P127 THE SLE-DAS ENABLES EASY IDENTIFICATION OF SLE PATIENTS WITH MODERATE-TO-SEVERE DISEASE ACTIVITY AND WORSE HR-QOL IN THE SCREENING FOR SLE CLINICAL TRIALS: A POST-HOC STUDY IN THE PHASE 2 AND 3 ANIFROLUMAB TRIALS

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Background The SLE-DAS is a recently validated 17-item instrument with high accuracy and sensitivity to changes in disease activity, that provides a validated and easy to assess definition for moderate-to-severe disease activity (MSDA).

Objectives To assess the ability of the SLE-DAS to identify patients with MSDA to participate in SLE clinical trials and to evaluate if patients with MSDA by SLE-DAS, SLEDAI-2K and BILAG-2004 present worse health-related quality of life (HR-QoL).

Methods Post-hoc analysis of aggregated intention-to-treat data from the placebo arms from MUSE, TULIP-1 and -2 trials (NCT01438489, NCT02446912 and NCT02446899) of anifrolumab versus placebo for moderate-to-severe SLE. We analyzed the BILAG-2004, SLEDAI-2K and patient reported outcomes (PROs) [FACIT-F, LupusQoL, EQ-5D and Patient Global Assessment (PtGA)]. The SLE-DAS was retrospectively scored at each visit. At the screening visit, we assessed the ability of SLE-DAS (>7.64) and SLEDAI-2K (>6) MSDA categories to identify patients in MSDA by BILAG-2004 (numerical score >7). We further compared the PROs between patients in MSDA *vs* non-MSDA by SLE-DAS, SLEDAI-2K and BILAG-2004, at week 12, using Mann-Whitney test. The magnitude of these differences was compared using Cohen's d.

Results We assessed 438 SLE patients in MSDA by BILAG-2004, at the screening visit. The SLE-DAS and the SLEDAI-2K identified 96.1% (95%CI 94.3%-97.9%) and 92.9% (95% CI 90.5%-95.3%) of these patients, respectively. At week 12, patients in MSDA by SLE-DAS and SLEDAI-2K presented significantly severe impact in all HR-QoL PROs, and patients in MSDA by BILAG-2004 in 4/8 domains of LupusQoL, EQ-5D, FACIT-F and PtGA (table 1). Importantly, the SLE-DAS MSDA presented numerically higher effect sizes in the majority aspects of HR-QoL PROs, as compared to BILAG-2004 and SLEDAI-2K.

Conclusion The SLE-DAS enables easy identification of patients in MSDA to participate in SLE clinical trials and may guide the physicians to identify patients requiring biologic therapy in clinical practice. The SLE-DAS moderate-to-severe disease activity identifies patients with worse aspects of HR-QoL, thus enabling good agreement between physicians' and patients' perspectives. This study suggests that SLE-DAS MSDA may present superior ability to discern patients with worse aspects of HR-QoL as compared to BILAG-2004 and SLEDAI-2K.

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Abstract P127 Table 1 Health-related quality of life comparison between patients in moderate-to-severe disease activity (MSDA) *vs* non-MSDA according to SLE-DAS (>7.64), BILAG-2004 (numerical score >7) and SLEDAI-2K (>6)

	SLE-DAS MSDA *vs* Non-MSDA		BILAG-2004 MSDA *vs* Non-MSDA		SLEDAI-2K MSDA *vs* Non-MSDA	
	*p**	Cohen's d (95%CI)	*p**	Cohen's d (95%CI)	*p**	Cohen's d (95%CI)
LupusQoL						
Physical Health	**<0.0001**	0.49 (0.29–0.68)	**0.0286**	0.26 (0.04–0.49)	**<0.0001**	0.43 (0.23–0.62)
Pain	**<0.0001**	0.51 (0.31–0.71)	**0.0145**	0.28 (0.05–0.50)	**<0.0001**	0.51 (0.31–0.70)
Planning	**<0.0001**	0.43 (0.24–0.63)	**0.0392**	0.22 (0.00–0.45)	**<0.0001**	0.44 (0.25–0.64)
Intimate relationship	**0.0181**	0.22 (0.15–0.43)	0.8112	-0.03 (-0.27–0.20)	**0.0029**	0.28 (0.08–0.49)
Burden to others	**0.0032**	0.28 (0.09–0.47)	0.1639	0.17 (-0.05–0.39)	**0.0002**	0.38 (0.17–0.57)
Emotional health	**0.0043**	0.27 (0.07–0.46)	0.8876	0.04 (-0.19–0.26)	**0.0013**	0.30 (0.10–0.49)
Body Image	**0.0160**	0.19 (0.00–0.39)	**0.0327**	0.22 (0.00–0.45)	**0.0033**	0.23 (0.03–0.43)
Fatigue	**<0.0001**	0.44 (0.24–0.63)	**0.0252**	0.25 (0.03–0.48)	**0.0006**	0.34 (0.14–0.54)
EQ-5D Index Score	**0.0007**	0.31 (0.11–0.50)	**0.0149**	0.21 (-0.02–0.43)	**0.0028**	0.28 (0.09–0.48)
EQ-5D VAS	**<0.0001**	0.41 (0.21–0.60)	**<0.0001**	0.44 (0.21–0.67)	**0.0024**	0.29 (0.10–0.49)
FACIT-F	**<0.0001**	0.54 (0.35–0.74)	**0.0034**	0.33 (0.11–0.56)	**<0.0001**	0.44 (0.24–0.64)
PtGA	**<0.0001**	0.48 (0.29–0.68)	**0.0049**	0.34 (0.12–0.57)	**0.0029**	0.29 (0.09–0.48)

MSDA: Moderate-to-Severe Disease Activity; Non-MSDA: Non-Moderate-to-Severe Disease Activity; PtGA: Patient Global Assessment; *Mann-Whitney test.

P128 AMPLIFYING THE LUPUS PATIENT VOICE: INSIGHTS INTO THE DIAGNOSTIC JOURNEY AND INFORMATIONAL NEEDS

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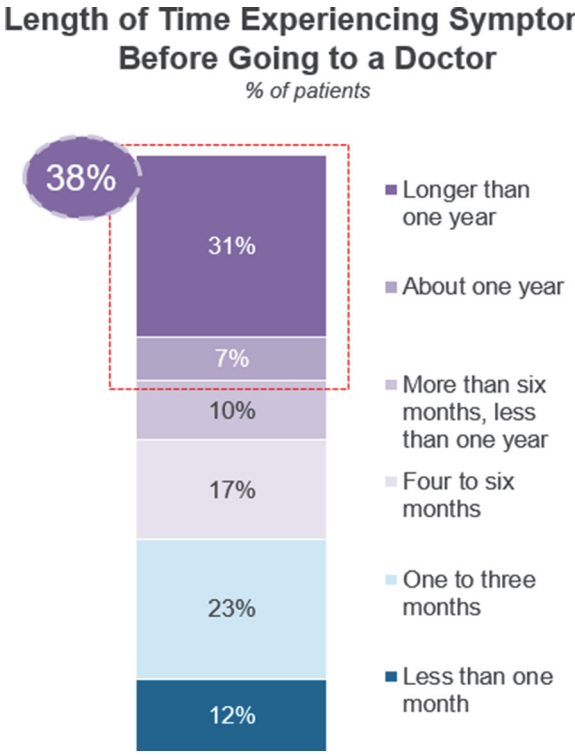
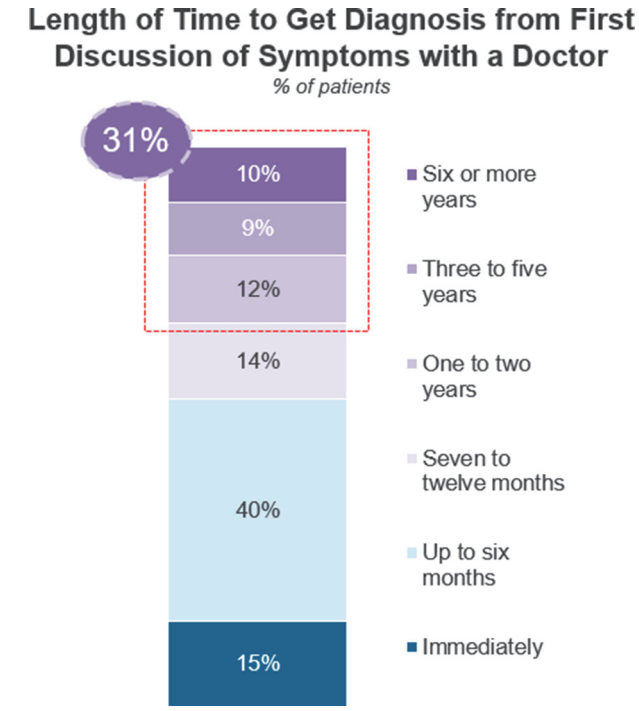
Objective To explore the experiences of lupus patients, with a focus on the diagnostic journey, treatment needs, and overall experience.

Methods An independent market analytics firm conducted a survey of 306 lupus patients in the United States. The survey assessed a variety of topics, including the time to diagnosis, treatment experiences, and unmet informational needs. Data was collected via an online survey fielded in July and August 2023.

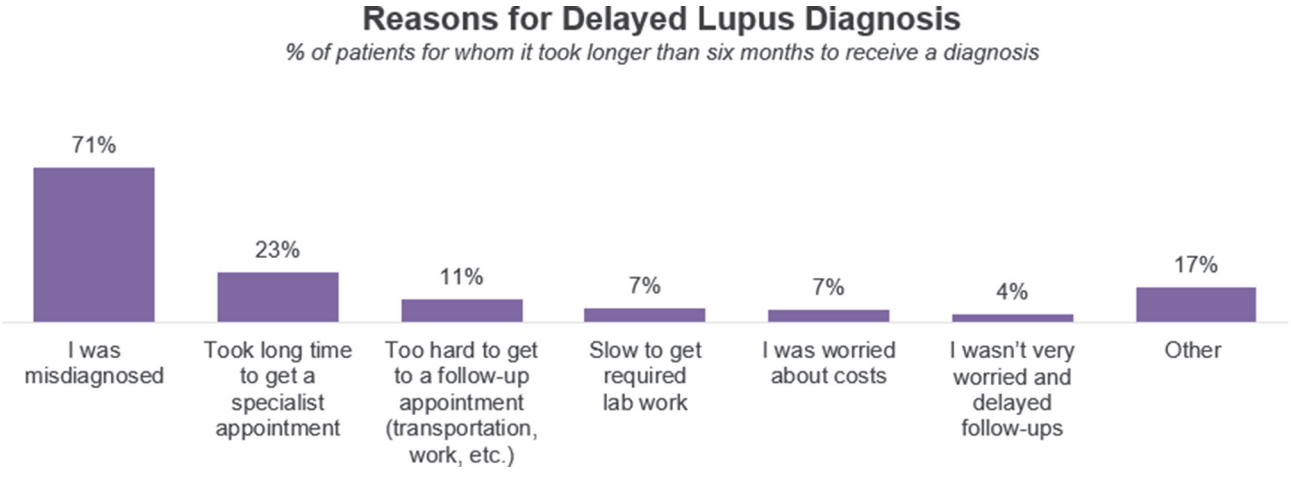
Results 38% of patients waited at least one year before seeking care after noticing symptoms, often delaying care because they did not believe their symptoms were severe enough [figure 1]. After seeking medical care, 31% of patients waited over one year to receive an accurate SLE diagnosis [figure 2]. This delay was often attributed to misdiagnosis, as lupus symptoms can mimic those of other conditions, such as migraine, hypertension, and rheumatoid arthritis. Additionally, the heterogeneous nature of lupus can make it difficult to diagnose [figure 3]. Patients who were misdiagnosed report that they were misdiagnosed 3.1 times on average. At diagnosis, lupus patients largely desired information on the specific treatments available, information on how to make lifestyle changes to improve outcomes, and information on how lupus would affect their other medical conditions. Despite these needs, many patients reported a lack of comprehensive education on lupus treatment options [figure 4].



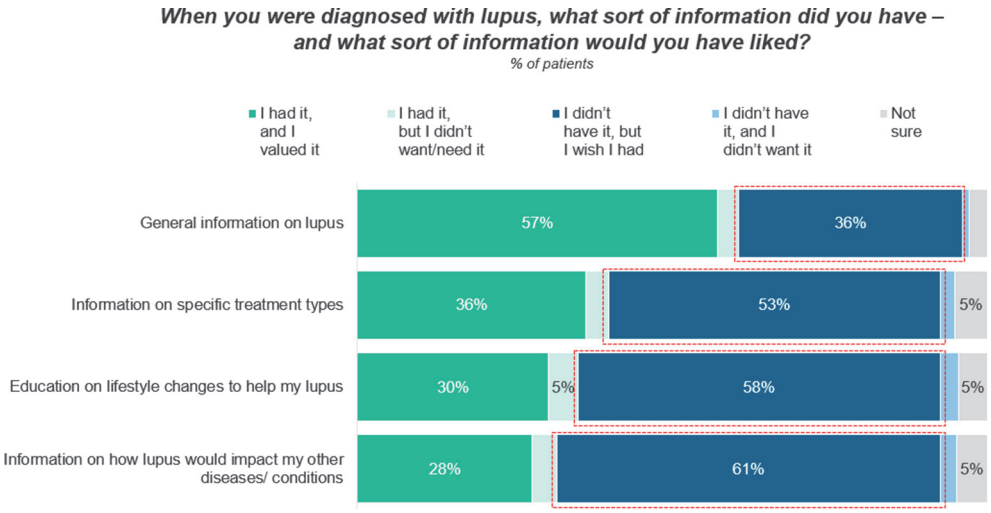
Abstract P128 Figure 1



Abstract P128 Figure 2



Abstract P128 Figure 3



Abstract P128 Figure 4

Conclusions Results highlight the importance of patient-centered care and the need for comprehensive, accessible education on lupus treatment options. The lack of patient education can lead to patient dissatisfaction and underutilization of advanced systemic treatments.

P129 DOES THE PERSPECTIVE OF SLE PATIENTS MATCH THE EXPERT OPINION AND DEFINITIONS OF REMISSION AND LOW DISEASE ACTIVITY STATE? PROSPECTIVE ANALYSIS OF 500 PATIENTS FROM A SPANISH MULTICENTER COHORT

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Background No data on agreement between patient perception, DORIS 2021 remission, LLDAS, or physician assessment is currently available.

The aim is to compare the SLE activity perceived by the patient using the Patient Acceptable Symptom State (PASS) question with the global assessment of activity by the physician, and the definitions of LLDAS/DORIS2021.

Methods A cross-sectional multicenter study involving SLE patients from seven Spanish Rheumatology Departments was conducted. The study applied DORIS 2021 remission criteria and LLDAS. Rheumatologists classified disease activity into five categories: remission, SACQ, low, moderate, or high. The patients were asked about their clinical SLE condition through the PASS question: 'Considering all the different ways your disease is affecting you, if you were to stay in this state for the next few months, do you consider your current state satisfactory?': PASS yes/PASS no. Statistical analysis included descriptive cross-sectional analysis and Cohen's kappa for agreement analysis.

Abstract P129 Table 1 Patient demographics and disease characteristics

	Number (%) or mean (± SD) (n = 503 patients)
Female gender	463 (92%)
Age at diagnosis (years)	40.7 (±21)
Disease duration at enrollment (years)	10,8 (± 9.9)
Age at enrollment (years)	50.4 (± 13.71)
ACR criteria (a)	
ANA	495 (96.5%)
Immunologic	398 (77.6%)
Arthritis	382 (74.5%)
Haematologic	291 (56.7%)
Malar rash	231 (45.0%)
Photosensitivity	229 (44.6%)
Mouth ulcers	178 (34.7%)
Renal	168 (32.7%)
Serositis	100 (19.5%)
Discoid rash	69 (13.5%)
Neurologic	28 (5.5%)
SLE activity	
SLEDAI-2K score at enrollment	2.8 (± 3.3)
SLICC/ACR-DI score at enrollment	0.96 (± 1.4)
Damage present at enrollment, n (%)	253 (49.8%)
Clinical SLEDAI-2 K (no complement or a-sDNA)	1.6 (±2.7)
PGA at enrollment	0.46 (± 0.59)
Treatment	
Prednisone	200 (39.7%)
Prednisone dose (mean ± SD)	5 (±6.27)
Antimalarials	366 (72.5%)
Inmunosupresants and/or biologic	219 (44%)

Abbreviations: SLE, systemic lupus erythematosus; ACR, American College of Rheumatology; SLEDAI, SLE disease activity index; PGA, physician global assessment; ANA, antinuclear antibody; ds DNA, double stranded DNA. SLICC/ACR-DI: Systemic Lupus International Collaborating Clinics (SLICC/American College of Rheumatology (ACR) damage index (SDI) (a) Ever present based on ACR criteria, LLDAS: Lupus Low Disease Activity State