All Subcomponents of the Cutaneous Lupus Erythematosus Disease Area and Severity Index–Activity (CLASI-A) are Relevant to Identify and Detect Changes in Skin Activity

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OBJECTIVES

- To evaluate the anatomical distribution of CLASI-A subcomponents and contribution of all five CLASI-A subcomponents to the total score change from baseline to Week 16 in participants with cutaneous lupus erythematosus (CLE) in the Phase 2 LILAC study.[1]
- To evaluate the association between sunlight-exposed body areas and severity of symptoms across the CLASI-A subcomponents.

CONCLUSIONS

- No single subcomponent of the measure drives the CLASI-A score or CLASI-A score changes.
- CLASI-A can identify skin activity in terms of both the overall severity and changes in exposed areas that are most vulnerable to photosensitivity and that are important to patients.
- These findings support the relevance of all five subcomponents of CLASI-A in describing disease activity in CLE.
- Our analyses also underline CLASI-A as an appropriate instrument to evaluate disease activity in CLE in clinical trials.

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Synopsis

- Part B of the Phase 2 LILAC study (NCT02847598; N=132) demonstrated the efficacy of litifilimab versus placebo, with a significant decrease in percent change from baseline in CLASI-A score at Week 16 in participants with active CLE with or without systemic lupus erythematosus (SLE).[1]
- Phase 3 studies are ongoing to further assess the efficacy and safety of litifilimab in CLE (NCT05531565) and SLE (NCT04895241, NCT04961567).[2–4]
- CLASI-A has been used as a primary or secondary outcome in previous clinical trials in SLE or CLE[1,5–7] to measure skin disease activity across 13 anatomical locations, based on five clinical subcomponents: Erythema, Scale/Hypertrophy, Mucous Membrane Lesions, Recent Hair Loss (preceding 30 days), and Non-scarring Alopecia.[8]
- This exploratory analysis assessed the contribution of each CLASI-A subcomponent individually.

Methods

- Study design and baseline characteristics for LILAC Part B participants were previously reported.[1]
- The distribution of the CLASI-A clinical subcomponents for the pooled LILAC Part B population (all litifilimab doses and placebo; N=132) was analyzed by anatomical location at baseline and at Week 16.
- For the following CLASI-A subcomponents, CLASI-A scores are categorized as follows:
  - Erythema (0: absent; 1: pink; 2: red; 3: dark red).
  - Scale/Hypertrophy (0: absent; 1: scale; 2: verrucous/hypertrophic).
  - Mucous Membrane Lesions (0: absent; 1: lesion/ulceration).
  - Recent Hair Loss (0: no; 1: yes).
  - Non-scarring Alopecia (0: absent; 1: diffuse, inflammatory; 2: focal or patchy in one quadrant; 3: focal or patchy in more than one quadrant).
- Changes in CLASI-A scores by subcomponent for the pooled study population at Week 16 were evaluated using point improvement / worsening from baseline at each anatomical location.
- Data are reported as observed without imputation of missing data.

Results

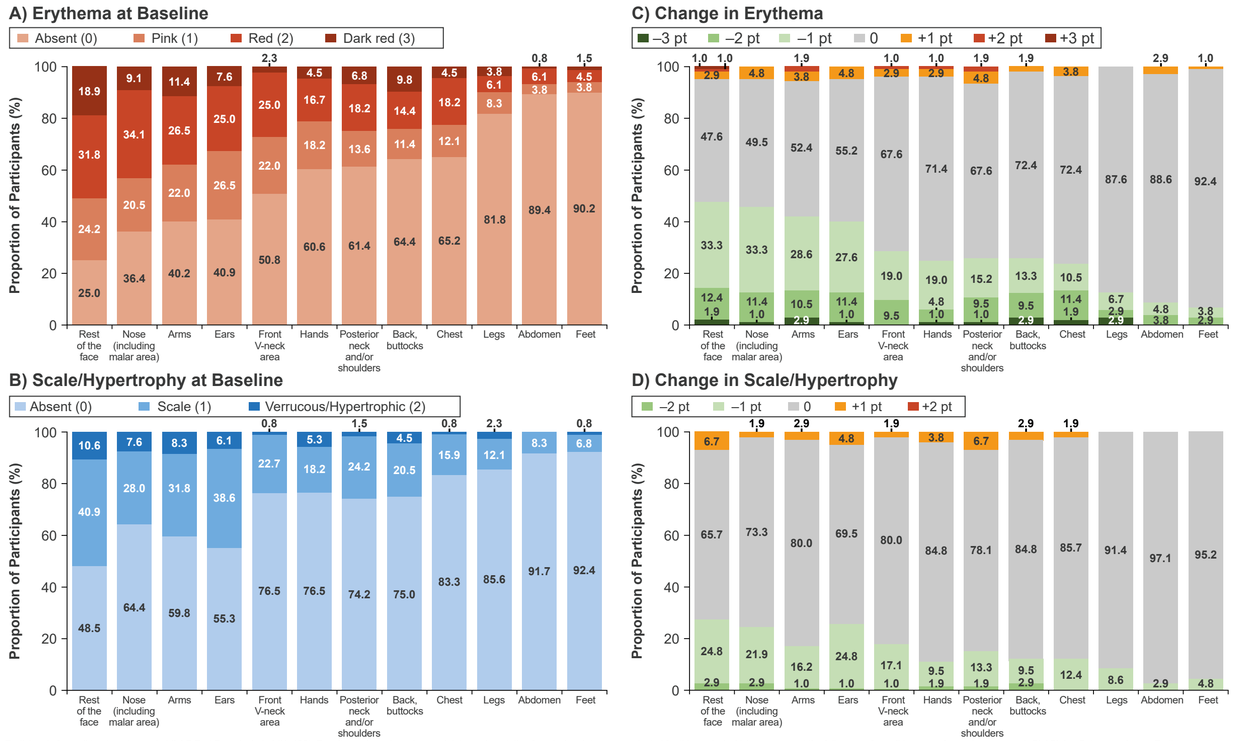
Distribution of Symptom Severity at Baseline

- In the pooled population, a higher proportion of participants reported 'red' (score 2; range across anatomical areas: 25.0%–34.1%) and 'dark red' (score 3; range: 2.3%–18.9%) erythema in the more sunlight-exposed areas of the front V-neck area, ears, arms, nose (including malar area), and rest of the face than in the less-exposed areas of the feet, legs, and abdomen (**Figure 1A; Figure 2**).
- Baseline scores for Scale/Hypertrophy are shown in **Figure 1B**, and those for Mucous Membrane Lesions, Recent Hair Loss, and Non-scarring Alopecia are shown in **Table 1.**

Distribution of Change in Symptom Severity From Baseline

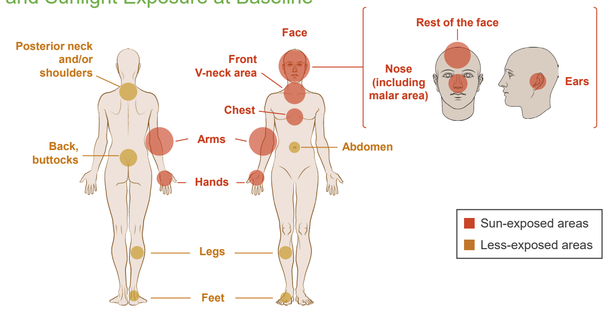
- At Week 16, improvements in CLASI-A scores by subcomponents were observed at all anatomical locations in the pooled population; these were consistent with the distribution of scores at baseline, with large improvements also observed in more highly exposed areas (**Figure 1C; Figure 1D; Table 1**).
  - Both 1-point and 2-point improvements in the Erythema subcomponent score were reported at all anatomical locations, in up to 33.3% and 12.4% of participants per location, respectively.
  - A 3-point improvement in Erythema was observed at almost all locations, in up to 2.9% of participants per location.
  - Similar findings were observed for Scale/Hypertrophy.
- The CLASI-A tool was able to capture both improvement and worsening of disease.

Figure 1. Distribution of CLASI-A Subcomponent Scores at Baseline (A, B) and Change From Baseline to Week 16 (C, D) for Each Anatomical Location



Participants from all treatment arms in LILAC Part B are included (N=132). Results are based on observed data; no imputation for missing data was conducted for this analysis. Values represent the full range of possible scores for each component. CLASI-A = Cutaneous Lupus Erythematosus Disease Area and Severity Index–Activity; pt = point(s).

Figure 2. Distribution of Erythema Severity by Anatomical Location and Sunlight Exposure at Baseline



Size of circle is proportional to the level of distribution of 'red' and 'dark red' scores for each anatomical location, which is defined as Erythema severity. Larger circle size indicates greater Erythema severity.

Table 1. Distribution of CLASI-A Mucous Membrane Lesions, Recent Hair Loss, and Non-scarring Alopecia Subcomponent Scores at Baseline and Change in Score From Baseline to Week 16

Distribution of Scores at Baseline (N=132), n (%)

MML		Recent Hair Loss		Non-scarring Alopecia			
Absent (0)	Lesions/ ulceration (1)	No (0)	Yes (1)	Absent (0)	Diffuse (1)	Focal/ patchy in 1 quadrant (2)	Focal/ patchy in >1 quadrant (3)
105 (79.5)	27 (20.5)	62 (47.0)	70 (53.0)	46 (34.8)	26 (19.7)	9 (6.8)	51 (38.6)

Distribution of Change in Score From Baseline to Week 16 (N=105), n (%)

MML			Recent Hair Loss			Non-scarring Alopecia						
−1	0	+1	−1	0	+1	−3	−2	−1	0	+1	+2	+3
18 (17.1)	85 (81.0)	2 (1.9)	33 (31.4)	66 (62.9)	6 (5.7)	6 (5.7)	2 (1.9)	11 (10.5)	82 (78.1)	4 (3.8)	0 (0.0)	0 (0.0)

Participants from all treatment arms in LILAC Part B are included (N=132). Results are based on observed data; no imputation for missing data was conducted for this analysis. Values represent the full range of possible scores for each component. CLASI-A = Cutaneous Lupus Erythematosus Disease Area and Severity Index–Activity; MML = Mucous Membrane Lesions.

References 1. Werth VP, et al. *N Engl J Med*. 2022;387(4):321–331; 2. NCT05531565. Updated December 04, 2025. Available from: https://clinicaltrials.gov/study/NCT05531565 (Accessed December 05, 2025); 3. NCT04895241. Updated November 03, 2025. Available from: https://clinicaltrials.gov/study/NCT04895241 (Accessed December 05, 2025); 4. NCT04961567. Updated November 21, 2025. Available from: https://clinicaltrials.gov/study/NCT04961567 (Accessed December 05, 2025); 5. Furie RA, et al. *N Engl J Med*. 2022;387(10):894–904; 6. Furie RA, et al. *Lancet Rheumatol*. 2019;1(4):e208–e219; 7. Morand EF, et al. *N Engl J Med*. 2020;382(3):211–221; 8. Albrecht J. *J Invest Dermatol*. 2005;125(5):889–894. **Disclosures** VPW: consultant of AbbVie, Amgen, AnaptysBio, argenx, AstraZeneca, Biogen, Bristol Myers Squibb, Cabaletta Bio, Calyx, Caribou Biosciences, Chrysalis BioTherapeutics, CSL Behring, Cugene, EMD Serono, Evommune, Gilead, GlaxoSmithKline, Horizon Therapeutics, Immunovant, Innovaderm Research, Janssen Pharmaceuticals, Kyowa Kirin, Lilly, Merck, Nektar Therapeutics, Nuvig Therapeutics, Pfizer, Regeneron, ROME Therapeutics, Sanofi, Takeda, UCB Pharma, Ventus Therapeutics, Vertex Pharmaceuticals, and Xencor; grant/research support from Amgen, argenx, AstraZeneca, Biogen, Bristol Myers Squibb, Celgene, Corbus Pharmaceuticals, CSL Behring, Genentech/Roche PI, Gilead, Horizon Therapeutics, Pfizer, Priovant Therapeutics, Regeneron, ROME Therapeutics, and Ventus Therapeutics. The University of Pennsylvania owns the copyright to CLASI; JFM: consultant of AbbVie, Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Incyte, Janssen, LEO Pharma, Lilly, MoonLake, Novartis, Pfizer, Sanofi-Regeneron, and UCB Pharma; grant/research support from Amgen, AstraZeneca, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Dermavant, Janssen, Lilly, MoonLake, Sanofi-Regeneron, Sun Pharma, and UCB Pharma; QL and WY: employees of Biogen and may hold Biogen stock; CB: former employee of Biogen and may hold Biogen stock. **Acknowledgments** We thank the LILAC investigators and participants for their valuable contributions. **Funding** This study was funded by Biogen (Cambridge, MA, USA). Writing and editorial support was provided by Megan Thomas, MSc, of Selene Medical Communications (Macclesfield, UK), funded by Biogen. Poster previously presented at LUPUS (May 21–24, 2025, Toronto, Canada), APLAR (September 3–7, 2025, Fukuoka, Japan), EADV (September 17–20, 2025, Paris, France), and RDS (October 25, 2025, Chicago, IL, USA).