hypogammaglobulinemia was previously demonstrated in almost 1/3 of LN subjects participating in a study of abatacept and cyclophosphamide (ACCESS study) and did not associate with serious infections. Proteinuria correlated inversely with serum IgG. Our preliminary findings demonstrate that a considerable number of patients with active, non-naïve LN are hypogammaglobulinemic, and confirm an inverse association between IgG levels with proteinuria. The CALIBRATE trial will follow levels of serum IgG and urinary protein prospectively and will monitor patients for the potential development of infectious events.

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Trial Registration ClinicalTrials.gov Identifier: NCT02260934

CT-03 ANIFROLUMAB REDUCES DISEASE ACTIVITY IN MULTIPLE ORGAN DOMAINS IN PATIENTS WITH MODERATE TO SEVERE SYSTEMIC LUPUS ERYTHEMATOSUS

[1]**Joan T Merrill***, [2]Richard Furie, [3,4]Victoria P Werth, [5]Munther Khamashta, [6]Jorn Drappa, [6]Liangwei Wang, [6]Gabor Illei. [1]*Oklahoma Medical Research Foundation, Oklahoma City, OK, USA*; [2]*Division of Rheumatology, Hofstra Northwell School of Medicine, Northwell Health, New York, NY, USA*; [3]*Philadelphia VA Medical Centre, Philadelphia, PA, USA*; [4]*University of Pennsylvania, Philadelphia, PA, USA*; [5]*Graham Hughes Lupus Research Laboratory, King's College London, The Rayne Institute, St Thomas' Hospital, London, UK*; [6]*MedImmune, One MedImmune Way, Gaithersburg, MD, USA*

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Background Anifrolumab was evaluated in a Phase IIb study of adults with moderate to severe systemic lupus erythematosus (SLE), in which 305 patients received intravenous infusions of anifrolumab (300 mg, 1000 mg) or placebo for 48 weeks. Global disease activity was reduced in both dose groups compared with placebo, although a more favourable risk-benefit profile was observed with the 300-mg dose. This analysis of the Phase IIb study compared the impact of anifrolumab on individual organ domains in patients.

Materials and methods Changes from baseline in organ domain activity were assessed at Week 52 using the SLE Disease Activity Index 2000 (SLEDAI-2K) and British Isles Lupus Assessment Group (BILAG). SLEDAI domain improvement required a lower score compared with baseline in at least one of its components. BILAG organ domain improvement was defined as the transitioning from "A" or "B" to a lower score.

Results The majority of patients had baseline involvement of the mucocutaneous and/or musculoskeletal domains of SLEDAI-2K and BILAG. A greater percentage of anifrolumab-treated patients demonstrated improvement in these frequently involved domains compared with placebo (Table 1). Potential benefits were observed in most of the other less frequently active domains, including SLEDAI-2K cardiorespiratory, vascular, haematological, and constitutional; and BILAG cardiorespiratory and constitutional domains. In patients with baseline involvement in the SLEDAI-2K immunological domain (positive anti–double-stranded DNA [anti-dsDNA] and/or low complement level), normalisation of anti-dsDNA and/or hypocomplementemia were seen more frequently at Day 365 in patients receiving anifrolumab compared with placebo (Table 1). However, among patients who had a normal anti-dsDNA and/or normal complements at baseline, a slightly greater number of patients in the 300-mg anifrolumab group had an increase in the score representing the development of a new anti-dsDNA or hypocomplementemia compared with baseline (Table 1).

Conclusions Treatment with anifrolumab resulted in greater rates of improvement in multiple organ domains compared with placebo. The greatest impact was seen with 300-mg anifrolumab.

Abstract CT-03 Table 1 Changes from baseline in organ domain activity at Day 365

	Placebo	Anifrolumab 300 mg*	*P*-Value	Anifrolumab 1000 mg*	*P*-Value
Organ domain improvement at Day 365					
BILAG, n (%)					
Mucocutaneous	24/87 (27.6)	49/84 (58.3)	<0.001	33/82 (40.2)	0.069
Musculoskeletal	47/95 (49.5)	64/94 (68.1)	0.005	54/91 (59.3)	0.149
SLEDAI-2K, n (%)					
Mucocutaneous	38/100 (38.0)	61/99 (61.6)	<0.001	51/102 (50.0)	0.082
Musculoskeletal	42/99 (42.4)	55/97 (56.7)	0.032	50/98 (51.0)	0.197
Immunological	4/53 (7.5)	9/43 (20.9)	0.068	18/59 (30.5)	0.004
Organ domain worsening at Day 365					
SLEDAI-2K, n (%)					
Immunological	7/79 (8.9)	11/82 (13.4)	–	6/79 (7.6)	–

*Every 28 days from Day 1 to Day 337. BILAG, British Isles Lupus Assessment Group; SLEDAI-2K, SLE Disease Activity Index 2000

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CT-04 USING THE AMERICAN COLLEGE OF RHEUMATOLOGY AND SYSTEMIC LUPUS INTERNATIONAL COLLABORATING CLINICS CRITERIA TO MEASURE DISEASE SEVERITY IN DISCOID LUPUS ERYTHEMATOSUS

[1,2]JK Presto, [1,2]JS Haber, [1,2]**VP Werth***. [1]*Corporal Michael J. Crescenz VAMC (Philadelphia), Phil, PA*; [2]*Dept of Derm, U Penn, Phil, PA. USA*

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Backgroun d Discoid lupus erythematosus (DLE) progresses to systemic lupus erythematosus (SLE) in up to 28% of cases. The 2012 Systemic Lupus International Collaborating Clinics (SLICC) criteria were developed to improve the American College of Rheumatology (ACR) criteria. So far, the SLICC criteria have not been evaluated in DLE.

Methods This is a case-control study comparing patients with DLE who meet ACR and/or SLICC criteria for SLE against patients with DLE-only disease. The data was obtained from an ongoing database with 142 DLE patients at Penn and from their respective medical records.

Results Using the ACR criteria, 75 (53%) patients were classified as DLE/SLE and 67 (47%) as DLE-only, compared with 66 (47%) DLE/SLE and 76 (53%) DLE-only patients using the SLICC criteria ($p = 0.08$). This net increase of eight patients meeting ACR criteria was due to the presence of the photosensitivity criterion and fewer immunologic criteria under ACR. Due to the

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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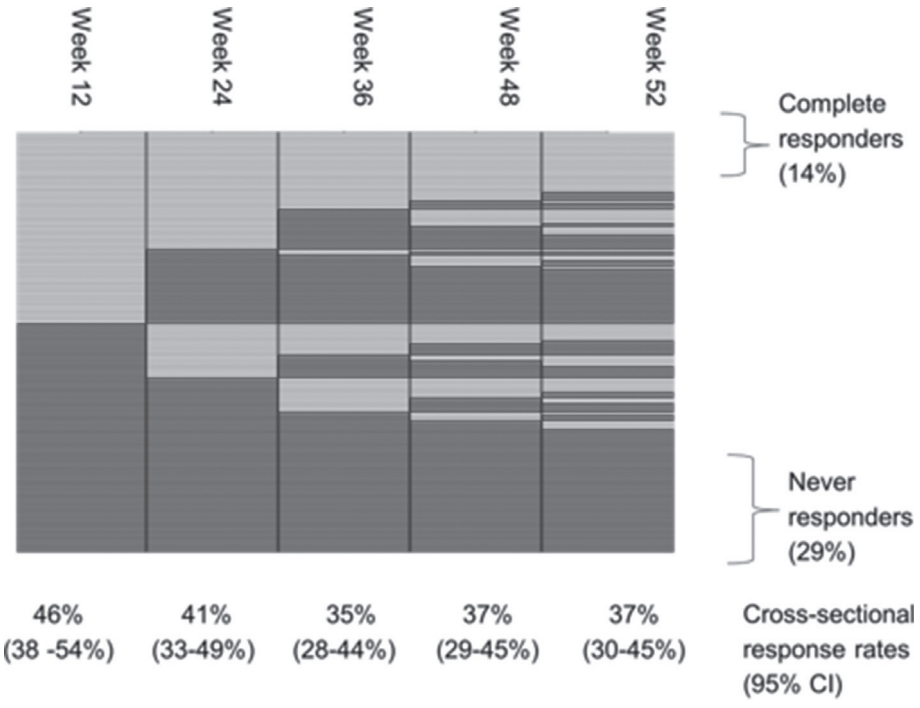
Background Most clinical trials of new treatments for systemic lupus erythematosus (SLE) have shown weak discrimination between investigational agents and placebo when added to standard of care (SOC). The design of future SLE trials may be improved by considering strategies for reducing placebo response 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)