assessed using Cronbach's alpha and intra-class correlation. **RESULTS:** The mean age was 76.3 (8.9) years, majority of the subjects were female (55.1%), residing in the United States (77.5%) and Caucasian (92.8%). The mean utility value calculated with the VFQ-UI was 0.68 (0.11), compared to the EQ-5D: 0.88 (0.12), HUI2: 0.81 (0.13), and HUI3: 0.73 (0.22). The VFQ-UI is associated with HUI2 ($r = 0.22$, $p < 0.05$) but not significantly associated with the EQ-5D or the HUI3. There was no significance in the correlation between VFQ-UI and visual acuity in the study eye. The VFQ-UI varied by known groups using a combination of study and fellow eye visual acuity; the more impaired visual acuity the lower the utility value (more disability in visual functioning). Internal consistency reliability for the VFQ-UI was 0.76 and the intra-class correlation was 0.84. **CONCLUSIONS:** Utility values calculated from the VFQ-UI demonstrated greater visual functioning impairment compared to the HUI and EQ-5D. The VFQ-UI showed good convergent validity with the HUI2, good discriminant validity with visual acuity known groups and good internal consistency and test-retest reliability in individuals with AMD.

PSS14

VALIDATION OF THE EYELASH SATISFACTION FOLLOW-UP QUESTIONNAIRE FOR FOLLOW-UP SELF-ASSESSMENT OF EYELASH SATISFACTION

Burgess SM[1], Walt J[2], Yang M[3], Hansen JE[1], Beddingfield FC[2], Hammond G[3], Cole J[4]

[1]Allergan, Irvine, CA, USA, [2]Allergan, Inc, Irvine, CA, USA, [3]QualityMetric Incorporated, Lincoln, RI, USA, [4]Independent Consultant, Torrance , CA, USA

OBJECTIVES: The Eyelash Satisfaction Questionnaire (ESQ), a static measure, has been previously validated for the assessment of eyelash-specific patient-reported outcomes (PROs) in subjects receiving a therapeutic treatment for hypotrichosis of eyelashes. The current study aimed to validate a similar questionnaire, the Eyelash Satisfaction Follow-up Questionnaire (ESFQ), a 39-item dynamic measure designed specifically to self-assess eyelash-specific PROs. **METHODS:** The ESFQ was initially examined in a 909-person validation sample consisting of online respondents. Confirmatory factor analysis (CFA) was initially used to test the measurement structure of the questionnaire. Item- and scale-level psychometric properties such as item-total correlations, internal consistency, and convergent and discriminant validities were reviewed. The ESFQ was then used in a clinical population receiving bimatoprost ophthalmic solution 0.03%, a product that improves eyelash prominence, during a 16-week randomized, controlled, masked, clinical trial. **RESULTS:** Initial CFA results revealed a "good fit" based on hypothesized similarity with the factor structure identified in the ESQ. A model using 9 indicators (3 per factor), similar to the structure of the ESQ, was chosen as the optimal method. The final model showed good internal consistency along with convergent and discriminant validities. However, the alpha-removed statistic for the length, fullness, and overall satisfaction (LFOS) construct showed a significant increase in scale consistency with the removal of item 8 (Compared to your first visit, overall, how satisfied are you with your eyelashes now?). Despite this, the model structure was retained to better facilitate comparisons between the ESQ and ESFQ and to provide sufficient measures to properly evaluate the construct. **CONCLUSIONS:** The 9-item ESFQ appears to be a valid measure to assess changes in eyelash-specific PROs. The factor structure showed near equivalence with the ESQ. Future research will involve further validation of the ESFQ in response to variations in hypotrichosis etiologies and clinical treatment paradigms.

PSS15

COMPARISON OF THE PRO ENDPOINTS FOUND IN LABELING CLAIMS OF PRODUCTS FOR THE TREATMENT OF PSORIASIS WITH THOSE RECOMMENDED BY THE CORRESPONDING EMEA GUIDANCE

Caron M, Emery MP

MAPI Research Trust, Lyon, France

OBJECTIVES: Our objective was to compare the PRO endpoints recommended by the EMEA note for guidance on the clinical investigation of medicinal products indicated for the treatment of psoriasis (CHMP/EWP/2454/02) published in November 2004, with those used for the approval of medicinal products for psoriasis. **METHODS:** The EMEA website was searched to identify all medicinal products approved specifically for psoriasis since 1995. PROlabels was searched to identify the products with a PRO labeling claim. **RESULTS:** The EMEA guidance specifies that *"Patient-assessed drug efficacy may be a secondary or tertiary endpoint in pivotal clinical trials. These measures correspond both to efficacy evaluated by patients and to health-related quality of life (HRQL) scales validated in dermatology"*. The guidance quotes simple measures such as symptom improvement, tolerability, cosmetic acceptability, ease of use, patient's assessment of global improvement and more complex measures, such as the patient's assessment of PASI, the Dermatology Life Quality Index (DLQI), Dermatology Quality Life Scales (DQOLS), Skindex, Psoriasis Disability Index (PDI), and Psoriasis Life Stress Inventory (PLSI). Three products were retrieved; two approved before the publication of the guidance (2003, 2004) and one after (2009). Methotrexate, cyclosporine and corticoids were not included for their lack of specificity. All three products had a PRO labeling claim. Improvement in the DLQI was used as a secondary endpoint in all products and quoted on the label. Itch was measured for 2 products (2004, 2009) by patient's symptom measures and included on the label. Two products (2003, 2009) used the SF-36. **CONCLUSIONS:** There is a close adherence to the guidance concerning the choice of PRO endpoints. However, comparison of the dates of the guidance publication and of the products' approval suggest that the guidance has only endorsed an existing practice in the choice of study endpoints for the evaluation of medicines indicated for psoriasis.

PSS16

SUSTAINED IMPROVEMENT IN SKIN DISEASE-SPECIFIC QUALITY OF LIFE IN PATIENTS WITH MODERATE TO SEVERE PSORIASIS RECEIVING USTEKINUMAB MAINTENANCE THERAPY: LONG TERM RESULTS FROM PHOENIX 1

Leonardi C[1], Papp K[2], Schenkel B[3], Zhao N[3], Yeilding N[4], Kimball A[5]

[1]St. Louis University, St. Louis, MO, USA, [2]Probity Medical Research, Waterloo, ON, Canada, [3]Johnson & Johnson Pharmaceutical Services, LLC, Horsham, PA, USA, [4]Centocor Research & Development, Inc., Malvern, PA, USA, [5]Harvard Medical School, Boston, MA, USA

OBJECTIVES: To assess the long-term impact of ustekinumab(UST) on quality of life (QoL) among patients responding to therapy at wk40. **METHODS:** In PHOENIX 1 psoriasis patients were randomized to UST45 mg (n = 255), UST90 mg(n = 256), or placebo(n = 255). Placebo patients crossed over to receive UST45 mg or 90 mg at wk12. At wk40, UST PASI75 responders were re-randomized to continue the same dose of UST q12 wks or be withdrawn from treatment.After losing 50% of the improvement gained while on UST, patients withdrawn from treatment re-initiated UST at the same dose previously received.The DLQI assessed skin disease-specific QoL (lower scores indicating better QoL) through 3 yrs;change of >= 5 points was defined as a clinically meaningful change and a score of 0/1 was defined as no negative effect on patient's life. **RESULTS:** 162 patients were re-randomized to UST at wk40 (n = 77,45 mg; n = 85,90 mg); 320 patients were withdrawn from UST at wk40 (n = 141,45 mg; n = 179,90 mg). Among patients re-randomized to UST, mean change from baseline in DLQI score for the 45 mg and 90 mg groups [mean(SD)] was: −9.1(7.0) and −10.0(6.1) at wk76 and −8.6(6.9) and −9.7(6.2) at Year3, respectively. Among patients withdrawn, mean change from baseline in DLQI score for the UST45 mg and 90 mg groups [mean(SD)] was: −1.4(5.8) and −4.2(4.7) at wk76 and 0.9(2.2) and −2.8(0.9) at Year3, respectively. At wk76 and Year3, 64.0% and 74.7%, and 64.6% and 65.4% of patients in the 45 mg and 90 mg groups,respectively,achieved a DLQI score of 0/1; at wks76 and Year3, 10.9% and 19.2%, and 3.1% and 13.9%, of patients withdrawn from 45 mg and 90 mg, respectively, achieved these results. In those re-randomized to UST, the proportion of patients in the 45 mg and 90 mg groups who experienced a ≥5 point improvement in DLQI was 73.3% and 78.5% at wk76, and 70.8% and 78.2% at Year3; in the withdrawal group, 19.6% and 20.9%, and 0.78% and 1.3%, of patients from 45 mg and 90 mg, respectively, achieved this result. **CONCLUSIONS:** Clinically meaningful QoL improvements are sustained through Year3 among patients responding at wk40 who continued to receive UST q12wks.

PSS17

IMPACT OF ADALIMUMAB ON QUALITY OF LIFE AND DEPRESSION IN PSORIASIS PATIENTS: RESULTS FROM PRIDE

Guh D[1], Papp K[2], Lynde C[3], Bansback N[1], Zhang W[1], Qian H[1], Martel MJ[4], Goyette A[4], Teixeira H[4], Anis A[5]

[1]Centre for Health Evaluation and Outcome Sciences, Vancouver, BC, Canada, [2]K. Papp Clinical Research, Probity Medical Research, Waterloo , ON, Canada, [3]Lynde Centre for Dermatology, Markham, ON, Canada, [4]Abbott Laboratories Ltd., St. Laurent, QC, Canada, [5]University of British Columbia, Vancouver, BC, Canada

OBJECTIVES: To evaluate the effect of adalimumab on health-related quality of life and patient-reported outcome (PRO) measures, including depression and health utility in patients with active plaque psoriasis. **METHODS:** PRIDE (A Canadian Open-Label Access PRogram to Evaluate the Safety and the Effectiveness of Adalimumab When Added to InaDEquate Therapy for the Treatment of Psoriasis) was an open-label, multicenter, Phase IIIb study in Canada. Patients with active moderate to severe plaque psoriasis who failed to respond to, or were intolerant of, prior therapies (phototherapy, cyclosporine, methotrexate, and/or oral retinoids) received adalimumab (80 mg) at Week 0 followed by adalimumab (40 mg) every other week starting at Week 1. Changes in the Dermatology Life Quality Index (DLQI), Beck Depression Inventory-II (BDI) and EQ-5D at baseline, Week 16 and Week 24 were evaluated. **RESULTS:** A total of 203 patients (male, 61%; mean age, 46 years; mean PASI score, 20) were enrolled at 26 sites. At baseline, mean DLQI, BDI and EQ-5D were 12.9, 9.3, and 0.79, respectively. At Week 16, the mean DLQI score had improved to 2.9 (change = 10.0; $p < 0.0001$); the BDI was reduced to 5.2 (change = 4.2; $p < 0.0001$), and the EQ-5D had improved to 0.89 (change = 0.10; $p < 0.0001$). A 16-week results were sustained to 24-weeks, and all outcomes showed statistically significant improvements from baseline. Improvements were even greater in patients with a baseline DLQI score >10. **CONCLUSIONS:** Adalimumab treatment was associated with statistically significant improvements in PROs of psoriasis patients in Canada, including depression. The results of this open-label study were consistent with outcomes observed in randomized placebo controlled clinical trials of adalimumab, confirming that adalimumab has a substantial impact on patient health-related quality of life.