immunologic criteria requirement under SLICC, it can be challenging to determine an SLE diagnosis retrospectively. Overall, DLE/SLE patients were more likely than DLE-only patients to exhibit hematologic and immunologic criteria with respect to leukopenia (ACR $p < 0.0001$; SLICC $p < 0.0001$), + anti-dsDNA (ACR $p < 0.0001$; SLICC $p < 0.0001$), and + ANA (ACR $p < 0.0001$; SLICC $p < 0.0001$) under both criteria. Furthermore, DLE/SLE patients were more likely than DLE-only patients to exhibit significant systemic symptoms with regard to arthritis (ACR 72% *vs.* 9%, $p < 0.0001$; SLICC 70% *vs.* 18%, $p < 0.0001$), serositis (ACR 21% *vs.* 0%, $p < 0.0001$; SLICC 22% *vs.* 3%, $p < 0.0001$), renal disorder (ACR 27% *vs.* 2%, $p < 0.0001$; SLICC 33% *vs.* 0%, $p < 0.0001$) using both criteria. DLE/SLE patients were more likely to have worse skin disease compared to DLE-only patients when classified according to the ACR criteria, with 40.8% of DLE/SLE patients having CLASI^{TM} activity ≥ 10 and 24.2% of DLE-only patients having CLASI^{TM} ≥ 10 (Table 1).

Abstract CT-04 Table 1A Skin activity in DLE/SLE vs DLE-only patients using ACR criteria. DLE/SLE patients are more likely to have worse skin disease compared to DLE-only patients when classified according to the ACR criteria

	DLE with SLE n (%)	DLE without SLE n (%)	P-value
CLASI^{TM} ≥ 10	31 (40.8)	16 (24.2)	0.0490*
CLASI^{TM} < 10	45 (59.2)	50 (75%)	

Abstract CT-04 Table 1B Skin activity in DLE/SLE vs DLE-only patients using SLICC criteria. There is a trend of DLE/SLE patients having worse skin disease compared to DLE-only patients when classified according to the SLICC criteria

	DLE with SLE n (%)	DLE without SLE n (%)	P-value
CLASI^{TM} ≥ 10	27 (40.9)	20 (26.3)	0.0755
CLASI^{TM} < 10	39 (59.1)	56 (73.7)	

Conclusion These findings suggest that DLE patients who meet SLE criteria are more likely than their DLE-only counterparts to have more significant internal disease. Both ACR and SLICC criteria are useful in distinguishing DLE patients with internal organ involvement from those without. DLE-only patients may have significant skin disease with 25% of DLE-only patients having moderate to severe skin disease.

CT-05 LONGITUDINAL PATTERNS IN SLE RESPONSE TO STANDARD OF CARE THERAPY: IMPLICATIONS FOR CLINICAL TRIAL DESIGN

[1]**Mimi Kim***, [2]Joan Merrill, [3]Kenneth Kalunian, [4]Bevra Hahn, [5]Anita Roach, [6]Peter Izmirly. *[1]Albert Einstein College of Medicine; [2]Oklahoma Medical Research Foundation; [3]University of California San Diego; [4]University of California Los Angeles; [5]Lupus Foundation of America; [6]New York University School of Med, USA*

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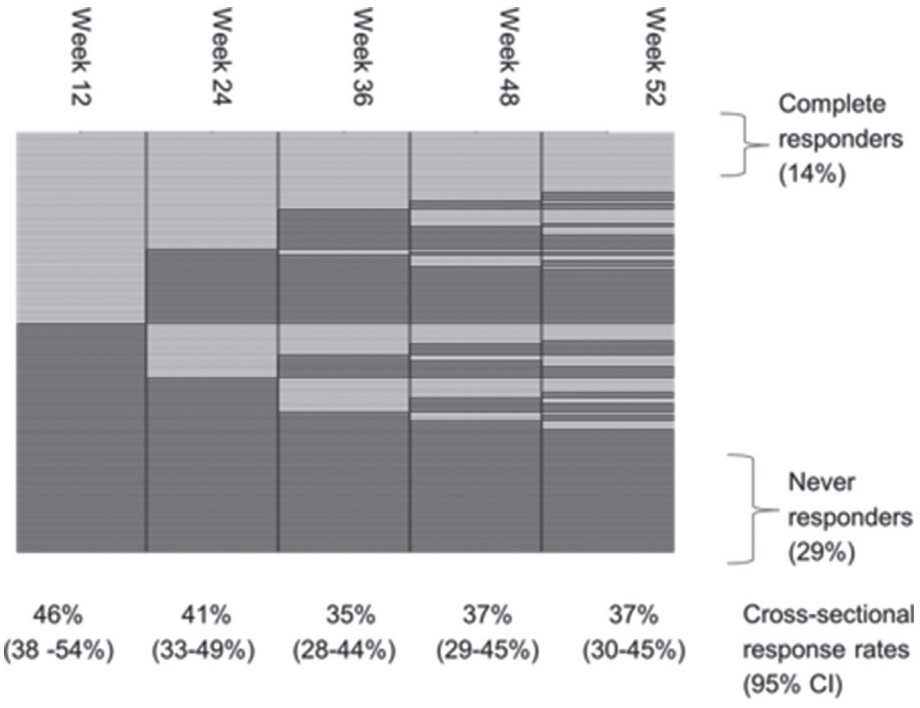
Background Most clinical trials of new treatments for systemic lupus erythematosus (SLE) have shown weak discrimination between investigational agents and placebo when added to standard of care (SOC). The design of future SLE trials may be improved by considering strategies for reducing placebo response rates and better understanding the within-patient variability in disease activity during follow- up. We evaluated longitudinal patterns of response in SLE patients who received placebo plus SOC in two completed 52-week clinical trials. Baseline characteristics that discriminated persistent responders from non-responders were also examined, with the goal of identifying characteristics that may define patient populations with unmet medical need who should be targeted for enrollment in future trials

Materials and methods Data was obtained from the Collective Data Analysis Initiative (CDAI) of the Lupus Foundation of



Abstract CT-05 Figure 1 Temporal patterns in response status (Light = Response; Dark = No Response)

America and included 147 patients from the placebo plus SOC arms of two randomised Phase II/III trials in moderately-to-severely active lupus patients without acute nephritis. BILAG-based response was evaluated at weeks 12, 24, 36, 48, and 52. Both cross-sectional and longitudinal analyses of response rates were performed. Baseline clinical variables that discriminated persistent responders and non-responders were identified using logistic regression.

Results Cross-sectional response rates for patients treated with placebo plus SOC decreased from 46% to 37% between 12–52 weeks (Figure 1). The rate of complete and sustained response, i.e., response at all visits between 12–52 weeks, was only 14.3% (95% CI: 8.6%–19.9%). Agreement between response status at 12 weeks and 36–52 weeks was low (kappa = 0.15–0.25); furthermore only 31% of initial 12 week responders maintained response at all subsequent visits. Baseline factors contributing to persistent response to SOC included fewer active organ systems, high C3 levels, and type of background therapy.

Conclusions An endpoint based on a sustained rather than landmark response may reduce high placebo response rates in SLE trials that continue aggressive SOC. Further exploration to assess the power of this endpoint to improve discrimination between active and placebo arms is indicated. The observed lack of stability in response to SOC over time highlights a potential weakness with shorter studies that use an endpoint of improvement. Our data also confirm earlier reports that the likelihood of response in the placebo group depends on the severity of disease and the aggressiveness of background treatments.

Acknowledgements Lupus Foundation of America Collective Data Analysis Initiative Group.

CT-06 FACTORS AFFECTING THE ATTITUDES OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS REGARDING POTENTIAL CLINICAL TRIAL PARTICIPATION

[1]E McNaughton, [2]S Lops, [2]E Felicione, [2]**C Wagner***. *[1]PatientsLikeMe, Inc, Boston; [2]Janssen Research and Development, LLC, Spring House, United States*

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Background Systemic Lupus Erythematosus (SLE) is an autoimmune disorder affecting skin, joints, kidneys, brain and other organs. Clinical trial recruitment is especially challenging in this patient population. To address challenges of recruiting patients with SLE into clinical trials, we conducted a survey study to: (1) explore patients' satisfaction with their current treatment; (2) assess participants' motivations to switch to a new treatment; and (3) identify the characteristics of patients willing to participate in a clinical trial.

Materials and methods 259 members of an online patient network with SLE aged 18–77 (mean age = 47; 96% female, 78% white) completed an online survey about their experience and attitudes. Data was collected over 7 days. The Chi square test was used to analyse the distribution of categorical variables; two sample t-tests to compare group means, and Pearson r correlation to identify the associations between continuous variables.

Results 60% of SLE patients reported being at least "somewhat satisfied" with their current treatment; 74% name worsening symptoms as an important factor for changing medications. Those patients (36%) who were motivated to change to a new treatment reported a slightly more severe daily impact of SLE (mean = 3.6 on a scale 1: not at all – 5 very much) than patients who did not view new treatment availability as a reason to change their current medication (SLE impact mean = 3.3; t (258) = 2.49; $p < 0.01$). 29% say knowing that a trial drug has never been tested before will increase the likelihood of their participation in the trial. Correlation analyses revealed slight, but significant association between a favourable view of novel drug trials and higher number of treatments, frequency of healthcare utilisation, and lupus daily impact (r ranged 0.13 – 0.22, $p < 0.03$). Disease-related factors positively associated with interest in clinical trial participation are SLE daily impact ($r = 0.26$, $p < 0.03$), headaches ($\chi^2 = 14.06$, $p < 0.01$), and pain ($\chi^2 = 8.8$, $p < 0.05$); treatment-related factors are burden of treatment, frequency of flares, frequency of healthcare utilisation, number of medications (r ranged 0.14 – 0.18, $p < 0.03$), and use of pain medications ($\chi^2 = 12.6$, $p < 0.05$).

Conclusions Investigators may achieve a higher recruitment rate by targeting: 1) patients whose SLE symptoms are under poor control and who therefore frequently utilise the healthcare system; and 2) those patients who are experiencing more pain and headaches and more frequently using pain medications.

CT-07 A PHASE 2, RANDOMISED, PLACEBO-CONTROLLED, DOUBLE-BLIND, ASCENDING DOSE STUDY TO EVALUATE EFFICACY, SAFETY, AND TOLERABILITY, PHARMACOKINETICS, PHARMACODYNAMICS AND PHARMACOGENETICS OF CC-220 IN SUBJECTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

[1]**Victoria Werth***, [2]Douglas Hough, [2]Shimon Korish, [2]Michael Weiswasser, [2]Peter Schafer, [2]Nikolay Delev, [2]Suktai Choi. *[1]University of Pennsylvania and the VA Medical Centre, Philadelphia, United States; [2]Celgene Corporation, Summit, NJ, United States*

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Background To evaluate the efficacy, safety and tolerability of CC-220 in subjects with Systemic Lupus Erythematosus [SLE] in a Phase 2, randomised, double-blind, placebo-controlled, ascending dose study

Materials and methods 42 adult SLE subjects with serological and clinical activity for ≥6 months, and a baseline Hybrid SELENA-SLEDAI [HSS] score ≥4 were randomised to one of four escalating doses of CC-220 or matching placebo. The four active treatments included CC-220 0.3 mg QOD, 0.3 mg QD, 0.3 mg alternating with 0.6 mg QD, and 0.6 mg QD, randomised 4:1 active to placebo in each group, for 12 weeks of treatment followed by 12 weeks of observational follow-up, and/or optional long term extension. Stable doses of corticosteroids (≤10 mg prednisone or equivalent daily), non-steroidal anti-inflammatory drugs, and antimalarials were permitted.

Efficacy assessments included HSS, Cutaneous Lupus Area and Severity Index [CLASI] skin scores, Physician Global Assessment [PGA], swollen joint counts [SJC] and tender joint counts [TJC].

Biomarkers, such as expression of Aiolos and Ikaros, and change from baseline in lupus serology markers and cell subsets were also assessed.

Safety assessments included type, frequency, severity, and relationship of adverse events [AEs] to CC-220, laboratory (chemistry, haematology including B cell differentiation and immunoglobulin profiling, inflammatory markers, urinalysis), electrocardiogram [ECG], physical examination and overall tolerability.

Results Baseline subject demographics included 39 women (93%) with a mean age 47.2 ± 10.6 years, and included 64% White, 31% Black, 2% Asian and 2% other races. The mean duration of SLE was 10.3 ± 8.0 years, 88% had arthritis, 78% cutaneous disease, 55% alopecia, 25% mucosal ulcers, and 19%