OP0147 **THE SLE-DAS REMISSION AND LOW DISEASE ACTIVITY STATES DISCRIMINATE DRUG FROM PLACEBO AND BETTER HEALTH-RELATED QUALITY OF LIFE: POST-HOC ANALYSIS OF THE BLISS-52 AND BLISS-76 PHASE III TRIALS.**

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Background: Accurate and practical outcome measures for clinical trials in systemic lupus erythematosus (SLE) are lacking. The SLE Disease Activity Score (SLE-DAS) is a recently validated 17-item instrument, with high accuracy and sensitivity to changes in SLE disease activity. The SLE-DAS definitions of remission and low disease activity (LDA) were newly validated in the clinical setting[1,2]. These definitions may constitute accurate and easy to apply endpoints for SLE trials.
Objectives: (1) To evaluate the ability of SLE-DAS remission and LDA definitions to discriminate drug from placebo in SLE phase 3 trials; (2) To determine if attainment of these SLE-DAS targets are associated with better health-related quality of life (HR-QoL).
Methods: Post-hoc analysis of the merged study population in the BLISS-52 and -76 trials (NCT00424476; NCT00410384) of intravenous belimumab versus placebo for moderate to severe SLE disease activity. We analyzed the British Isles Lupus Assessment Group (BILAG), Physician Global Assessment (PGA), Functional Assessment of Chronic Illness Therapy (FACIT) and 36-Item Short Form Survey (SF-36) trial data. The fulfillment of SLE-DAS remission and LDA definitions were retrospectively assessed from the individual participants' data. Proportion of patients attaining SLE-DAS Boolean remission (defined as absence of all SLE-DAS clinical items and prednisone ≤5mg/day) and LDA (defined as SLE-DAS≤2.48 and prednisone ≤7.5mg/day), at week 52, was compared between belimumab and placebo arms, using likelihood ratio chi-square test. We further compared the SF-36 physical component summary (PCS) and mental component summary (MCS) and domain scores and the FACIT score between patients attaining SLE-DAS remission *vs* non-remission and SLE-DAS LDA *vs* non-LDA, using t-test and Mann-Whitney test.
Results: A total of 1684 SLE patients were included: 562 on placebo, 559 on belimumab 1mg/Kg and 563 on belimumab 10mg/Kg. At week 52, significantly more patients attained SLE-DAS LDA on belimumab 1mg/Kg and 10mg/Kg as compared with placebo (13.0% *vs* 17.9%, OR=1.459, p=0.023, and 13.0% *vs* 21.7%, OR=1.853, p<0.001, respectively). Likewise, more patients attained SLE-DAS remission on belimumab 10mg/Kg as compared with placebo (10.1% *vs* 14.7%, OR= 1.532, p=0.019) (Table 1). Importantly, none of the patients achieving SLE-DAS remission or LDA presented a new BILAG A or more than 1 new B domain score, neither a worsening in PGA≥0.3.
At week 52, patients attaining SLE-DAS remission and SLE-DAS LDA presented higher SF-36 domain and summary scores (all p<0.001) (Figure 1). Additionally, FACIT scores were higher in patients attaining SLE-DAS remission than non-remission patients (mean±SD: 38.24±10.65 *vs* 33.45±12.13, p<0.001), and in patients attaining SLE-DAS LDA than non-LDA (mean±SD: 37.22±11.00 *vs* 33.37±12.17, p<0.001), at week 52.

Table 1. Attainment of SLE-DAS Boolean remission and LDA at week 52 in BLISS-52 and BLISS-76 trials, according to the treatment groups (n =1684).

	Placebo	Belimumab 1mg/Kg	Belimumab 10mg/Kg
SLE-DAS remission (n=211)	10.1%	12.7%, OR=1.289 (0.89-1.866), p=0.178	14.7%, OR 1.532 (1.069-2.195), p=0.019
SLE-DAS LDA (n=295)	13.0%	17.9%, OR=1.459 (1.052-2.025), p=0.023	21.7%, OR 1.853 (1.349-2.545), p<0.001

LDA: Low disease activity; SLE-DAS Boolean remission: absence of all SLE-DAS clinical items and prednisone ≤5mg/day; SLE-DAS LDA: SLE-DAS≤2.48 and prednisone ≤7.5mg/day.

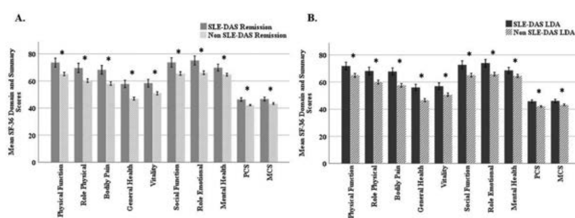

Figure 1. Mean SF-36 domain and summary scores at week 52; *p<0.001; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-36, Medical Outcomes Survey Short Form.

Conclusion: The SLE-DAS remission and LDA showed discriminant validity for identifying patients receiving active drug in clinical trials. These treatment targets are associated with better HR-QoL and lower fatigue.

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Spondyloarthritis in practice: imaging, outcome assessment and comorbidities

OP0148 **THE ASAS CORE MEASUREMENT SET FOR AXIAL SPONDYLOARTHRITIS**

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Background: Recently, the core domains of the 20-years old core outcome set for ankylosing spondylitis were updated.[1] The next step is to define the measurement core set, which includes at least one instrument for each domain.
Objectives: To define the instruments for the ASAS-OMERACT core outcome set for axial spondyloarthritis (axSpA).
Methods: The scientific committee invited an international working group representing all key stakeholders (patients, rheumatologists, health professionals and pharmaceutical industry). The instrument selection process is presented in Figure 1.

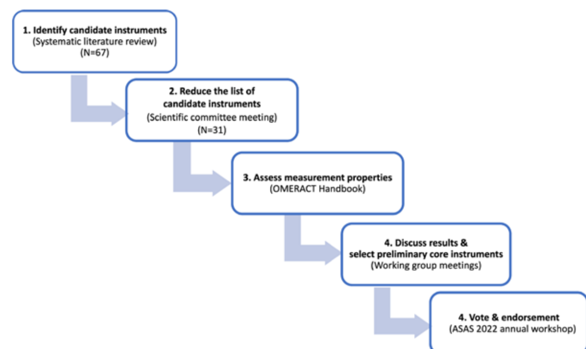

Figure 1. Development process to determine the core measurement set

Results: The updated core measurement set for axSpA is shown in Table 1. This includes seven instruments for six domains that are mandatory for all trials: ASDAS and NRS patient global assessment for disease activity, NRS total back pain for pain, composite index for morning stiffness, NRS fatigue for fatigue, BASFI for physical function, and ASAS Health Index for overall functioning and health. There are 9 additional instruments for disease modifying drugs (DMARDs): two MRI activity scores (SPARCC SIJ and SPARCC spine) for disease activity, the three extra-musculoskeletal manifestations uveitis, IBD and psoriasis assessed as recommended by ASAS[2], the three peripheral manifestations (44 swollen joint count, MASES and Dactylitis count[2]) and mSASSS for structural damage. The imaging outcomes are mandatory to be included at least in one trial for a drug that is considered to be a DMARD. The other instruments specific for DMARDs should be included in every trial. This core set is applicable to patients with radiographic and non-radiographic axSpA. Furthermore, 11 other instruments were also endorsed by ASAS and can additionally be used in axSpA trials: BASDAI, CRP, Berlin MRI-SIJ and MRI-spine activity scores for disease activity, NRS back pain at night for pain, severity (BASDAI Q5) and duration (BASDAI Q6) for morning stiffness, SF-36 for overall functioning and health, 66 swollen joint count and SPARCC enthesitis for peripheral manifestations and MRI-SIJ erosions scores (SPARCC SSS) for structural damage.

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