

**Supplemental Table 1. Summary of Key Baseline Demographic and Disease Characteristics**

<b>All Randomized Subjects</b>	<b>N=516</b>
Female, %	93.4
Age, mean $\pm$ SD	43.5 $\pm$ 8.9
Race, %	
White	66.7
African American	8.1
Asian	20.0
Disease duration, mean $\pm$ SD	8.9 $\pm$ 7.8
SLEDAI-2K (0-105), mean $\pm$ SD	10.4 $\pm$ 3.5
PGA (VAS 0-3), mean $\pm$ SD	1.8 $\pm$ 0.4
BILAG, %	
$\geq$ 1A	43.2
$\geq$ 2B	57.0
Tender Joint Count, mean $\pm$ SD	14.6 $\pm$ 11.0
Swollen Joint Count, mean $\pm$ SD	8.8 $\pm$ 6.6
Joints with Both Tenderness & Inflammation, mean $\pm$ SD	8.3 $\pm$ 6.3
CLASI activity score (0-70), mean $\pm$ SD	8.2 $\pm$ 6.6
Anti-dsDNA Antibodies Positive ( $>$ 75 kIU/L), %	36.8
Low Complement Present, %	
C3	42.4
C4	26.4
Patients with lupus nephritis, %	19.4
Concomitant Medications, % (mean $\pm$ SD dose, mg/day)	
Oral glucocorticoids, % (mean $\pm$ SD dose, mg/day)	79.8 (9.7 $\pm$ 5.1)
Antimalarials, %	73.3

**Supplemental Table 2a.** Number of patients included in the correlations between LFA-REAL ClinRO and SLE disease activity measures, LFA-REAL PRO and other PRO measures, PGA with SLEDAI and BILAG at baseline, 24 and 52 weeks

	LFA-REAL ClinRO				LFA-REAL PRO at visit				PGA		
	Baseline	Week 24	Week 52		Baseline	Week 24	Week 52		Baseline	Week 24	Week 52
PGA	494	449	248	FACIT-F	114	117	77	BILAG	498	440	244
BILAG	480	443	248	Lupus QoL	114	117	77	SLEDAI 2K	512	425	237
SLEDAI-2K	494	449	248	SF-36 v2 Vitality	114	117	77				
				SF-36 PCS	114	117	77				

LFA-REAL ClinRO, Lupus Foundation of America Rapid Evaluation of Activity in Lupus Clinician Reported Outcome; LFA-REAL PRO, Lupus Foundation of America Rapid Evaluation of Activity in Lupus Patient Reported Outcome; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; BILAG, British Isles Lupus Assessment Group 2004 Index Total Score; PGA, Physician Global Assessment. LFA-REAL PRO, Lupus Foundation of America Rapid Evaluation of Activity in Lupus Patient Reported Outcome; SF-36, Short-Form Health Survey; SF-36 PCS, SF-36 Physical Component Summary; Lupus QoL, Lupus Quality of Life questionnaire; FACIT-F, Functional Assessment of Chronic Illness Therapy Fatigue Scale. SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; BILAG Index Total, British Isles Lupus Assessment Group 2004 Index Total Score; PGA, Physician Global Assessment.

**Supplemental Table 2b.** Number of patients included in the correlations between LFA REAL ClinRO Total Score from baseline and composite response measures/disease activity measures, and LFA-REAL PRO change from baseline with other PROs at 24 and 52 weeks

	LFA-REAL ClinRO Change from Baseline			LFA-REAL PRO change from baseline	
	Week 24	Week 52		Week 24	Week 52
DORIS Remission	441	242	FACIT-F	106	70
LLDAS	416	231	Lupus QoL	106	70
BICLA Response	435	239	SF-36v2 Vitality	106	70
SRI-4 Response	417	232	SF36-PCS	106	70
PGA	442	242			
BILAG	436	241			
SLEDAI-2K	419	234			

LFA-REAL ClinRO, Lupus Foundation of America Rapid Evaluation of Activity in Lupus Clinician Reported Outcomes; LFA-REAL PRO, Lupus Foundation of America Rapid Evaluation of Activity in Lupus Patient Reported Outcomes; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; BILAG, British Isles Lupus Assessment Group 2004 Index Total Score; PGA, Physician Global Assessment; SRI-4, SLEDAI-2K SLE Responder Index; BICLA, BILAG-based Composite Lupus Assessment; LLDAS, Lupus Low Disease Activity State; DORIS Remission, Clinical Remission on Treatment; SF-36, Short-Form Health Survey; SF-36 PCS, SF-36 Physician Component Summary; Lupus QoL, Lupus Quality of Life questionnaire; FACIT-F, Functional Assessment of Chronic Illness Therapy Fatigue Scale.

**Supplemental Table 2c.** Number of patients included in correlations between LFA-REAL ClinRO and PRO Scores, ClinRO Rash and PRO Rash, ClinRO alopecia and PRO Hair Loss, ClinRO Arthralgia/Arthritis and PRO Overall Arthritis at Baseline, Week 24 and Week 52 visits as well as Change from Baseline to Week 24 and Week 52.

	At Visit			Change from baseline	
	Baseline	Week 24	Week 52	Week 24	Week 52
ClinRO arthralgia/arthritis/ PRO overall Arthritis	114	116	77	105	70
ClinRO Alopecia and PRO Hair Loss	114	116	77	105	70
ClinRO Rash and PRO Rash	114	116	77	105	70
ClinRO Total and PRO Total	114	116	77	105	70

LFA-REAL ClinRO, Lupus Foundation of America Rapid Evaluation of Activity in Lupus Clinician Reported Outcomes; LFA-REAL PRO, Lupus Foundation of America Rapid Evaluation of Activity in Lupus Patient Reported Outcomes

**Supplemental Table 2d.** Number of patients included in correlation between LFA REAL ClinRO PRO Musculoskeletal and Mucocutaneous Components and individual components of disease activity measures

	LFA-REAL ClinRO: Arthralgia/arthritis			LFA-REAL PRO symptoms of arthritis: Overall Arthritis		
	Baseline	Week 24	Week 52	Baseline	Week 24	Week 52
SLEDAI Arthritis	494	452	252	114	116	77
Subset: Subjects with >= 8 Active Counts At Baseline	220	202	118	71	70	48
Subset: Subjects with >= 4 Active Counts At Baseline	413	380	216	102	102	67
All Subjects Active Joint Count	494	451	248	114	116	76

	LFA-REAL ClinRO				LFA-REAL PRO		
	Baseline	Week 24	Week 52		Baseline	Week 24	Week 52
ClinRO Mucosal Ulcers/SLEDAI Mucosal Ulcers	494	454	252	NA	NA	NA	
ClinRO Alopecia/SLEDAI Alopecia	494	454	252	PRO Hair Loss/SLEDAI Alopecia	114	117	77
ClinRO Rash/SLEDAI Rash	494	454	252	PRO Rash/ SLEDAI Rash	114	117	77
ClinRO Mucocutaneous Global/BILAG Mucocutaneous	494	454	252	PRO Rash/BILAG mucocutaneous	114	117	77
ClinRO Mucocutaneous Global/CLASI Total Activity	489	452	250	PRO Rash/ CLASI Total activity	114	117	77

LFA-REAL ClinRO, Lupus Foundation of America Rapid Evaluation of Activity in Lupus Clinician Reported Outcomes; LFA-REAL PRO, Lupus Foundation of America Rapid Evaluation of Activity in Lupus Patient Reported Outcomes; CLASI, Cutaneous Lupus Erythematosus Disease Area and Severity Index is a measure of skin-disease severity, with scores ranging from 0 (least severe) to 70 (most severe).

Active Joint Counts (62 joints) are defined as joints with pain and signs of inflammation. Tender (Pain) Joint count (64 Joints) are defined as joints with pain on examination.

Lupus Foundation of America Rapid Evaluation of Activity in Lupus Patient Reported Outcomes (LFA-REAL PRO) Symptoms of Arthritis consist of 3 individual symptom domains each scored on 0-100 mm Visual Analogue Scale (VAS). Overall Arthritis is a 0-100 mm VAS indicating patient's global consideration of Joint pain, Swelling and Stiffness. LFA-REAL ClinRO Mucocutaneous Global is a 0-100 mm VAS as an overall consideration of 3 Mucocutaneous domains: Rash, Alopecia, Mucosal.

**Supplemental Table 3a.** Summary of Area Under the Curve (AUC) for LFA-REAL ClinRO Score Change from Baseline In Discrimination of Disease Measure Responses: SRI-4, Composite SRI-4, BICLA; Presenting N and AUC (95% CI) For Pooled (Combined) Treatments

AUC (95% CI) for LFA-REAL ClinRO Score in Discrimination of:	Change from Baseline	
	Week 24	Week 52
SRI-4 Response	N=417 0.76 (0.71, 0.80)	N=232 0.76 (0.70, 0.83)
Composite SRI-4 Response	-	N=245 0.72 (0.66, 0.79)
BICLA Response	N=435 0.70 (0.65, 0.75)	N=239 0.70 (0.64, 0.77)

Area under the curve (AUC) is in terms of LFA-REAL ClinRO Score change from baseline in discrimination of the noted Response (SRI-4, Composite SRI-4, or BICLA). Estimates are based on a logistic regression model for Response (Yes) with LFA-REAL ClinRO Score change from baseline as the single covariate. 95% confidence intervals are in terms of the Wald method.

**Supplemental Table 3b.** Sensitivity and Specificity of LFA-REAL ClinRO Score Change from Baseline at Week 52 In Discrimination of SRI-4 Response; Presenting Six Cut-Points

Cut-Point Selection Method: Either "Of Clinical Interest" or Through Use of Optimal			
Cut-Point Estimation	Cut-Point	Sensitivity	Specificity
<i>Of Clinical Interest</i>	-60	0.69	0.70
Sensitivity, Specificity Equality	-59	0.69	0.70
Closest Distance to ROC "Ideal Point"	-55	0.75	0.68
<i>Of Clinical Interest</i>	-50	0.79	0.61
Youden Index	-41	0.86	0.58
<i>Of Clinical Interest</i>	-40	0.88	0.54

The six cut-points within this table are selected as follows. Three cut-points are of general clinical interest: -60, -50, -40. In addition, 3 standard methods are used to estimate an optimal cut-point and, for these data, include: -59, -55, and -41. The 3 methods are described throughout literature and not expanded here.

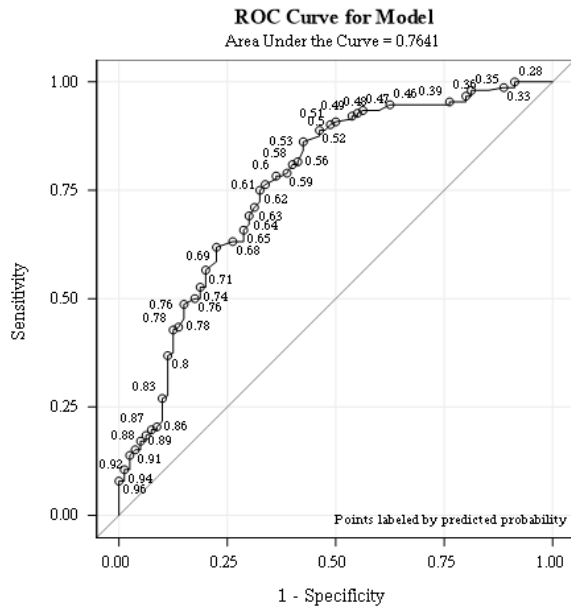
**Supplemental Table 3c.** Sensitivity and Specificity of LFA-REAL ClinRO Score Change from Baseline at Week 52 In Discrimination of BICLA Response; Presenting Six Cut-Points

<b>Cut-Point Selection Method:</b>			
<b>Either "Of Clinical Interest" or Through Use of</b>			
<b>Optimal Cut-Point Estimation</b>	<b>Cut-Point</b>	<b>Sensitivity</b>	<b>Specificity</b>
<i>Of Clinical Interest</i>	-68	0.64	0.64
Sensitivity, Specificity Equality	-60	0.69	0.57
Closest Distance to ROC "Ideal Point"	-58	0.76	0.57
<i>Of Clinical Interest</i>	-50	0.83	0.49
Youden Index	-43	0.90	0.44
<i>Of Clinical Interest</i>	-40	0.90	0.39

The six cut-points within this table are selected as follows. Three cut-points are of general clinical interest: -60, -50, -40. In addition, 3 standard methods are used to estimate an optimal cut-point and, for these data, include: -59, -55, and -41. The 3 methods are described throughout literature and not expanded here.



**Supplemental Figure 4a.** Area Under the Curve (AUC) for LFA-REAL ClinRO Score Change from Baseline at Week 52 In Discrimination of SRI-4



**Supplemental Figure 4b.** Area Under the Curve (AUC) for LFA-REAL ClinRO Score Change from Baseline at Week 52 In Discrimination of BICLA

