Abstract 07 Figure 1 Forest plot of the malformation rates comparing CQ/HQ treated group vs. non-treated controls

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PERFORMANCE OF THE EULAR/ACR 2019 CLASSIFICATION CRITERIA FOR SYSTEMIC LUPUS ERYTHEMATOSUS IN MEN, ETHNICITIES, AND EARLY DISEASE

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Background Supported by both the ACR and EULAR, the EULAR/ACR 2019 Classification Criteria for SLE employ positive ANA (ever) as an entry criterion and use a weighted scheme with values ranging from 2 to 10, for a classification cut-off of 10. Criteria items are attributed to SLE only if there is no more likely alternative diagnosis in the individual patients. Items are organized in domains, and only the highest ranking item within a domain is counted. These criteria have been validated in a cohort of 696 SLE patients and 574 non-SLE patients from a total of 21 centers, reaching an overall sensitivity of 96.1% and a specificity of 93.4%. To at least estimate the performance in groups underrepresented in the validation cohort of this transatlantic project, we analyzed this cohort for patient subsets with regard to sex, ethnicity, and disease duration.

Methods The full EULAR/ACR 2019 classification criteria validation cohort was analyzed for female (n=1,098) and male (n=172) patients, Asian (n=118), Black (n=68), Hispanic (n=124) and White (n=941) patients, and patients with an SLE duration of less than 1 year (n=34), one to less than 3 years (n=196), 3 to less than 5 years (n=157), and 5 or more years (n=879). Sensitivity and specificity were calculated for the EULAR/ACR 2019 criteria, the SLICC 2012 criteria and the ACR 1997 criteria each.

Results As shown in table 1, most of the point estimates for sensitivity and specificity in subsets lay within the 95% confidence intervals of the sensitivity and specificity of the EULAR/ACR 2019 criteria validation. In particular, sensitivity and specificity for all ethnic groups were within the confidence

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	N	EULAR/ACR 2019 Criteria		ACR 1997 Criteria		SLICC 2012 Criteria	
		Sensitivity	Specificity	Sensitivity	Specificity	Sensitivity	Specificity
95% CI	1,270	0.96	0.93	0.83	0.93	0.97	0.84
		0.95–0.98	0.91–0.95	0.80–0.85	0.91–0.95	0.95–0.98	0.80–0.87
Sex							
Women	1,098	0.97	0.94	0.83	0.93	0.97	0.82
Men	172	0.93	0.96	0.78	0.94	0.94	0.90
Ethnicity							
Asian	118	0.97	0.91	0.77	0.93	0.99	0.91
Black	68	0.98	1.00	0.82	1.00	0.98	0.92
Hispanic	124	1.00	0.96	0.86	0.96	1.00	0.78
White	941	0.95	0.94	0.83	0.93	0.96	0.83
Disease duration							
<1 year	34	0.89	0.92	0.56	0.92	0.89	0.92
1 to <3 yrs	196	0.97	0.96	0.81	0.95	0.98	0.88
3 to <5 yrs	157	0.96	0.99	0.81	0.94	0.91	0.89
≥5 years	879	0.96	0.93	0.84	0.93	0.97	0.81

intervals or even higher. Formally, the sensitivity was slightly lower for male patients, corresponding to a higher specificity, but the male 95% confidence intervals (0.86–0.98 for sensitivity, 0.90–0.99 for specificity) overlapped. While sensitivity appeared independent of disease duration from year 1 on, sensitivity was only 89% in the first year of disease, identical to the SLICC criteria (89%) and numerically higher than the ACR criteria (56%), but all confidence intervals overlapped.

Conclusion While not all subgroups of SLE patients in the validation cohort are of adequate size to fully explore the sensitivity and specificity of the EULAR/ACR 2019 SLE classification criteria in the respective subsets, the point estimates of sensitivity and specificity suggest that the new criteria perform at least reasonably well in all ethnic groups, in men and in early disease. Nevertheless, sensitivity and specificity should be independently validated in larger groups of Asian, Black and Hispanic patients, male patients and in early disease.

09 REDUCTION OF INTERFERON- γ AND ELEVATED BASELINE CYTOTOXIC GENE EXPRESSION IN THE BLOOD ASSOCIATE WITH USTEKINUMAB RESPONSE IN SLE

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Background/Purpose Ustekinumab (anti-IL-12/23) improved SLE-disease activity vs. placebo in patients with active SLE despite standard therapy.¹ We investigated whether biomarkers collected in this trial could distinguish responders (UST-R) from non-responders (UST-NR) (response defined by SLE Responder

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Abstract O9 Figure 1 Gene-Set-Variation Analysis (GSVA) at Baseline