study also aimed to determine whether the composite disease measures provide a better estimate of utility over other measures and whether the components of the composite measures influence the relationship with QOL. METHODS: The data was made available from the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) which collected data from an international cohort of PaA patients. Different regression models were used to estimate the relationship between the generic QOL measure, SF-6D and disease specific measures (HAQ, Composite Disease Activity Index (CDAI), Psoriatic Arthritis Disease Activity Score (PASDAS) and the Arithmetic Mean Desirability Function Score (AMDF)). Model fit was determined using the R² statistic, root mean square error, Akaike information criterion and regression coefficients are also presented. RESULTS: The optimal model for each of the disease specific measures and SF-6D was a multiple regression model. The difference in model fit between the linear and multiple regression models was greatest for the composite disease measures specific to PaA. The CDAI and SF-6D provided the best fit to utility score for PaA, followed by the PASDAS. CONCLUSIONS: PaA is a heterogeneous disease for which composite disease measures may be more appropriate than measures such as the HAQ. This study provides mapping coefficients, allowing utility estimation from these measures which may be collected in trials where no preference-based utility measure has been used.

PM1120 PATHWAYS TO EFFECTIVE CLINRO DOSSIER DEVELOPMENT
Bennett BM1, Ballard R2, Nixon A2
OBJECTIVES: To highlight some of the common areas that require particular attention when preparing clinical outcome assessment (COA) dossiers, suitable for FDA regulatory label claims, with a particular focus on clinician-reported outcome (ClinRO) measures. The FDA has provided guidance for the use of Patient-Reported Outcomes (PRO) measures in the endpoints of clinical trials to support label claims (FDA, 2009). Although several authors have indicated that the standards used to evaluate PRO’s will apply to all COA’s (Burke, 2011; Gwaltney, 2012), the FDA have not published guidelines on ClinRO measures to support label claims. This is surprising given that the ratio of label claims based on ClinRO’s is approximately three ClinRO’s to every PRO measure (Burke, 2010). METHODS: We conducted a review of the literature to ascertain the general level of use of ClinRO’s and to find examples of widely used ClinRO’s. The available evidence for these ClinRO’s was then compared to the standards of the PRO guidance, specifically in reference to content and construct validity, reliability and other psychometric properties. RESULTS: The literature review revealed that ClinRO’s are common endpoints in clinical trials. However, it was also apparent from the sample of ClinRO’s reviewed, that ClinRO’s did not meet the evaluative standards prescribed by the FDA particularly in being “well defined and reliable”. CONCLUSIONS: ClinRO’s used as endpoints in clinical trials to support FDA label claims may lack the required evidence set out in the FDA PRO guidance document. Specifically, many ClinRO’s have been developed by clinicians, and widely accepted by clinical peers, without undergoing psychometric evaluation. If the FDA were to evaluate ClinRO’s to the same standards as PRO’s, the ratio of label claims between ClinRO’s and PRO’s may decrease significantly.

PM1121 BURDEN OF ORTHOARThRITIS: DEVELOPMENT OF A QUESTIONNAIRE
Bertolotto MC1, Montanari S1, Ranoux P2, Taisch C1
1Comité Lutte contre la Douleur, Limorges, France, 2PSFA, Boulogne Billancourt, France, 3Hôpital Cochin, Paris, France, 4CHU Grenoble, Grenoble, France, 5CREES PSFA, Boulogne, France
OBJECTIVES: Osteoarthritis (OA) also known as degenerative arthritis or degenerative joint disease, is a group of mechanical abnormalities involving degradation of cartilage and subchondral bone. OA can be primary or secondary, with a prevalence of 15% of women and 7% of men over 50 years of age. In addition, OA is the leading cause of disability in persons over 65 years of age. OBJECTIVES: To develop a questionnaire to evaluate the impact of OA in different areas of patients life. METHODS: Patients attending orthopedic clinics in 3 tertiary hospitals in France were invited to participate. A questionnaire including 274 questions was developed and validated in a pilot study. The questionnaire was then administered to a larger group of OA patients (n=72). RESULTS: The questionnaire was validated as a reliable tool to evaluate the burden of OA in different areas of patients life. The final questionnaire included 226 questions, and consists of 4 subscales: pain, function, physical activity limitations, and psychological impact. CONCLUSIONS: The Burden-Osteoarthritis-New-Scale (BONeS) is a valid and reliable tool to evaluate the burden of OA in different areas of patients life. It can be used as a screening tool for OA, or as a outcome measure in clinical trials. It can also be used in clinical practice to assess the condition of OA patients and their quality of life.
The findings from this study concur with an expanding evidence base highlighting discrepancies in adult and adolescent values for identical health states. The differences in adolescent and adult values were more profound for the CHU9D, particularly in relation to mental health impairment states, and may be significant enough to strongly affect the findings of economic evaluations using the ABS questionnaire. A clear definition and understanding of the concepts to be translated; and (2) The involvement of trained professionals. Hyperlinks are provided in each part of the table to lead to the evidence documents required for each area listed by the FDA.