core-set were also obtained both at baseline and 4 week apart. These included tender joint count (out of 28), swollen joint count (out of 28), physician’s and patient’s global assessment of disease activity, pain score and Westergren erythrocyte sedimentation rate (ESR). Disease activity was measured using the DAS28 score, which was obtained at baseline and at the end of the study for each patient. RESULTS: The median age of the 60 study patients was 48 yr ±9.53 and the median duration of symptoms was 17 months ± 5.53. Thirty of these received the English version of the HAQ and the other 30 received the Hindi version. Baseline HAQ values for English and Hindi groups were 1.84±0.48 and 1.91±0.49, respectively. After treatment, the HAQ values changed to 0.71±0.42 and 0.62±0.51, respectively, demonstrating a very good sensitivity to change (Student’s unpaired t-test: p<0.05). Construct validity was assessed using Pearson’s correlation coefficient between the corresponding values of HAQ and DAS28, both at baseline (r=0.87, p<0.001) and at intervention (r=0.60, p<0.01). CONCLUSIONS: These results support the validity, and reliability of the IND-HAQ as a measure that captures the impact of RA on patients’ health-related quality of life.

PSM93
PAPER AND WEB EQUIVALENCE OF THE ENSEMBLE MDS - A TOOL USED TO COLLECT PHENOTYPIC INFORMATION PRIOR TO TREATMENT
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OBJECTIVES: The ENSEMBLE MDS is a battery of phenotypic generic patient-reported outcome (PRO) instruments designed for use in clinical studies or observational research. The component instruments assess baseline patient characteristics that are believed to either be predictors (health status, illness burden, depression, anxiety, and perceived stress) or effect-modifying factors (perceived social status, objective social status, perceived social support, income) of clinical outcomes and patient well-being. We sought to examine the equivalence of the component instruments across two different modes of administration - paper and web. METHODS: This study was a data collection effort that used a randomized cross-over design in the United States (English) and Singapore (Simplified Chinese). Participants were outpatients with a clinical diagnosis of one of five targeted health conditions: depression, type 2 diabetes, psoriasis, rheumatoid arthritis and chronic kidney disease. Those enrolled were randomized to initially complete the MDS on paper or web format, and returned 24 hours later to complete the alternate format. Equivalence was evaluated by the intra-class correlation coefficient (ICC) with equivalency defined as 0.70 or above for the minimal acceptable level of 0.70. These analyses were performed individually for each of the nine MDS component measures. RESULTS: A total of 314 participants (258 in US, 56 in Singapore) were analyzed. In the US, mean age was 49±13 years, 61% were female; in Singapore mean age was 57±12, 59% female. The ICSSs between paper and web administration of the different components of the ENSEMBLE MDS ranged between 0.74 and 0.98 in the US, and between 0.75 and 0.97 in Singapore. CONCLUSIONS: Equivalence between paper and web-based administration of the ENSEMBLE MDS was demonstrated statistically for the US-English Version and the Chinese version for Singapore, indicating stability of sub-items across different languages and cultures.

PSM94
INTEGRATING PATIENT-REPORTED OUTCOMES (PRO) AND MEDICAL RECORD DATA (MR) IN OBSERVATIONAL STUDY DESIGNS: RESULTS FROM A DIRECT-TO-PATIENT PILOT STUDY IN GOUT
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OBJECTIVES: The growth in patient empowerment and increase in on-line patient pools has given rise to new direct-to-patient research methods (i.e., direct recruitment of patients, without physician sites). One key concern, however, is the absence of physician-reported data to validate diagnosis and provide other study outcomes. The objective of this study was to employ a direct-to-patient approach to collect patient-reported outcomes (PRO) and medical record (MR) information. METHODS: In July 2011, a random sample of US MediGuard.org members ages 18 to 80 were invited to participate via email based on a gout diagnosis and treatment. Interested members clicked on an email link to access study information and screen based on self-reported diagnosis and willingness to release medical records. The first 50 consenting participants continued on to complete an online survey and submit electronic patient medical records forms. Completed forms were provided to Outcomes Health Information Solutions to contact physicians and obtain participant charts. RESULTS: A total of 120 members clicked on 1250 emails sent (9.6%). 5 members (4%) explicitly declined to participate due to the medical record requirement, although this could be as high as 30% if all individuals expressing the interest were included. Of the 50 participants completing the on-line survey and electronic release, 42 (84%) returned the paper form. With these forms, we obtained 38 of 50 charts (76%); 28 of 38 (74%) with electronic and 10 of 38 (26%) with paper; 35 charts had a gout diagnosis and an additional 2 had a gout medication, only 1 chart was missing any record of gout. CONCLUSIONS: Patients can be recruited directly for observational study designs that include PRO and MR data with over 75% data completeness. Although concern exists regarding validity of self-reported data, in this PRO MR pilot, nearly all (37 of 38) charts confirmed patient-reported data.