score distributions and indices of reliability and validity. RESULTS: The literature review and subsequent study identified PROs associated with a range of symptoms (e.g., pain, drainage, itchiness) and impacts (e.g., difficulty with movement and interference with sexual activities). These concepts were organized into a conceptual model to facilitate the construction of the questionnaires. Results from the cognitive debriefing interviews indicated that both the HSIA and HSSA were easily understood by patients and characterize their condition well. Forty subjects completed the observational study (females = 58%, Caucasian = 65%, and age [mean] = 41 years; 85% Hispanic). HSIA scores were shown to be well psychometrically with strong evidence of test-retest (ICC = 0.92 and 0.80, respectively) and internal consistency (α = 0.97 and 0.96, respectively) reliability and known groups (P < 0.001 and 0.0, respectively) and construct-related validity (via correlations between the target measures and other, concurrently administered tools). CONCLUSIONS: There is robust evidence supporting the HSIA and HSSA as content valid and psychometrically sound questionnaires for assessing symptoms and impacts in patients with HS.

PSS30 SENSITIVITY OF FUNCTIONAL READING INDEPENDENCE (FRI) INDEX TO CHANGING SIZE OF GEOGRAPHIC ATROPHY
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OBJECTIVES: Visual acuity does not fully capture the effect of geographic atrophy in persons with AMD. Our research aimed to assess the sensitivity of the Functional Reading Independence (FRI) Index to changes in geographic atrophy size.
METHODOLOGY: In a secondary analysis from MAHALO, a phase 2 study of lampalizumab, a complement factor monoclonal antibody fragment, for treatment of GA. For each reading activity performed in the past 2 weeks, the FRI index was calculated by weighting each item by the extent to which they required vision aids, adjustments in the activity or help from another person. The FRI Index yields continuous mean scores (range 1–4) and ordinal level scores (from Level 1 = Unable to do to Level 4 = Totally Independently) as a measure of functional reading independence as measured by the FRI Index is linked to GA lesion growth, an objective clinical measure of disease progression.
RESULTS: At 18 months, the mean change in FRI index scores (SD) from baseline for patients with more lesion size growth was 0.03 (0.5, n=13) vs -0.7 (n=42) for patients with less growth (P=0.02). For patients with more growth, 36% declined ≥ 1 FRI Level vs 15% for less growth. Excluding patients at FRI Level 1 at baseline, 41% of patients with more growth (N=54) declined > 1 FRI Level vs 18% with less growth (N=11). CONCLUSIONS: In MAHALO, changes in FRI index scores stratified by more (≥0.94mm²/yr) vs less (<0.94mm²/yr) GA lesion growth results provide evidence that patient-reported functional reading independence as measured by the FRI Index is linked to GA lesion growth, an objective clinical measure of disease progression.

PSS31 DEMONSTRATING CONCEPTUAL EQUIVALENCE: TRANSLATION OF THE URticaria ACTIVITY and IMPACT MEASURE (U-AIM) FROM ENGISH INTO SPANISH
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OBJECTIVES: Translation and linguistic validation of patient reported outcomes (PRO) measures is an essential component of research methodology in preparation for multi-national clinical trials. The U-AIM is a condition specific tool developed in English to assess the impact of chronic urticaria from the patient’s viewpoint. The objective of this work was to translate and linguistically validate the U-AIM from English to Spanish for use in the US. METHODOLOGY: The U-AIM was translated into universal Spanish according to industry standard methodology. After the translation was completed, five Spanish-speaking patients in the US diagnosed with chronic idiopathic urticaria completed the translated questionnaire and participated in a cognitive debriefing interview. Interviews were conducted using a standardized guide to assess the relevance, understandability, and appropriateness of the translations. Qualitative analyses were performed to ensure equivalence and that the content validity of the U-AIM was maintained for the Spanish version. RESULTS: Of the five patients (40% male), the mean age of four was 37 years [one patient did not report his age]. All U-AIM items were well understood and proved relevant to the patients in this sample. Of interest, terms such as, “urticaria,” “hives,” “angioedema,” “generalized swelling” were clearly understood as intended. CONCLUSIONS: For patients, inclusion of PROs ensured the full benefit of the product was demonstrated, including improvement in symptoms, quality of life, and/or treatment satisfaction. For prescribers, comparative trials reported PRO data information on each product’s benefits and risks and also which product was superior from the patient perspective. For regulators, for all except one of the six products, PROs were included in the product label. For payers, utility values based on PROs were used in cost-effectiveness evaluations for three of the six products. For the patient, the PRO framework, the generated label and numerous publications that allowed extensive public dissemination of product benefits. CONCLUSIONS: Patient-reported assessment of the treatment impact on disease during drug development has many benefits for all stakeholders.

PSS32 PATIENT REPORTED OUTCOMES IN GLAUCOMA A SYSTEMATIC REVIEW AND META-ANALYSIS
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OBJECTIVES: Patient reported outcomes (PRO) are becoming useful tools for collecting and grading quality of care from patients’ perspective in medical practice; they show improvement in the quality of life (QQOL). Glaucoma is a chronic disease with high importance for patient HQOL. The objective of this study was to review, analyze, and understand trends in the PRO instruments used in patients with HS and GC. METHODS: A systematic literature search for Glaucoma trials with PROs endpoints was undertaken for the databases Pubmed, Embase, Biois, Google Scholar and Cochrane. Data was extracted and analyzed. Analysis for conducted to identify trends in commonly used PRO instruments and categorize results as positive, neutral or negative. RESULTS: 31 studies with a total of 9815 patients were identified. In these studies there were eleven different PROs instruments and one health technology agency score. These studies were identified based on the use of PROs in pivotal clinical trials for the product. METHODS: A targeted literature review was conducted in PubMed from 2004 to 2014 for six products (Atopiclar for atopic dermatitis, Lipocortin for hyperbacteriosis, ciclesonide- done-pipocitrate for psoriatic arthritis, picnemol and talormolus for atopic dermatitis, and ustekinumab for psoriasis). Regulatory and health technology agency websites and publications were searched for documentation of PRO label claims and mentions. RESULTS: For patients, inclusion of PROs ensured the full benefit of the product was demonstrated, including improvement in symptoms, quality of life, and/or treatment satisfaction. For prescribers, comparative trials reported PRO data information on each product’s benefits and risks and also which product was superior from the patient perspective. For regulators, for all except one of the six products, PROs were included in the product label. For payers, utility values based on PROs were used in cost-effectiveness evaluations for three of the six products. For the patient, the PRO framework, the generated label and many publications that allowed extensive public dissemination of product benefits. CONCLUSIONS: Patient-reported assessment of the treatment impact on disease during drug development has many benefits for all stakeholders.